

Distributive Conflicts, Regime Complexes, and The International Regulation of Genetically Modified Organisms

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Note to workshop participants: In this paper, we present a brief abstract of the book as a whole, followed by a slightly abbreviated version of Chapter 3 on bilateral and multilateral cooperation about the regulation of GMOs. While we welcome feedback on the entire paper, readers interested solely in the nested and overlapping regimes aspect of the paper may want to focus primarily on section 3.2, on pages 16-32.

Introduction

In the early 1990s, the US Food and Drug Administration approved the first genetically engineered food – Calgene’s Flavr Savr Tomato – for sale and marketing in the United States. Encouraged by a regulatory system that treated genetically modified foods and crops as substantively equivalent to their conventional counterparts, US scientists have subsequently created, farmers have grown, and companies have marketed a wide range of genetically modified (GM) foods and crops. Approximately 81% of soybeans, 73% of cotton, and 40% of corn grown in the United States consist of genetically modified varieties, and over 75 percent of processed foods available in US groceries are now derived from genetically modified organisms (GMOs), which figures are rising annually. This represents “the most rapid adoption of a new technology in the history of agriculture” (Hill and Battle 2000).

By contrast with the US embrace of agricultural biotechnology, European publics and regulators at both the national and European Union (EU) levels have taken a far more cautious approach to GMOs, treating GM foods and crops as different from their conventional counterparts, and adopting increasingly strict and complex regulatory procedures for their approval and marketing. By contrast with the United States, GM foods and crops face considerable regulatory hurdles in the EU, including requirements for mandatory pre-approval of all GM varieties, as well as provisions on the mandatory labeling and traceability of all GM products. These internal EU decisions have had worldwide impacts on account of the size and importance of the European market, making it difficult, if not impossible, for US farmers (and an increasing number of growers in Argentina, Brazil, Canada, China and elsewhere) to export genetically modified grains and foods to Europe. In light of the difficulty and expense of segregating grains under the current global distribution system, potential new GM varieties (as for wheat) have been simply abandoned.

These sharp regulatory differences and the trade conflicts that they have generated lie at the intersection of major economic interests and fundamental social values. The resulting transatlantic and global conflicts have affected research, investment, and planting decisions worldwide, implicating one of the world’s most revolutionary (and

controversial) technologies. US and EU representatives have attempted over the past decade to manage the conflicts over their divergent regulatory approaches to biotechnology regulation, engaging in consultation and negotiation in a number of bilateral and multilateral contexts. Despite such efforts, the two sides have demonstrated few if any signs of convergence in their regulatory approaches, prompting the United States to file a complaint before the World Trade Organization (WTO) in May 2003.

This book examines the transatlantic and global conflicts over the regulation of agricultural biotechnology and its risks, explaining the divergent social attitudes and regulatory approaches on both sides of the Atlantic, the failure of cooperative and conciliatory efforts, the escalation of the conflict, and the risks, limits and prospects of meaningful intervention by WTO dispute settlement panels. We do so not simply because of the manifest economic, political, legal, environmental, and ethical importance of the topic – although these factors themselves justify the study – but also because the global dispute over the regulation of agricultural biotechnology illuminates the broader challenges faced when jurisdictional diversity and technological risk meet economic interdependence. Put simply, the regulation of agricultural biotechnology – like the regulation of other agricultural and industrial processes and products – remains primarily a national (or, in the EU case, regional) responsibility, while the increasing integration of the global economy means that differences in national regulations frequently manifest themselves as restrictions to international trade, affecting the entire chain of agricultural investment and distribution and the future of what biotechnology advocates call the most important technological development in the history of agriculture. The resulting conflict between the world’s two great economic powers, the United States and European Union, has great implications for agriculture worldwide, including in the developing world. Understanding the origins of these regulatory disputes, the barriers to their resolution, and the potential role of the WTO dispute settlement system (if any) is therefore central not only to the case of agricultural biotechnology, but to the broader question of how regulatory systems can co-exist in a global economy in which the risks and benefits of controversial technological developments are rapidly diffused.

The core arguments of the book are fourfold. First, the United States and the European Union have adopted starkly different standards and systems for the regulation

of agricultural biotechnology, reflecting distinctive social attitudes, domestic politics, institutional structures, and national interests, as well as the impact of contingent events. The development of these distinctive regulatory approaches (explained in *Chapter 2* of the book) have led increasingly to trade tensions and trade disputes between the two sides that give rise to efforts at international cooperation and conciliation and conflict resolution.

Second, we assess how the record of both bilateral and multilateral cooperation and coordination on GMOs has largely been one of stark failure. Despite high hopes for a new type of bilateral cooperation through flexible and deliberative networks of government regulators touted in legal and political science studies (Slaughter 2004; Risse 2000), the record of US/EU regulatory cooperation on agricultural biotechnology has been dismal, with little evidence of genuine deliberation, convergence or accommodation of views between the two sides. Cooperation within multilateral regimes, such as the WTO, the Convention on Biodiversity, and the Codex Alimentarius Commission, has been similarly poor, marred by distributive conflicts and by the challenge of cooperation in multiple, overlapping and often inconsistent regimes for trade, the environment, and food safety (assessed in *Chapter 3*).

Third, we argue that this failure of international cooperation is reflected in the striking lack of convergence between the US and EU regulatory systems for agricultural biotechnology, with the system's remaining largely unchanged in their respective approaches despite intensive regulatory exchange and significant internal debate over and revision of the regulatory frameworks in the US and the EU (as shown in *Chapter 4*).

Fourth and finally, in light of the poor record of international cooperation and regulatory convergence and accommodation, we suggest that, despite considerable risks, the United States' complaint before the WTO Dispute Settlement Body (examined in *Chapter 5*) could potentially offer the prospect of clarification and a greater possibility for mutual acceptance and conciliation that have so far eluded the two sides in their encounters in bilateral and multilateral fora. International adjudicators such as the WTO can facilitate co-existence of diverse regulatory systems, we suggest, provided that they resist taking sides on *substantive* issues, while clarifying the minimum *procedural* requirements that members must meet, in this case before implementing trade-restrictive

regulations of GM foods and crops.¹ We conclude in *Chapter 6* by summarizing our findings and examining the broader implications of the GMO conflict for international regulatory cooperation involving technological risk in a global market economy.

Chapter 3

The Promise, and Failure, of Transatlantic Regulatory Cooperation

The dispute over the regulation of agricultural biotechnology presented the US and the EU with a dilemma: On the one hand, both sides sought to regulate GM food and crops in line with their respective regulatory traditions and the demands of their citizens, while on the other both sides had a clear interest in preventing the GMO issue from escalating into a full-scale trade war. Faced with such tensions, US and EU officials attempted bilateral cooperation, enlisting networks of scientists, civil-society groups and – especially – government regulators from both sides to deliberate together, and to understand and overcome their regulatory differences. In doing so, they drew on both an increasing social-scientific consensus about the virtues of governance by “transgovernmental” networks, and on the positive experiences of transatlantic cooperation among regulators in other fields such as competition policy. Such networks, it was hoped, could foster genuine deliberation, a joint search for the best solution to the challenges of regulating agricultural biotechnology, among US and EU regulators. Despite these high hopes, the record of US/EU regulatory cooperation in the area of agricultural biotechnology has been disappointing, with little evidence of genuine deliberation or joint problem-solving among US and EU regulators, whose approaches remain distinct and who remain under intense pressure from their respective legislatures and from a highly politicized public opinion. The first half of this chapter accordingly examines the prospects and expectations for bilateral regulatory cooperation, and examines and explains the failure of bilateral cooperation to produce any significant formal or informal agreements or any evidence of genuine deliberation between US and EU regulators.

¹ This section, as well as Chapter 5 of the book, will of course be redrafted prior to publication in light of the WTO panel report as well as the likely appeal to the Appellate Body expected later in 2006.

In the absence of successful bilateral cooperation, both the US and the EU attempted to find cooperative solutions to the problems of biotech regulation in various multilateral fora. Such multilateral regimes, it was believed, could help states to cooperate by lowering the costs of negotiation, promoting deliberative decision-making, monitoring compliance with international agreements, and providing a forum for international dispute settlement. As we shall see, however, multilateral cooperation in the area of agricultural biotechnology faced two distinct challenges. First, while both sides had a clear incentive to avoid an all-out trade war, each had a strong preference to retain and to “export” its own regulatory system to the international level, placing the burden of adaptation on the other side. In the language of game theory, international cooperation on the regulation of GMOs is characterized not only by joint gains but also by distributive conflicts, posing substantial obstacles to successful cooperation and deliberation. Second, the regulation of GM foods and crops is the subject of what Kal Raustiala and David Victor (2004) have termed a “regime complex” – a set of partly overlapping regimes regulating various aspects of GM foods and crops. International cooperation in such regime complexes, the authors argue, is likely to be characterized by several inter-related phenomena: inter-state negotiations will be bound and limited by precedents in multiple regimes; states will “forum-shop,” seeking the most favorable regimes within which to advance their interests; and legal inconsistencies are likely to arise among regimes, creating new problems of inter-regime coordination. The regulation of agricultural biotechnology, we argue, falls within such a regime complex, being subject to a number of regimes relating to trade, environmental protection, and food safety.

