Chapter 6

Biotechnology and Biosafety

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Biosafety: An Anticipatory Governance Challenge

Use of the techniques of modern biotechnology in agriculture and food production has given rise to impassioned debates over the last two decades about the benefits versus the risks posed by genetically modified organisms (GMOs) and products thereof. So-called transgenic varieties now constitute significant percentages of important globally traded commodity crops, such as maize, canola, soybean, and cotton (James 2011).

Governance of such products and ensuring their biosafety (i.e. safe uptake and use) remains a quintessentially *anticipatory* challenge, one where the very existence and nature of risk and harm remains scientifically and normatively contested (Gupta 2001; see also Guston 2010). Its anticipatory nature is related to the existence of "epistemological uncertainty" in this domain, whereby uncertainty and outright unknowability "lies at the core of a problem" (Funtowicz and Ravetz 1992: 259). Such uncertainty complicates the process of devising appropriate, adaptable, and stable biosafety governance arrangements. Anticipatory governance has to *co-evolve* with rapid socio-technical and environmental change, the contours of which are not easily discernible.

Global governance of GMOs has thus been shaped by the contested nature of concerns over potential environmental, human health, and socio-economic risks posed by GMOs and the resultant diverse framings of the nature of the governance challenge. This chapter reviews current global policy approaches to biosafety, including their central elements as well as potential conflicts between the global institutions wherein they take shape. It also reviews the national ramifications of existing global biosafety policy approaches. In so doing, it assesses diverse scholarly perspectives

The Handbook of Global Climate and Environment Policy, First Edition. Edited by Robert Falkner.

on the suitability and effectiveness of these approaches, with implications for future policy directions and scholarship.

The (Contested) Problem of Biosafety

Modern biotechnology can be defined as

> the application of (i) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers (WHO 2005: 1).

Use of such technologies can result in introduction of novel traits into plants, animals, and microorganisms that go beyond what would be feasible with traditional breeding techniques. It is this crossing of species barriers and the novel genetic material introduced into food and feed crops that raises a variety of ecological, health, and safety concerns.

Ecological concerns include, for example, potential adverse impacts on biodiversity from novel gene flow from engineered plants, such as creation of herbicide-tolerant weeds; or adverse impacts on non-target organisms or development of pest resistance to toxins engineered in plants (e.g. Rissler and Mellon 1996; Wolfenbarger and Phifer 2000). Human health concerns include potential allergenicity or toxicity from consuming genetically modified ingredients in food (McHughen 2000). Going beyond this, various socio-economic and ethical concerns include potential adverse impacts of relying on high-tech, capital-intensive interventions such as genetic engineering for local and subsistence food production systems; the creation of patentable monopolies and concentration of ownership in seed and plant varieties of vital food and commodity crops; or the moral (un)acceptability of modifying nature (Nuffield Council on Bioethics 2003; Kleinman and Kinchy 2007).

Such claims of adverse ecological, health-related, or socio-economic impacts are countered by those who emphasize, instead, the multiple benefits to be derived from transgenic crops. For some scholars and practitioners, such benefits include, *inter alia*, enhanced food production, reduced use of synthetic pesticides, and improved food security. According to such a perspective, the central risk to be guarded against is development of overly stringent biosafety regulations that will impede spread of this technology globally, to the detriment of the world's poorest (Herring 2007; Paarlberg 2008; for a detailed critique of "pro-poor" biotechnology perspectives, see Jansen and Gupta 2009).

A central feature of global biosafety governance is thus the lack of societal consensus on the existence, nature, and extent of risks or benefits posed by use of modern biotechnology in agriculture; whether these risks and benefits are likely to materialize; and how they will be distributed within and across societies. As a result, norms underpinning global governance remain contested as well, and diverse global governance forums become sites of conflict to negotiate contested meanings of biosafety. Furthermore, the role of science and expertise in shaping biosafety policy choices comes to the fore. Devising appropriate mechanisms by which to provide scientific input into governance of such new technologies is then a central challenge in biosafety

governance. These features underpin and shape current global policy approaches in this domain, as discussed next.

Global Policy Approaches

Two dominant policy approaches to ensuring biosafety currently coexist at the global level. The first is the *science-based harmonization* of national biosafety decisions encouraged by the global trade regime of the World Trade Organization (WTO), so as to facilitate transfers of transgenic products worldwide. This is the approach promoted by the WTO's Agreement on the Application of Sanitary and Phytosanitary Standards (henceforth SPS Agreement) to govern GMO trade. The second is *mandatory disclosure* by GMO producers of biosafety information and the intention to export GMOs, as a way to facilitate *informed choice* about import of transgenic products in diverse national contexts. This is the approach adopted by the multilaterally negotiated Cartagena Protocol on Biosafety (CPB) under the United Nations Convention on Biological Diversity, concluded in 2000.

Both approaches have unleashed multifaceted scholarly debates, of which four strands are discussed in this chapter. The first is the *appropriate role of science* in anticipatory risk governance, given a (global) push for science-based decision-making in this area. A second is whether *harmonization or a privileging of diversity* is promoted by existing global policy approaches, particularly in the current context of globalization. A third relates to potential *normative conflicts* between global biosafety policy approaches and associated *institutional conflicts* between international trade and environmental regimes. And a fourth relates to the promise versus perils of relying on *information disclosure* in anticipatory risk governance. Each of these areas of scholarly debates is discussed in turn.

Global Biosafety Governance: What Kind of Science–Society Contract?