The second half of the chapter therefore focuses on the promise as well as the difficulties of multilateral cooperation in the area of agricultural biotechnology, with a focus on three major international regimes: the World Trade Organization and its Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), which addresses trade-related aspects of GM foods and crops; the Biosafety Protocol signed at Cartagena in 2000, which deals with the environmental implications of GMOs; and the Codex Alimentarius Commission, which handles food-safety issues. As we shall see, multilateral cooperation in this area has indeed been subject to sharp distributive disputes,

with each side attempting to export its own regulatory approach to the global level and shift the burden of adaptation to the other side. In addition, multilateral cooperation on agricultural biotechnology has also been plagued by the problems of regime complexes, including forum-shopping by both sides and persistent legal inconsistencies among the various international regimes. Here again, as in bilateral negotiations, evidence of genuine deliberation is hard to find, and the result thus far has been a series of untidy compromises between the two positions, with no clear victory for either side, striking inconsistencies across different regimes, and little or no evidence of convergence of views on the central issues.

3.1 Regulatory Networks, Deliberation, and Bilateral Cooperation

As it happens, the rise of the transatlantic dispute over GMOs during the 1990s coincided with a revival, among practitioners and scholars, of the concept of governance through so-called “transgovernmental” networks of lower-level government officials cooperating and deliberating directly with their counterparts in other jurisdictions. The term “transgovernmental relations” was coined in the 1970s, by Robert O. Keohane and Joseph Nye, who defined the term as “sets of direct interactions among sub-units of different governments that are not controlled by the policies of the cabinets or chief executives of those governments” (Keohane and Nye 1974: 43). Transgovernmental relations have always existed, according to Keohane and Nye, but became more significant after World War II as a result of the expansion of the social and economic role of national governments, as well as their increasing economic interdependence. Under these circumstances, they argued, “bureaucracies find that to cope effectively at acceptable cost with many of the problems that arise, they must deal with each other directly rather than indirectly through foreign offices” (1974: 42).

More recently, reflecting the end of the Cold War and the emergence of “globalization” as a defining social issue, scholars have increasingly examined the role of transgovernmental and other networks to address the challenges of domestic and international governance. Ruggie (1995), for example, defines governance by networks as “a collaborative form of organization, based on complementary strengths, characterized by relational modes of interaction, exhibiting interdependent preferences,

stressing mutual benefits, and bonded by considerations of reputation.” Much of this literature examines the role of private or *transnational* networks, including epistemic communities of scientists, transnational advocacy networks, and business associations, in shaping perceptions of problems and promoting particular understandings of the best means to address them. By providing scientific expertise, framing issues, and pressuring states to live up to their obligations, it is argued, such transnational groups can influence political outcomes in world politics (Haas 1992, Risse-Kappen 1995; Keck & Sikkink 1998; Price 1998; Legro 1996; Wapner 1997).

At the same time, Anne-Marie Slaughter (1997, 2004) and others have revived the study of transgovernmental networks, which Slaughter characterizes as a “new world order” governed in large part by trans-border networks of regulatory agencies (“the new diplomats”) and courts, who interact and cooperate to provide joint governance of issues ranging from anti-trust and financial markets to food safety and the protection of the environment. While recognizing the problems of democratic oversight of such groups, Slaughter maintains that these new transnational mechanisms are normatively desirable because they are more likely to provide a “fast, flexible, and effective” means of transnational governance. In her words (Slaughter 2004: 5),

Stop imagining the international system as a system of states—unitary entities like billiard balls or black boxes—subject to rules created by international institutions that are apart from, “above” these states. Start thinking about a world of governments, with all the different institutions that perform the basic functions of government – legislation, adjudication, implementation – interacting both with each other domestically and also with their foreign and supranational counterparts. States still exist in this world; indeed, they are crucial actors. But they are “disaggregated.”

Perhaps the best examples of such transgovernmental networks are to be found within the European Union, where government officials have long interacted through networks such as the Committee of Permanent Representatives (Coreper, charged with negotiating the details of draft EU legislation) and “comitology” committees (charged

with overseeing the Commission's implementation of common EU regulations). In recent years, moreover, these traditional networks have been joined by others, such as the European Competition Network (bringing together the EU Commission and the national competition regulators in each of the Union's 25 member states) as well as similar networks of utilities and financial regulators. In many cases formally independent of their own domestic governments, these networks of regulators generally meet out of the public eye, seeking common solutions to common problems.

Emblematic of these developments, the EU has begun to experiment with the so-called "Open Method of Coordination" (OMC), an essentially transgovernmental network of national officials who meet regularly to compare and coordinate public policy in a range of issue-areas. Based on previous EU experience in areas such as economic policy coordination and employment policy, the OMC was codified and endorsed by the Lisbon European Council in March 2001, and is characterized as an intergovernmental and legally non-binding form of policy coordination based on the collective establishment of policy guidelines, targets and benchmarks, coupled with a system of periodic "peer review" in which member governments present their respective national programs for consideration and comment by their EU counterparts. Echoing Slaughter's views on transgovernmental networks, numerous scholars argued that the OMC offered a flexible means to address common policy issues in sensitive areas such as employment policy and pension reform, representing a "third way" between supranational and purely national governance (Hodson and Maher 2001; Scott and Trubek 2002).

Perhaps most interestingly for our purposes, an increasing number of scholars have identified these new and emerging networks as promising venue for what Christian Joerges (2001) has called "deliberative supranationalism," an efficient and normatively desirable system in which national government officials meet and *deliberate* in search of the best solution to common policy problems.

Joerges' emphasis on deliberation – reiterated in an exploding body of literature – derives largely from the work of Jürgen Habermas (1985, 1998), whose theory of communicative action has been adapted to the study of international relations and to the study of EU governance. The core claim of the approach, as popularized by Risse (2000) in the field of international relations, is that there are not two but three "logics of social action,"

namely (1) the logic of consequentiality (or utility maximization) emphasized by rational-choice theorists, (2) the logic of appropriateness (or rule-following behavior) associated with constructivist theory, and (3) a “logic of arguing” derived largely from Habermas’s theory of communicative action.

In Habermasian communicative action, or what Risse (2000: 7) 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. In the view of many democratic theorists, moreover, such processes lead to the promise of a normatively desirable “deliberative democracy,” in which societal actors engage in a sincere collective search for truth and for the best available public policy, and in which even the losers in such debates accept the outcome by virtue of their participation in the deliberative process and their understanding of the principled arguments put forward by their fellow citizens (Elster 1998; Bohman 1998).

Habermas and his followers concede that genuine communicative action, or argumentative rationality, is likely only under a fairly restrictive set of three preconditions. First, the participants in a deliberation must demonstrate an ability to empathize, to see the world through others’ eyes. Second, the participants must also share a “common lifeworld,... a supply of collective interpretations of the world and of themselves, as provided by language, a common history, or culture.” Third and finally, an ideal speech situation requires that the discourse be undertaken openly and that all actors have equal access to the discourse (Risse 2000: 10-11). These are demanding preconditions, and all the more so at the international level, where a common lifeworld cannot be taken for granted and where relationships of power are ubiquitous. For this reason, Risse (2000: 19-20) concedes, we should expect international deliberation or arguing only under certain conditions, including most notably:

- The existence of a common lifeworld 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.

- International institutions based on nonhierarchical relations enabling dense interactions in informal, network-like settings.

These conditions are by no means satisfied everywhere in international politics; but where they are present, Habermasian and constructivist scholars predict that international actors will engage in arguing rather than bargaining, presenting their arguments in a common language of law or science and proceeding to decisions on the basis of “the better argument” rather than the bargaining power of the respective actors. Empirical studies of deliberation face significant methodological hurdles in distinguishing between arguing and bargaining, or between genuine communicative action and “cheap talk” (Checkel 2001, Magnette 2004: 208). Despite these challenges, a growing number of studies have pointed to at least suggestive evidence of deliberation within EU regulatory networks, including Coreper (Lewis 2003), comitology committees (Joerges and Neyer 1997), and the OMC (Jacobsson and Vifell 2003; Borrás and Jacobsson 2004; Zeitlin et al. 2005).

Against this background, it is not surprising that both scholars and practitioners began, from the late 1990s onwards, to hold out the promise of transgovernmental networks and deliberative decision-making between the United States and the European Union. In the area of agricultural biotechnology, for example, some scholars have advocated ambitious proposals to establish a global “epistemic community of knowledgeable state and non-state actors representing a wide range of affected interests, common perspectives and bargaining positions” which could “develop convergent policies and expectations,” and which ultimately could lead to a stronger “transnational legal regime” with “more complete and precise rules” that would be “more likely to promote state compliance” (Murphy 2001: 339).

The expectation that GMOs might be dealt with through transgovernmental networks was also encouraged by an empirical development, namely the establishment of the New Transatlantic Agenda (NTA) in 1995 and the Transatlantic Economic Partnership (TEP) in 1998, both of which represented efforts by Washington and Brussels to deepen their economic ties and to address long-standing trade-related regulatory tensions. One of the core elements of the NTA and TEP programs was the establishment

of informal and (increasingly) formal regulatory cooperation between US and EU regulators in various issue-areas (Pollack 2003). As early as 1991, the Commission Directorate-General for Competition had signed a regulatory cooperation agreement with the US Federal Trade Commission and the Department of Justice, instituting an ambitious and largely successful program of day-to-day cooperation and information-sharing in cases of mutual interest. Later, the US and EU established formal Mutual Recognition Agreements in half a dozen economic sectors, in which each side would recognize the validity of the other's testing and certification procedures. Additional cooperation agreements were to follow in other issue-areas such as data privacy, where the US/EU Safe Harbor Agreement provided an innovative mechanism pursuant to which US firms could be certified as meeting more demanding data-privacy requirements so as to comply with an EU directive (Shaffer 2003).

In the context of the NTA and the TEP, biotechnology was quickly identified by policy-makers as an area in which a structured dialogue among regulators might build mutual understanding and trust, provide early warning of disputes, and perhaps, in time, contribute to a gradual convergence of regulatory approaches to GM foods and crops. Throughout the late 1990s, therefore, the US and EU established numerous working groups of scientific experts to exchange information relating to GMOs.² For example, the 1995 New Transatlantic Agenda established a High Level Environment Consultation Group which was to work in conjunction with a Permanent Technical Working Group on biotech issues. The latter was to bring together representatives from the EU's Environment and External Relations Directorates-General and from the Office of the United States Trade Representative, the Environmental Protection Agency and the US Department of Agriculture. This group was soon complemented by two new groups focusing on information exchange over biotech issues: the Agrifood Biotech Group (which consisted of governmental representatives from the Commission's agricultural and industry directorates-general and from the US Department of Agriculture and USTR) and the US-EC Task Force on Biotechnology Research (which coordinated workshops

² The US Congress even explicitly amended the Federal Food, Drug and Cosmetics Act to instruct the FDA "to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods... between the European Unions and the United States." See FFDC, 21 U.S.C. 383(c)(2) (1994).

bringing together US and European scientists). Then, in connection with the 1998 Transatlantic Economic Partnership, the two trading partners set up another group – the TEP Biotech Group – to coordinate discussions and information-exchange, this time focusing on the trade effects of each side’s regulation of agricultural biotechnology.³

The output of these working groups, however, disappointed both sides. Some groups, such as the TEP Biotech Group, only met a few times.⁴ Even where transatlantic dialogue occurred more consistently, the two sides never progressed to a formal cooperation agreement in the biotech sector; nor was there any clear sign of convergence in the views of US and EU regulators as a result of these exchanges. In 1999, for example, Commission officials consulted widely with their US counterparts in designing the fledgling European Food Safety Authority, closely examining the structure and procedures of the FDA as a potential model. The Commission’s eventual proposal for the EFSA, however, drew at best selectively on the FDA model, accepting the role of independent agencies in scientific risk assessment, but insisting that risk management continue to be undertaken by political bodies such as the Commission, Council, and European Parliament.⁵ In fact, when fully operational, EFSA is expected to employ only around 250 people and have a budget of only 40 million euros, a tiny agency compared to the US FDA that employs over 9,000 people and has 2,100 scientists working for it.⁶ The FDA and the Commission therefore remained very different types of regulators guided by distinctive mandates, with the FDA in particular refusing to consider any serious challenge to its model of (in its view) independent and “science-based” decision-making, and with the Commission politically unable or unwilling to move towards a more independent regulatory agency model along the lines of the FDA.

As little progress was made among US and EU governmental representatives, the US and EU decided to form two transatlantic civil-society groups in November 1999: a transatlantic scientific advisory committee consisting of scientists specifically working on

³ European Commission, “Biotechnology in Bilateral and Multilateral Fora,” mimeo, Brussels, 25 July 2000.

⁴ The TEP Biotech Group is known to have met three times in 1999 and once in 2000, but the authors know of no subsequent meetings of this group. Interviews, US and EU Commission officials, Brussels, July 2002, and Washington, DC, March 2005.

⁵ *Official Journal of the European Communities*, C 96 E, 27.3.2001, p. 247.

⁶ See Buonanno 2003.

genetically modified organisms, and an EU-U.S. Biotechnology Consultative Forum composed of twenty independent experts charged with examining the issues posed by biotechnology for regulators on both sides of the Atlantic. In the optimistic words of acting EU ambassador to the US John Richardson, these groups could help forge “a transatlantic consensus on where we go with biotechnology in the future” (Yerkey 1999: 2025). The transatlantic scientific advisory committee was to provide counsel to the Commission until its proposed Food Safety Authority was approved and operational. The Consultative Forum issued its final report, a consensual document representing the views of a range of European and American experts, in December 2000 (EU-U.S. Biotechnology Consultative Forum 2000). The report was welcomed by both sides, and indeed offered each side a partial endorsement of its own views. For example, the report endorsed the precautionary principle as a core element of biotech regulation, and also called for mandatory pre-market approval of all GMOs, including those generally recognized as safe – both core elements of the EU regulatory procedure.⁷ By contrast, the US State Department highlighted the report’s emphasis on the potentially beneficial effects of biotechnology as well as its discussion of openness and transparency in the regulatory process – “many of [which] are already a part of the U.S. regulatory system.”⁸ Following this initial expression of support, however, the report itself was essentially shelved by both sides, which have scarcely ever made reference to it in the subsequent years of conflict over the issue.⁹

Along similar lines, finally, both the United States and the European Union fostered the development of official “civil-society dialogues” among business, consumers, environmentalists, and labor unions. Although the latter two groups met only a few times and are currently defunct, the Transatlantic Business Dialogue (TABD) and the Transatlantic Consumer Dialogue (TACD) have met regularly since the mid-1990s and have taken clear stances on the regulation of biotechnology. The TABD established an Agri-Food Biotechnology Group to conduct studies and prepare recommendations,

⁷ See European Commission, “Commentary on the Report by the Commission Services,” http://europa.eu.int/comm/external_relations/us/biotech/ec_commentary.htm, accessed on 11 June 2004.

⁸ See U.S. Department of State, “Fact Sheet: Report of U.S.-EU Biotechnology Consultative Forum,” 19 December 2000, http://www.usembassy.it/file2000_12/alia/a0121901.htm, accessed on 11 June 2004.

⁹ Confirmed in discussion with a former high level official of the European Commission, June 2004.

and, throughout the 1990s, the TABD generally adopted a position aligned with that of the United States, calling for compatible standards between the US and the EU to promote transatlantic trade in GMOs and arguing that mandatory labeling of GMOs “unfairly discriminates among identical or like products” (TABD 2002). Faced with increasing public opposition to GMOs, however, as well as organizational difficulties among the CEOs who constituted its membership, the TABD has since taken a much lower profile on the issue of biotechnology regulation, with no mention of GMOs or biotechnology in its 2004 annual report (TABD 2004; Corporate Europe Observatory 2001).

By contrast, the Transatlantic Consumer Dialogue has been consistently active on the issue of biotechnology regulation since its creation in the 1990s, with US consumer organizations joining their European colleagues in calling for mandatory pre-market approval of all GMOs as well as mandatory labeling and traceability provisions. Clearly closer to the EU position than the US position on biotech regulation, the TACD has also called on several occasions for the US to abandon its WTO complaint against the EU, warning of “a ‘pyrrhic victory’ by the U.S. given the reaction of European consumers” (TACD 2004). In recent years, however, TACD representatives have grown increasingly frustrated at their apparently limited influence upon and access to US leaders in particular; hence the main importance of the TACD thus far appears to be its impact on US non-governmental groups, which have been regularly exposed to the more critical views of their European counterparts.

In sum, both EU and US policymakers, as well as many scholars in the academic community, placed great hope in the promise of transatlantic regulatory cooperation as an institutional forum to that would facilitate open deliberation, mutual understanding, and ultimately convergence of the disparate US and EU regulatory approaches to genetically modified foods and crops. However, as its proponents acknowledge, genuine deliberation is something of a hothouse flower, relying on a highly restrictive set of scope conditions including a high degree of institutionalization, scientific uncertainty, regularized and informal network contacts, and – most elusively – a “common lifeworld” among the participants. In the case of agricultural biotechnology, bilateral efforts at cooperation demonstrate few signs of genuine deliberation – of “arguing,” in the

Habermasian sense, rather than bargaining from fixed positions. Such a genuine deliberative dialogue has repeatedly been impeded in practice by starkly distinctive regulatory procedures, and indeed by regulatory philosophies that are sufficiently different to call into question the existence of a common transatlantic “lifeworld” with respect to the regulation of GMOs. Furthermore, even if the regulators from the two sides were able to bridge their differences and deliberate together, they would – and already do – find themselves operating in a highly politicized issue-area characterized by strongly mobilized interest groups and by often volatile public opinions limiting their ability to engage in any substantive compromise. With this failure – at least so far – of bilateral deliberation, both actors turned their attention to negotiations and deliberation in wider multilateral fora.

3.2 Transatlantic Contestation in Three Multilateral Fora

The pressures for the United States and the European Union to look to multilateral regimes was due not only to the failure of bilateral negotiations, but also to the very nature of agricultural biotechnology, which by the late 1990s had emerged as a global issue, with other OECD members and less developed countries increasingly enmeshed in the debate over the adoption of GM foods and crops. The first signs of this globalization appeared in the anti-GMO movement, which spread rapidly from Europe to much of the rest of the world. Japan and Korea, two WTO members traditionally raising barriers to US agricultural exports, announced that they would tighten approval procedures for genetically modified varieties and require mandatory labeling of genetically modified seeds and foods. Even Australia and New Zealand, large agricultural exporters, announced in 1999 that they would require labeling of all GMO-derived foods. The majority of developing countries, generally concerned over the expansion of patent and other rights over seeds and plant varieties, supported a move toward a restrictive new treaty on genetically modified foods, criticizing the monopoly rights that large US and European firms hold over new seed technologies. Some, such as Thailand, welcomed new price premiums available for their GMO-free varieties. In 2002 the African countries of Zambia, Zimbabwe and Mozambique even rejected donated food from the United States that was produced using biotechnology. The United States responded forcefully to

these developments. In a June, 2003 speech to the Biotechnology Industrial Organization (BIO), President George Bush denounced EU limits on the imports of GMOs based on “unfounded, unscientific fears.... For the sake of a continent threatened by famine,” Bush continued, “I urge the European governments to end their opposition to biotechnology.”¹⁰

In this context, neither the US nor the EU limited its attention to bilateral discussions, but sought to advance their interests through multilateral regimes such as the World Trade Organization and its Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), which addresses trade-related aspects of GM foods and crops; the Biosafety Protocol signed at Cartagena in 2000, which deals with the environmental implications of GMOs; and the Codex Alimentarius Commission, which handles food-safety issues. Multilateral regimes such as these, it has been argued by regime theorists, can help states cooperate by performing a number of key functions. Defined in a collective research project (Krasner 1983) as “sets of implicit or explicit principles, norms, rules, and decision-making procedures around which actors’ expectations converge in a given area of international relations,” international regimes have been credited with performing a number of useful functions, at both the negotiating stage and during the subsequent implementation of international agreements.

At the negotiating stage, international regimes can reduce the transaction costs of negotiating international agreements, by providing fora for regular meetings of officials, and by providing secretarial and other logistical support for international negotiations (Keohane 1984). The various trade rounds of the WTO, the regular meetings of the parties to the UN Convention on Biodiversity, and the working groups of the Codex Alimentarius Commission have all performed this basic function in the area of agricultural biotechnology, although as we shall see presently these various fora are characterized by different memberships, different voting rules, and differing modes of representation. Constructivist scholars, moreover, go beyond this simple transaction-cost

¹⁰ United States Mission to the European Union, “Bush: Biotech Key to Fighting Global Hunger, Terrorism,” 23 June 2003, <http://www.useu.be/Categories/Biotech/June2303BushBiotech/html>, accessed on 11 June 2004. The African situation was also invoked in the US’s WTO complaint; see e.g. “US Argues EC GMO Moratorium Hurts Developing Countries,” *Bridges Weekly World Trade Digest*, Vol. 8, No. 15, 28 April 2004.

approach, arguing that the institutionalization of a given issue-area in international politics can also encourage the sorts of ongoing, face-to-face interactions that Risse (2000) and others believe to be conducive to deliberative decision-making. Put differently, international regimes can at the very least increase the efficiency of decision-making, and at best can transform international decision-making from a logic of bargaining to one of arguing.

Once a given agreement is adopted, international regimes can also play a key role in their implementation, most notably by monitoring member-state compliance with their provisions and reporting instances of non-compliance. In the classic Prisoner's Dilemma (PD) scenario that serves as the backdrop for much regime theory, each state could potentially benefit from international cooperation if its negotiating partners comply with their agreements; but each state also faces a strong post-decisional temptation to renege on its agreements. In that context, regime theorists have argued, international regimes can increase the costs of renegeing – and hence the effectiveness of international agreements – by monitoring state compliance and reporting instances of non-compliance to the members of the regime. Examples of such monitoring functions can be found in regimes designed to protect global environmental commons such as the earth's ozone layer, where each state faces both an incentive to cooperate to protect a commonly valued resource and an incentive to free-ride on the conservation efforts of other states. In such circumstances, international regimes such as the Framework Convention on the Protection of the Ozone Layer (1985) and the subsequent Montreal Protocol (1987) have created secretariats whose primary function is to report on member-state compliance with the provisions of the agreement. Some international regimes, such as the WTO, go beyond this reportorial function, establishing courts and other dispute-settlement bodies designed to adjudicate disputes about the meaning of the relevant agreement and the responsibilities of the various parties to the agreement. In the area of agricultural biotechnology, all three of the aforementioned regimes provide some degree of reporting on member-state compliance, while the WTO goes further with the establishment of a powerful Dispute Settlement Body for the adjudication of disputes among the members.

All else being equal, therefore, we might expect multinational regimes such as the WTO, the Convention on Biodiversity and the Codex Alimentarius to facilitate the

adoption and implementation of cooperative outcomes in areas like agricultural biotechnology – and indeed all three fora have witnessed extensive negotiations and the adoption of formal agreements about the regulation of GMOs. Critics of regime-theoretic approaches, however, have identified a number of potential obstacles to successful regime-based cooperation, including two issues – the importance of distributive conflict, and the existence of multiple, overlapping regimes – that have played important roles in international efforts to cooperate on the regulation of GM foods and crops.¹¹

The first, distributive, critique of regime theory focuses on the appropriateness of the Prisoner's Dilemma (PD) as the proper model for many instances of international cooperation. In the PD model, states have a common interest in reaching a cooperative outcome, and the primary impediment to successful cooperation is fear that other states will cheat on their agreements. If this is an accurate description of the situation facing states, then international regimes should indeed facilitate cooperation by monitoring compliance and (in the case of dispute-settlement bodies) providing for decentralized enforcement as well. However, as Stephen Krasner (1991) has argued in an influential article, the Prisoner's Dilemma game deemphasizes another important obstacle to successful cooperation, namely conflicts among states over the *distribution* of costs and benefits of cooperation. In many cases, Krasner argues, the proper specification of the situation is not PD but rather the so-called Battle of the Sexes game. In the classic Battle game, two people (say, a husband and wife) agree that they want to take a vacation together, but disagree on the destination (he prefers the mountains, she the beach). In such a Battle game, the primary challenge is not the threat of cheating (since both players prefer some joint vacation to being alone), but rather of deciding which of two players' preferred equilibria (the mountains or the beach) will be selected.

In an analogous fashion, Krasner argues, many international situations more closely approximate Battle than PD, and the primary challenge in these situations is not to prevent cheating but to reach agreement among difficult options that have real

¹¹ For a series of powerful critiques of regime theory and in particular of Keohane's (1984, 1988) liberal institutionalism, see Grieco 1988, Krasner 1991, the essays in Baldwin 1993, and the excellent review in Hasenclaver et al. 1997: chapter 4. Much of this critique is concerned with the problem of "relative gains," which is distinct from the distributional argument presented here; for good discussions see Grieco 1988, Powell 1991, Snidal 1991, and Baldwin 1993.

distributive implications for the states involved. International regimes may contribute to cooperative outcomes in such situations, by facilitating negotiations and establishing stable rules, but those outcomes are likely to reflect the power of the various parties, with more powerful states using positive and negative issue-linkages to induce their partners to agree to their preferred outcomes. Furthermore, as we have seen above, stark distributive conflicts are widely considered to be inimical to the emergence of a deliberative “logic or arguing” – hence, to the extent that international situations approximate the conditions of the Battle game, we should expect states to engage in bargaining rather than deliberative behavior.

In the case of agricultural biotechnology, we argue, the United States, the European Union, and other countries share a common interest in avoiding a global trade war over the regulation and marketing of GMOs, but they differ sharply in their preferred solutions, with the United States preferring a more liberal and science-based approach and the European Union preferring a more precautionary approach, each in line with its own domestic system and standards. Under these circumstances, we expect each side – the US and the EU – to attempt to export its own model to the international level, using positive and negative issue-linkages to influence the positions of other states and demonstrating little predilection for deliberative decision-making and for the “power of the better argument.”

A second critique of traditional regime theory comes from Raustiala and Victor (2004), who accept that regimes may play a useful role in promoting international cooperation but question the assumption that international regimes can be clearly associated with clearly demarcated issue-areas. Given the proliferation of international regimes, the authors argue, an increasing number of real-world problems do not fall neatly within the jurisdiction of a single international regime, but rather lie at the intersection of multiple regimes, or what they call:

... a *regime complex*: an array of partially overlapping and nonhierarchical institutions governing a particular issue-area. Regime complexes are marked by the existence of several legal agreements that are created and maintained in distinct fora with participation of different

sets of actors. The rules in these elemental regimes functionally overlap, yet there is no agreed upon hierarchy for resolving conflicts between rules. Disaggregated decision making in the international legal system means that agreements reached in one forum do not automatically extend to, or clearly trump, agreements developed in other forums (Raustiala and Victor 2004: 279).

Decision-making in such regime complexes, the authors continue, is characterized by several distinctive features, of which we emphasize three. First, negotiations in a given regime will not begin with a blank slate but will demonstrate “path dependence,” taking into account developments in related international regimes. Second, individual states seeking to advance their interests will engage in “forum shopping,” selecting particular regimes that are most likely to produce their preferred outcomes. More specifically, states will select regimes based on characteristics such as their membership (e.g., restricted or universal), voting rules (e.g. one-state-one-vote vs. weighted voting), institutional characteristics (e.g., presence or absence of dispute-settlement procedures), substantive focus (e.g. trade or environment), and functional representation of member states (e.g. by trade or environment ministers), each of which might be expected to influence substantive outcomes in more or less predictable ways. Third, the dense array of institutions in a given regime complex will create legal inconsistencies, and states will respond to these inconsistencies with efforts to either demarcate clear boundaries among various regimes, and/or to assert the primacy or hierarchy of one regime over others depending on their substantive preferences. Raustiala and Victor’s empirical analysis focuses on the issue of plant genetic resources, which they argue exists at the intersection of intellectual property, environmental, protection, agriculture and trade. In a similar fashion, we argue that the regulation of agricultural biotechnology is the subject of a similar regime complex, taking in regimes dealing with trade, environmental protection, food safety, and agriculture; and within this regime complex we find the expected characteristics of path-dependence, forum-shopping, and legal inconsistency among regimes.

In the rest of this section, we examine the record of international cooperation on

agricultural biotechnology in three overlapping multilateral regimes: the WTO (trade), the Convention on Biodiversity and the Cartagena Biosafety Protocol, (environment) and the Codex Alimentarius Commission (food safety). Within each of these fora, we demonstrate, the United States has sought to promote its more “science-based” approach to biotechnology regulation, while the European Union has sought to secure international recognition for its regulatory approach and in particular for its interpretation of the precautionary principle. Here again, as in bilateral negotiations, evidence of genuine deliberation is hard to find. The result thus far has been a series of untidy compromises between the two positions, with no clear victory for either side and little or no evidence of convergence of views on the central issues. Moreover, the international institutions to which the US and EU have attempted to export their approaches have overlapping competences with no overarching hierarchy to resolve differences among treaty provisions. These differences result in turn in legal inconsistencies that have been left for subsequent political and judicial resolution, if at all.

The WTO and the SPS Agreement

As we have seen, differences among national risk regulations can create significant non-tariff barriers to trade in agricultural and food products. The problem of non-tariff barriers arising from these differences was addressed explicitly in the 1994 WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which was negotiated as part of the Uruguay Round of Trade Agreements that created the WTO and its binding dispute settlement system.¹² The SPS Agreement does not establish international standards for biotechnology or other food-safety questions (a role left to the Codex Alimentarius Commission, examined below), nor does it preempt the adoption of non-discriminatory national food safety regulations that might inhibit international trade. However, the Agreement does incorporate and promote the adoption of international standards and establishes trade rules that limit the ability of states to adopt trade-restrictive regulations without scientific support. More specifically, the SPS Agreement places the onus on a state that would restrict trade through national

¹² Issues regarding agricultural biotech regulation, and in particular regarding the labeling and traceability of GMO foods, also arise under the WTO Agreement on Technical Barriers to Trade, which is discussed in Chapter 5 below.

regulations to demonstrate that such regulations are based on a scientific risk assessment, and are not otherwise disguised restrictions on trade. The terms of the SPS Agreement, are, moreover, binding under international trade law, and enforceable before WTO dispute settlement panels and the WTO Appellate Body.¹³

Not surprisingly, given the importance of transatlantic trade in foodstuffs, the political pressure from EU farmers to protect the EU market and from US farmers to open it, and the differences in the US and EU regulatory systems, the first and most important food safety dispute under the SPS Agreement was brought by the United States against the European Union, over the issue of hormone-treated beef. The dispute began in 1989, when the European Union (acting under the terms of a 1988 directive) instituted a ban on the use of synthetic growth hormones in beef cattle within the Community, and prohibited the import of animals, or meat from animals, that had been treated with such hormones. Although the EU directive had been adopted primarily on the grounds of European consumer concerns about the safety of hormone-treated beef, the ban had an immediate and dramatic impact on beef producers in the United States, where some ninety percent of all beef cattle are treated with synthetic growth hormones, and where FDA studies have consistently shown that the growth hormones in question are safe for human consumption.

In 1995, after the entry into force of the SPS Agreement and the WTO's Understanding on Rules and Procedures Governing the Settlement of Disputes ("Dispute Settlement Understanding"), the US initiated legal action against the EU, alleging that the EU ban was inconsistent with the terms of the SPS Agreement because it was not based on scientific evidence, a risk assessment, or agreed international standards, and it arbitrarily differentiated between products. The EU, by contrast, argued that the SPS Agreement acknowledges the right of states to determine the appropriate level of health protection for their consumers, and that the ban was justified under the precautionary principle. A WTO dispute settlement panel was established in May 1996, and issued its report in favor of the US in August 1997. The EU appealed the panel's decision, and the WTO Appellate Body issued a second report in January 1998, once again in favor of the United States. The WTO panel and appellate decisions were both complex, involving

¹³ For good discussions, see Victor (2000: 865-937) and Howse (2000: 2329).

hundreds of pages of legal reasoning and scientific testimony. While the Appellate Body overrode the panel's assessment on several issues, it agreed that the EU had failed to base its beef-hormone ban on a scientific risk assessment, undermining the EU's claims that the ban was adopted to protect human health. In response to the EU's invocation of the precautionary principle, both the original panel and the Appellate Body found that the precautionary principle could not override the express provisions of the SPS Agreement, in particular the requirement of a risk assessment (Article 5.1 of the SPS Agreement).¹⁴ In accordance with the Appellate Body's findings, the Dispute Settlement Body ruled in February 1998 that the EU ban was inconsistent with the terms of the SPS Agreement, and instructed the EU to bring its regulations into compliance by no later than 13 May 1999.

Facing continuing pressure from its own consumers, however, and hopeful of producing additional scientific findings that might justify the ban, the EU failed to act, and the US retaliated on 17 May 1999, applying tariffs in the amount of \$116.8 million targeted against specific EU products such as *foie gras*, Roquefort cheese and Dijon mustard. These US tariffs in turn sparked a wave of protests among French and other European farmers, including an attack in August 1999 by a group of French farmers on a McDonald's restaurant, selected as the symbol of the threat of globalization and, more specifically, American food culture to French traditions. "McDonald's encapsulates it all," said one commentator. "It's economic horror and gastronomic horror in the same bun."¹⁵ Although the leader of the farmer's group, Jose Bové, was jailed for his part in the attack, he was later hailed as a hero in the French press for his opposition to American efforts to force upon Europeans foods that were widely seen as unwanted and unsafe. As of September 2004, both the EU's beef hormone ban and the US punitive tariffs remained

¹⁴Article 5.1 provides, "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal, plant life or health, taking into account risk assessment techniques developed by the relevant international organizations." The EU invoked the precautionary principle as "a general customary rule of international law." See WTO Report of the Appellate Body on U.S. Complaint Regarding EC Measures Concerning Meat and Meat Products (Hormones), 2 International Trade Law Rep., No. 4, at 1113, par. 16. The EU, however, did not invoke the precautionary principles as set forth in Article 5.7 of the SPS Agreement, which provides for "provisional measures" adopted on precautionary grounds. See Mavroidis 2003:235.

¹⁵ Guillaume Parmentier, quoted in Henley 1999.

in place, in spite of the expressed desire of both sides to reach a negotiated settlement (Mavroidis 2003).

The transatlantic dispute over the EU's moratorium on the approval of new GM varieties (and its subsequent decision that all GM products be subject to pre-approval traceability and labeling requirements) is analytically similar to the dispute over beef hormones. EU trade-restrictive regulations on GMOs were adopted once again without being based on a scientific risk assessment, leaving the Union open to WTO legal challenge. US governmental authorities again sided with US producers and repeatedly protested to the EU bilaterally and before relevant WTO committees. Until 2003, however, the Clinton and then the Bush administration refrained from taking legal action before the WTO, fearing that such a case could prompt a European consumer backlash against GMOs.¹⁶ In the interim, the EU and US took their regulatory dispute to other international fora, each seeking to alter the terms of the international debate in its own favor.

The Convention on Biodiversity and the Cartagena Biosafety Protocol

From the perspective of the EU, the most promising of these fora was the 1992 Convention on Biodiversity, one of a series of framework agreements adopted at the 1992 Conference on Environment and Development at Rio de Janeiro, Brazil. By contrast with the case of hormone-treated beef, where no other international treaty existed to support EU claims regarding its right to restrict imports of hormone-treated foods, the Convention on Biodiversity (CBD) offered a forum within which the EU could press for an international environmental agreement supporting its precautionary approach to biotech regulation. By contrast to the WTO, the CBD was characterized by nearly universal membership, including many less developed countries, with parties to the negotiations generally being represented by environment, rather than trade, ministries. More concretely, the vast majority of parties to the Convention supported a protocol to address the transfer of living modified organisms (LMOs). By contrast, the United States (which had failed to ratify the CBD) was more reluctant about negotiating in that forum,

¹⁶ The WTO panel issued its interim report in favor of the US in early February 2006. The panel decision, which has been made available only to the parties to the dispute at this writing and remains subject to change, will be discussed in full in Chapter 5.

and indeed a reticent United States and a small number of grain exporting countries were initially able to block the signature of a protocol in February 1999 in Cartagena, Columbia. However, all countries eventually compromised and the Biosafety Protocol was signed in Montreal on January 29, 2000.

The three central issues that divided the US from the EU and most of the world were: (1) the application of the precautionary principle to decisions to ban imports and require labeling; (2) whether the Protocol should cover bulk commodities intended for consumption (e.g. crops) or be limited to organisms intended for direct introduction into the environment (e.g. seeds); and (3) the relation of the Protocol to WTO rules, with the US seeking to establish the primacy of WTO law and the EU using the CBD forum to strengthen the precautionary principle in international law. The parties compromised on all three issues, although the greatest compromises were made by the United States in that the Protocol undermines some US positions under the WTO's Sanitary and Phytosanitary Agreement.

First, the two sides compromised over the issue of the integration of the precautionary principle into the Protocol. On the one hand, Article 15 of the Protocol provides that countries will undertake "risk assessments... in a scientifically sound manner." On the other hand, Article 10 of the Protocol expressly incorporates the precautionary principle, providing that a country may reject the importation of "a living modified organism for intentional introduction into the environment" where there is "lack of scientific certainty regarding the extent of the potential adverse effects... on biological diversity in the Party of import, taking also into account risks to human health." A similar provision applies to a country's rejection of bulk genetically modified commodities (such as soybeans, wheat, corn and cotton) for food, feed or processing (Article 11). While US government authorities may maintain that this reference to "human health" is only made in the context of a treaty on biodiversity that does not address food safety *per se*, clearly the US would have preferred for such broad statements to be excluded.

At first glance, the US largely prevailed as regards the second issue in having the Protocol's mandatory pre-shipment notification and consent provisions limited to genetically modified organisms intended for release into the natural environment (e.g. planting), so that these provisions do not apply to bulk crops intended for food processing

and mass consumption (Article 5). Rather, as for bulk shipments of crops, the US is only obligated to notify a Biosafety Clearing-House once it approves a GMO for the US market. However, the Protocol leaves it to each country to decide whether to permit the importation of such products and provides that they may apply the precautionary principle in making this decision (Article 11). In addition, such shipments must be clearly labeled that they “may contain” living modified organisms (Article 18).

Third and finally, as for the relation of the Protocol to WTO rules, the US failed to obtain a clear reservation of its WTO rights.¹⁷ Rather, references to other “international agreements” are only made in the Protocol’s preamble, and these references are contradictory. The preamble provides that “this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements.” The next phrase, however, states that “the above recital is not intended to subordinate this Protocol to other international agreements.” As an EU representative stated, the two clauses effectively “cancel each other out,” leaving the legal relationship between the two regimes unclear and allowing both sides to claim a partial victory (Inside US Trade 2000). The EU, therefore, could point to the Biosafety Protocol as evidence of an international consensus (involving over 130 signatory countries) regarding the application of the precautionary principle to the regulation of biotechnology. The US, by contrast, could plausibly claim that nothing in the Biosafety Protocol compromised US rights under the SPS Agreement, which it would invoke in its WTO challenge to the EU’s biotech regime in 2003.

The Protocol itself took effect on 11 September 2003, and, as of June 2005, had been ratified by 124 parties, including the European Community.¹⁸ The United States, by contrast, is not a party to the Convention on Biological Diversity and hence has not signed or ratified the Cartagena Protocol. Nevertheless, the US participated as an observer in the first and second conferences of the parties in February 2004 and June 2005, respectively, and has indicated that “as a practical matter, firms in non-Party countries wishing to export to Parties will need to abide by domestic regulations put in

¹⁷ For useful overviews of the Cartagena Biosafety Protocol and its relation to the SPS Agreement, see Safrin 2002, Winham 2003.

¹⁸ See the Protocol website at: <http://www.biodiv.org/biosafety/>, accessed on 12 July 2005.

place in the importing Parties for compliance with the Protocol.”¹⁹ Even so, the implementation of the Protocol through the subsequent meetings of the parties has continued to demonstrate the fundamental tensions in national approaches to GM regulation. In the February 2004 conference, the parties to the protocol agreed to stricter labeling requirements for trade in genetically modified seeds and bulk crops, and paved the way toward new liability rules,²⁰ and additional progress was made at the second conference in establishing the work program of the new biosafety clearing house, agreeing measures to promote capacity-building among less-developed countries, and approving the rules of the Protocol’s committee on compliance. Nevertheless, the June 2005 meeting also demonstrated the stark divide that remains between, on the one hand, the EU and other countries (including Japan and many less-developed countries in Africa) which continue to advocate a highly precautionary approach, and, on the other hand, GM producers and other states (including most notably Brazil and New Zealand, as well as non-members the United States and Canada) that advocate a less restrictive approach. According to the terms of the Protocol, the Parties were to agree, by 11 September 2005, on the detailed documentation requirements for bulk shipments of LMOs, supplementing the original requirement that such shipments bear a label indicating that they “may contain” living modified organisms. At the June 2005 meeting in Montreal, however, the Parties split into three competing factions. Many African countries, led by Ethiopia, argued for a substantial tightening of the labeling requirements, replacing the “may contains” language of the protocol to a less equivocal “contains,” together with a list of all LMOs contained in a given shipment. These countries, lacking the technical capability to test for LMOs in imported shipments, sought to place as much of the burden as possible on agricultural exporters. The EU, by contrast, took a more flexible position on the “may contains” language, but sought binding provisions on the thresholds for adventitious presence of GMOs, in keeping with the EU’s own legislation on labeling and traceability (see Chapter 4). These proposals

¹⁹ United States Department of State, “Fact Sheet: Cartagena Protocol on Biosafety,” <http://www.state.gov/g/oes/rls/fs/2004/28621.htm>, accessed on 11 June 2004.

²⁰ “International Conference Deals Blow to US on labeling of gene modified food,” *Financial Times*, 8 (Feb. 28, 2004); “Delegates End Biosafety Talks with Rules on Documentation, Basis for Liability Regime,” *International Trade Reporter (BNA)*, vol. 21:10, 388 (March 4, 2004).

were rejected, however, by Brazil and New Zealand, which argued that strict rules on adventitious presence would impose an unreasonable burden on exporters. In the end, the June meeting broke up amid mutual recriminations without agreement on labeling requirements, which will be examined again at the third meeting of the parties in March 2006.²¹ While some agreement is likely in the future, the debate over labeling illustrates the stark differences among the parties to the agreement – even in the absence of the United States.

The Codex Alimentarius Commission

The Codex Alimentarius Commission (Codex) is an intergovernmental body established in 1962 by the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to facilitate international trade in food through the adoption of international food-safety standards. Throughout the post-war era, the United States and the European Union countries (represented individually by the EU's member governments) have cooperated within Codex on the establishment of international food-safety standards. The WTO's SPS Agreement, however, substantially increased the Codex Commission's notoriety, providing that national food safety standards based on international (Codex) standards are presumed to comply with WTO law. For this reason, the United States and European countries have placed increasing importance on the negotiation of new regulatory principles and standards within Codex, since these principles and standards may be invoked (and already have been invoked) in the decisions of WTO panels and of the Appellate Body. This enhanced importance of Codex also led to a major campaign by the EU to gain full membership in Codex, culminating in the EU's formal accession to Codex in November 2003.²² The Commission now speaks and votes on behalf of the EU "where an agenda item deals with

²¹ For details of the second meeting, see the official CBD website at <http://www.biodiv.org/biosafety/cop-mop/second-meeting.aspx?menu=mop2>. See also International Institute for Sustainable Development, *Earth Negotiations Bulletin*, Vol. 9, No. 320, 6 June 2003; "International Centre for Trade and Sustainable Development, "Divisions over Labeling Prove Insurmountable at Biosafety Meet," *Bridges Trade BioRes*, Vol. 5, No. 11 (June 2005), accessed on-line at <http://www.ictsd.org/biores/05-06-10/story1.htm> on 17 July 2005; and "Genetic Engineering: Agreement on GM Grain Trade Rules Blocked by Brazil and New Zealand," *European Report*, No. 2968 of 8 June 2005.

²² See Council Decision of Nov. 17, 2003 on the accession of the European Community to the Codex Alimentarius Commission, 2003 O.J. (L 309) 14.

matters of exclusive Community competence.”²³ In practice, this means that the Commission will almost always represent the member states in Codex on biotech matters, since annex II of the Council Decision provides: “As a general rule, the European Community has exclusive competence for agenda items dealing with harmonization of standards on certain agricultural products, foodstuffs...., including labeling, methods of analysis and sampling, as well as codes and guidelines.”²⁴

The subject of biotechnology regulation first came before Codex during the 1990s. A dedicated Working Group on Biotechnology was established in 1999, and subsequently negotiated and adopted a number of international guidelines on the regulation of biotechnology before being disbanded in 2003. Here again, as in the CBD, we find little evidence of deliberative decision-making among the various national experts, but rather strenuous negotiations between the governments of the United States and the European Union, each of which has once again put forward distinctive and sharply opposed proposals for international standards on issues such as the use of the precautionary principle, the use of “other legitimate factors” besides science in risk management, and the use of labeling and traceability requirements for bioengineered foods.²⁵

First, as regards the application of the precautionary principle, the Working Group on Biotechnology was charged with devising guidelines on risk regulation under uncertainty, with the EU and the US each advocating their traditional approaches to the question (Poli 2003: 133-137). The EU sought an expansive definition of the precautionary principle as applying to both risk assessment and risk management. The US delegation, in contrast, noted pointedly that, “a precautionary approach was already built into risk assessment; this concept should not be used by risk managers to overrule risk assessment” (quoted in Poli 2003: 134). After nearly four years of debate, the Codex

²³ Id., Annex III, Agreement between the Council and the Commission regarding preparation for Codex Alimentarius Meetings and statements and exercise of voting rights.

²⁴ Id. Annex II, par. 1. Single Declaration by the European Community on the exercise of competence according to Rule VI of the Rules of Procedure of the Codex Alimentarius Commission.

²⁵ This section benefits from the excellent overviews in Poli (2003 & 2004). For other discussions of biotechnology in the Codex, see e.g. the articles in Kalaitzandonakes and Phillips, eds. (2000) as well as the reports and recommendations of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, accessible on the FAO web page at http://www.fao.org/es/ESN/food/risk_biotech_taskforce_en.stm.

Commission finally agreed to a compromise text that acknowledged precaution “as an inherent element of risk analysis,” while offering little clarification about its use at either the national or international levels.

The US and the EU clashed in predictable fashion on a second transversal issue, namely the guidelines for the invocation of “other legitimate factors” (dubbed OLFs) besides science that could be invoked by Codex in establishing international standards. Following domestic EU law and practice, EU members argued that the Codex should consider a range of OLFs, such as consumer concerns and animal welfare, while the United States argued that “giving consideration to... these factors could open a Pandora’s box,” and therefore sought to restrict Codex decision-making to scientific considerations. Here again, the members eventually reached agreement on an amendment to the Codex Manual of Procedure allowing the invocation of OLFs in risk management decisions, but it provided no listing of these other legitimate factors, noting instead that “only those other factors that can be accepted on a world-wide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex.” The statement went on to note that consideration of other relevant factors should not affect the scientific basis of risk analysis or create “unjustified barriers to trade” (quoted in Poli 2003: 140). In effect, the compromise reached within the committee allowed for the invocation of unspecified OLFs in Codex decision-making, but proceeded to constrain that invocation with a series of more or less vaguely stated restrictions.

Finally, the US and EU engaged in contentious negotiations over the issues of labeling and traceability of GM foods. Although the Codex members were eventually able to agree in July 2003 to new “Principles and Guidelines on Foods Derived from Biotechnology,” the document provides no guidance regarding the labeling of GM foods because US and EU positions proved impossible to reconcile.²⁶ With regard to traceability, the Principles acknowledge the use of “tracing of products” as a risk-

²⁶ The principles were formally adopted in July 2003. See Codex Alimentarius Commission, Report of the Twenty-sixth Session (Rome, 30 June-7 July 2003), par. 52, document available at http://ftp.fao.org/es/esn/food/princ_gmfoods_en.pdf. See also Anne Mackenzie, “The Process of Developing Labelling Standards for GM Foods in the Codex Alimentarius,” 3 *AgBioForum* 203 (2000); and Vogel 2001, at 11.

management tool, representing a partial victory for the European countries, but goes on to note in a footnote that they “should be consistent with the provisions of the SPS and TBT Agreements.”²⁷

The results of these negotiations, Poli (2003: 146-47) points out, have thus far proven disappointing. “After lengthy discussions,” she argues, “these conflicts led to poor compromises, which do not have practical impact on the activity of the Codex Commission.” Like the paragraphs of the Cartagena Protocol dealing with the relation between Cartagena and WTO law, much of the Codex texts simply paper over rather than settle the differences among the parties, potentially delegating clarification of these issues, if at all, to the WTO dispute settlement system.²⁸

3.3 The Failure of Cooperation

The record of US/EU cooperation on the regulation of biotechnology has been largely a story of high, and disappointed, expectations. As we have seen, both scholars and policymakers first placed great stock in the promise of bilateral regulatory cooperation among governmental and (to a lesser extent) non-governmental experts in agricultural biotechnology. Various expert groups and working groups were created, with the aim of sharing experience and expertise, deliberating on the fundamental questions of biotech regulation, and finding common ground among US and European regulators. Despite repeated efforts, however, such transatlantic groups failed to reach consensus on any substantive issues, in part because their regulatory backgrounds and views were sufficiently diverse as to call any “common lifeworld” into question, but also

²⁷ See Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, *Codex Principles and Guidelines on Foods Derived from Biotechnology*, available at http://ftp.fao.org/esn/food/princ_gmfoods_en.pdf, at par. 21, accessed on 9 June 2004.

²⁸ Most recently, the Codex Committee on Food Labeling has deadlocked over the labeling of GM foods (which falls outside the Cartagena Protocol). In this case, the United States, supported by Argentina, Australia, Paraguay, the Philippines, Paraguay and Thailand, have argued that labeling of GM foods should be limited to foods that are substantially different from their conventional counterparts in terms of composition, nutritional value or allergenic content, while the EU, Japan and other countries have called for process-based labeling in which any and all GM foods would be clearly labeled as such. The Canadian chair of the talks has proposed a compromise, in which “mandatory” labels would apply to GM foods substantially different from their counterparts, while “optional” labels would apply to all other GM foods. This proposal has been put to a Codex working group, which is scheduled to report back to the committee in 2006. For an excellent discussion, see International Centre for Trade and Sustainable Development, “GMO Labelling Continues to Divide Codex,” *Bridges Monthly*, Year 9, No. 5 (May 2005), p. 18.

because regulators on both sides were subject to intense political pressures from their respective producers and consumers not to compromise on either their regulatory standards or the regulatory systems that produce them. This failure of bilateral cooperation does not mean that transgovernmental networks and deliberation offer no promise in the international arena, but it does confirm the view that genuine deliberation is indeed a hothouse flower, which has failed to take root in the controversial and highly politicized arena of agricultural biotechnology.

US/EU cooperation in multilateral fora has delivered similarly disappointing results. Here again, it was hoped that multilateral regimes might lower the transaction costs of negotiations, promote deliberation, and improve compliance with international agreements; and indeed the issue of agricultural biotechnology was taken up within several multilateral regimes including the WTO, the Convention on Biodiversity, and the Codex Alimentarius. Effective cooperation and deliberation, however, were impeded by both distributive conflicts among the US and the EU, and by the difficulties of adopting binding agreements within multiple and overlapping international fora. As we have seen, the intense politicization of the issue and the prior failure of deliberation at the bilateral level meant that the various multilateral negotiations on agricultural biotechnology took the form of a Battle of the Sexes game in which each side sought to use its influence to export its own regulatory system and standards and impose the costs of adjustment onto the other side. Given the roughly equal power resources brought to bear by the two sides, however, the result in each case was not a clear victory for either side, but a series of muddled compromise that papered over rather than resolved the fundamental transatlantic differences. Effective cooperation was further hampered by the difficulty of negotiating simultaneously in the various “elemental regimes” within the regime complex for agricultural biotechnology. Thus, as we have seen, both sides have effectively “forum-shopped,” with the United States clearly preferring the WTO with its emphasis on trade and its strong dispute settlement system, and the EU preferring cooperation within the Convention on Biodiversity, whose universal membership and strong environmental emphasis appeared to favor the EU’s more precautionary approach. These differences led in turn to inconsistencies among the various regimes and to efforts by each side to assert the primacy of its own preferred regime. In no case, however, was a clear

hierarchy of regimes established, leaving enormous uncertainty among governments, producers and consumers about the definitive global rules for the regulation of GM foods and crops.

References

Baldwin, David A., ed. (1993). *Neorealism and Neoliberalism: The Contemporary Debate* (New York: Columbia University Press).

Bohman, J. (1998). "Survey Article: The Coming of Age of Deliberative Democracy," *Journal of Political Philosophy*, Vol. 6, No. 4, pp. 400–25.

Borrás, Susana, and Kerstin Jacobsson (2004). "The Open Method of Coordination and the New Governance Patterns in the EU," *Journal of European Public Policy*, Vol. 11, No. 2, pp.185–208.

Buonanno, Laurie (2003). "Politics versus Science: Apportioning Competency in the European Food Safety Authority and the European Commission," in Ansell, Chris, and David Vogel, eds. (2003). *Why the Beef? The Contested Governance of European Food Safety* (MIT University Press, under review), draft available at <http://www.polisci.berkeley.edu/Faculty/bio/permanent/Ansell.C/FoodSafety/HY.pdf>.

Checkel, Jeffrey T. (2001). "Taking Deliberation Seriously," ARENA Working Papers, WP 01/14, http://www.arena.uio.no/publications/wp01_14.htm, accessed 11 June 2004.

Corporate Europe Observatory (2001). "TABD in Troubled Water: A CEO Issue Briefing," Global Policy Forum website, <http://www.globalpolicy.org/socecon/tncs/2001/1008tabd.htm>, accessed on 13 June 2004.

Elster Jon (ed.) (1998). *Deliberative Democracy* (New York: Cambridge University Press).

EU-U.S. Biotechnology Consultative Forum (2000). *Final Report*, http://europa.eu.int/comm/external_relations/us/biotech/report.pdf, accessed on 11 June 2004.

Grieco, Joseph M. (1988). "Anarchy and the Limits of Cooperation: A Realist Critique of the Newest Liberal Institutionalism," *International Organization*, Vol. 42, pp. 485-508.

Haas, Peter (1992). "Introduction: Epistemic Communities and International Policy Coordination," *International Organization*, vol. 46, pp. 1-

Habermas J. (1985). *The Theory of Communicative Action*, Vols. 1 and 2 (Boston: Beacon Press).

Habermas J. (1998). *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy* (Cambridge: MIT Press).

Hasenclaver, Andreas, Peter Mayer, and Volker Rittberger (1997). *Theories of International Regimes* (New York: Cambridge University Press).

Henley, Jon (1999). "McDonald's Campaign Spawns French Hero: Political Activist Turned French Peasant Has Fast Food on the Run," *The Guardian*, 11 September, p. 14.

Hill, Lowell B., and Sophia C. Battle (2000). *Search for Solutions in the EU-US GMO Debate*, proceedings of a conference, *GMO Regulations: Food Safety or Health Barrier?*, held at the Wyndham Hotel in Chicago, Illinois, October 22 and 23, 1999 (Department of Agricultural and Consumer Economics, Agricultural Experiment Station/Office of Research, College of Agricultural, Consumer and Environmental Sciences, University of Illinois at Urbana-Champaign, AE-4731).

Hodson Dermot, and Imelda Maher (2001). "The Open Method of Coordination as a New mode of Governance: The Case of Soft Economic Policy Co-ordination," *Journal of Common Market Studies*, Vol. 39: 719-46.

Howse, Robert (2000) "Democracy, Science and Free Trade; Risk Regulation on Trial at the World Trade Organization," *Michigan Law Review*, Vol. 98 p. 2330.

Inside US Trade (2000). "GMO Protocol Offers Compromise on Crops, WTO Relationship," *Inside US Trade*, Vol. 18, p. 1 (Feb. 4).

Jacobsson Kerstin, and Asa Vifell (2003). "Integration by Deliberation? On the Role of Committees in the Open Method of Coordination," paper prepared for the workshop on *The Forging of Deliberative Supranationalism in the EU*, European University Institute, Florence, 7-8 February 2003.

Joerges, Christian (2001). "Deliberative Supranationalism – A Defence," *European Integration online Papers*, (EIoP) Vol. 5 (2001) N° 8; <http://eiop.or.at/eiop/texte/2001-008a.htm>, accessed on 11 June 2004.

Joerges, Christian and Jürgen Neyer (1997). "From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology," *European Law Journal*, Vol. 3, pp. 273-299.

Kalaitzandonakes, N., and P.W.B. Phillips, eds. (2000). *The Codex Alimentarius Commission and GM Food Labeling*, special issue of *AgBioForum: The Journal of Agrobiotechnology Management and Economics*, Vol. 3, No. 4.

Keck, Margaret and Kathryn Sikkink. 1998. *Activists Beyond Borders* (Ithaca: Cornell University Press).

Keohane, Robert O. (1984). *After Hegemony: Power and Discord in International Politics* (Princeton: Princeton University Press).

Keohane, Robert O. (1989). "Neoliberal Institutionalism: A Perspective on World Politics," in his *International Institutions and State Power* (Boulder: Westview Press), pp. 1-20.

Keohane, Robert O., and Joseph S. Nye. 1974. "Transgovernmental Relations and International Organizations." *World Politics*

- Krasner, Stephen D. (1983). "Structural Causes and Regime Consequences: Regimes as Intervening Variables," in S. Krasner, ed., *International Regimes* (Ithaca: Cornell University Press), pp. 1-22.
- Krasner, Stephen D. (1991). "Global Communications and National Power: Life on the Pareto Frontier," *World Politics*, Vol. 43, pp. 336-66.
- Legro, Jeffrey. 1997. "Which Norms Matter? Revisiting the 'Failure' of Internationalism." *International Organization* Vol. 51, No. 1. p. 38.
- Lewis J. 2003. "Institutional Environments and Everyday EU Decision Making: Rationalist or Constructivist?" *Comparative Political Studies*, Vol. 36, Nos. 1/2, pp. 97-124.
- Magnette, Paul (2004). "Deliberation or Bargaining? Coping with Constitutional Conflicts in the Convention on the Future of Europe," in E.O. Eriksen, J.E. Fossum, and A.J. Menéndez (eds.), *Developing a Constitution for Europe* (London: Routledge), pp. 207-225.
- Mavroidis, Petros (2003). "Trade Disputes Concerning Health Policy Between the EC and the US," in Ernst-Ulrich Petersmann and Mark A. Pollack, eds., *Transatlantic Trade Disputes: The US, the EU, and the WTO* (New York: Oxford University Press), pp. 233-45.
- Murphy, Sean (2001). "Biotechnology and International Law," *Harvard International Law Journal* Vol 42, pp. 47-139.
- Poli, Sara (2004). "The European Community and the Adoption of International Food Standards within the Codex Alimentarius Commission," *European Law Journal*, vol. 10:5, pp 613-630.
- Poli, Sara (2003). "Setting Out International Food Standards: Euro-American Conflicts within the Codex Alimentarius Commission," Giandomenico Majone, ed., *Risk Regulation in the European Union: Between Enlargement and Internationalization* (Florence: European University Institute), pp. 125-147.
- Pollack, Mark A. (2003). "The Political Economy of Transatlantic Trade Disputes," in Ernst-Ulrich Petersmann and Mark A. Pollack, eds., *Transatlantic Trade Disputes: The US, the EU, and the WTO* (New York: Oxford University Press), pp. 65-118.
- Powell, Robert (1991). "The Problem of Absolute and Relative Gains in International Relations Theory," *American Political Science Review*, Vol. 85, pp. 1303-20.
- Price, Richard. 1998. "Reversing the Gun Sights: Transnational Civil Society Targets Landmines." *International Organization*, Vol. 53, No. 3.
- Raustiala, Kal & David Victor (2004). "The Regime Complex for Plant Genetic Resources," *International Organization*, Vol. 58, pp. 277-309.
- Risse-Kappen, Thomas. 1995. *Bringing Transnational Relations Back In: Non-State Actors, Domestic Structures and International Institutions*, 94. (New York: Cambridge University Press).
- Risse, Thomas. (2000). "Let's Argue!': Communicative Action in World Politics," *International Organization*, Vol. 54, No. 1, pp. 1-39.

Safrin, Sabrina (2002). "Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements," *American Journal of International Law*, Vol. 96, pp. 606-628.

Scott, Joanne, and David M. Trubek (2002). "Mind the Gap: Law and New Approaches to Governance in Europe," *European Law Journal*, Vol. 8, No. 1, pp. 1-18.

Shaffer, Gregory C. (2003). "Managing US-EU Trade Relations through Mutual Recognition and Safe Harbor Agreements: 'New' and 'Global' Approaches to Transatlantic Economic Governance?" in Ernst-Ulrich Petersmann and Mark A. Pollack, eds., *Transatlantic Trade Disputes: The US, the EU, and the WTO* (New York: Oxford University Press), pp. 297-325.

Slaughter, Anne-Marie (1997). "The Real New World Order," *Foreign Affairs*, Vol. 76:5, pp. 183-197.

Slaughter, Anne-Marie (2004). *A New World Order* (Princeton University Press).

Snidal, Duncan (1991). "International Cooperation Among Relative Gains Maximizers," *International Studies Quarterly*, Vol. 35, No. 4, pp. 387-402.

TABD (2004). "Report to the US-EU Summit in Ireland, 26 June 2004 – Establishing a Barrier-Free Transatlantic Market: Principles and Recommendations," <http://128.121.145.19/tabd/media/TABDReportFINAL22AprilUS.pdf>, accessed on 13 June 2004.

TACD (2004). "Report: 6th Annual Meeting," http://www.tacd.org/events/meeting6/meeting_report.htm, accessed on 26 April 2004.

Victor, David (2000). "The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment After Five Years," *New York University Journal of International Law and Politics*, Vol. 32, No. 4, pp 865-937.

Vogel, David (2001). "Ships Passing in the Night: GMOs and the Contemporary Politics of Risk Regulation in Europe," *European University Institute Working Paper*, No. 2001/16.

Wapner, Paul. 1997, "Governance in Global Civil Society." In Oran R. Young, ed., *Global Governance: Drawing Insights from the Environmental Experience*. (Cambridge: MIT Pres).

Winham, Gilbert (2003). International regime conflict in trade and environment: the Biosafety Protocol and the WTO," *World Trade Review*, Vol. 2, No. 2, pp. 131-155.

Yerkey, Gary (1999). "US and EU Agree to Set Up Forum with NGOs to Review Biotech Dispute," *International Trade Reporter*, Vol. 16, p. 2025 (Dec. 16).

Zeitlin, Jonathan, and Philippe Pochet, with Lars Magnusson (eds.) (2005). *The Open Method of Coordination in Action: The European Employment and Social Inclusion Strategies* (Brussels: P.I.E.-Peter Lang), forthcoming.