An oft-deployed lens for assessing the suitability and effectiveness of global biosafety policy approaches is scrutinizing the role of science in this contested domain of global policy. The focus on science is stimulated, in the first instance, by the WTO-SPS Agreement's call for national sanitary and phytosanitary measures (relating to animal and plant health, thus also including biosafety measures) to be based on scientifically sound evidence of harm, so as to prevent unnecessary restrictions on trade, and avoid protectionism masquerading as risk avoidance, both key concerns of the global trade regime (SPS Agreement 1994; see also Christoforou 2000; Gupta 2002; Eckersley 2004).

The WTO-SPS Agreement also, however, allows for legitimate context-specific differences in judgments of appropriate levels of safety. This balancing act is reflected in the Agreement's preamble, which states that

> no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute an arbitrary or unjustifiable discrimination between members where the same conditions prevail or a disguised restriction on international trade (SPS Agreement 1994: Preamble).

While this attempted balance between permitting legitimate difference while preventing illegitimate discrimination is laudable in principle, in practice it has been complicated to interpret and institutionalize. In particular, science is increasingly implicated in such determinations, with the WTO-SPS Agreement specifying that national (trade restrictive) decisions should be based upon scientifically sound assessments in order to be compatible with trade rules. Thus the Agreement states that nationally appropriate measures should be "applied only to the extent necessary to protect human, animal or plant life or health, [be] based on scientific principles and . . . not [be] maintained without sufficient scientific evidence" (SPS Agreement 1994: Article 2). At the heart of the WTO-SPS Agreement, then, is a requirement that higher national standards must have clear scientific justification. Given the inevitable existence of scientific uncertainties in certain instances, the agreement permits recourse to trade-restrictive precautionary measures, as long as these are strictly time-bound and documentable efforts are ongoing to generate concrete scientific evidence of harm (SPS Agreement 1994: Article 5.7).

While analyses of the precautionary principle in environmental and biosafety governance abound (e.g. O'Riordan and Jordan 1995; Foster *et al.* 2000; Paarlberg 2001; Sunstein 2005) the essential debate turns on how precaution is to be interpreted and institutionalized, and whether it is part of or goes beyond a "sound-science" decision-calculus. This is related to whether biosafety governance itself transcends (or should transcend) science-based decision-making, even one that permits precautionary actions in the face of scientific uncertainty (Gupta 2002). Should biosafety governance, in other words, be *socially precautionary* as well?

These questions occupied center stage in negotiation and subsequent interpretation of the obligations of the Cartagena Protocol on Biosafety, seen by many as an important counter to the WTO SPS-Agreement's science-based harmonization imperative (for detailed histories of these negotiations, see Gupta 2000; Bail *et al.* 2002). When concluded in 2000, the Cartagena Protocol was hailed by many as the first to institutionalize a precautionary approach to multilateral environmental and biosafety governance (Falkner 2000). The Protocol was demanded by developing countries and confers upon a potential importing country the right to give its "advance informed agreement" prior to trade in certain GMOs (Cartagena Protocol on Biosafety 2000: Article 15). However, such agreement is also to be based upon an assessment of scientific harm. The Protocol nonetheless permits precautionary restrictions in the face of scientific uncertainty. In this, it appears to give more flexibility to countries than the WTO-SPS Agreement, since it does not specify a time frame within which precautionary decisions must be reviewed (Gupta 2002; Millstone and Van Zwanenberg 2003).

Analyses of how the Protocol's inclusion of precaution is to be interpreted vary greatly, ranging from arguments that it is much more far-reaching than the WTO, thus providing an essential counterweight to the global trade regime (Isaac and Kerr 2003) to a view that the Protocol's language on precaution is largely aligned with the WTO-SPS agreement's push for science-based decision-making even if it does permit greater consideration of scientific uncertainties (e.g. Gupta 2002) to claims that its excessive emphasis on precaution hampers global spread of transgenic crops, particularly to the poor in Africa (e.g. Morris 2008).

These global policy debates and developments are grounded in early efforts in key OECD countries in the 1970s and 1980s – particularly in the United States and Europe – to develop biosafety regulatory frameworks to address risks posed by use of modern biotechnology (for early histories, see Wright 1994; Gottweis 1998). These efforts have resulted in the well-known transatlantic divide in GMO regulatory approaches between the USA and the EU over the last two decades (Jasanoff 1995; Levidow 2007; Pollack and Shaffer 2009; Cho 2010).

The United States has evolved a product-based approach to biosafety and biotechnology regulation since the late 1980s, based on the principle of substantial equivalence (e.g. Jasanoff 2005). According to this principle, products of genetic engineering do not require regulation if judged to be substantially equivalent to a non-genetically modified product, regardless of whether genetic engineering techniques were used in the production process (Millstone *et al.* 1999; Bernauer 2003). This focus on substantial equivalence has long prompted impassioned debate, not least because the United States remains the main producer and exporter of GM seeds, food, and crops (James 2011), ensuring that its own regulatory approach has consequences for global biosafety governance and for diffusion of biosafety regulatory frameworks to other parts of the world (Murphy and Levidow 2006).

In an influential early critique of substantial equivalence, Millstone and colleagues questioned both the adequacy of tests relied upon to establish equivalence, and the underlying assumption that equivalence of transgenic with conventional foods could even be established. Their conclusion was that substantial equivalence was a "pseudo-scientific concept because it is a commercial and political judgment masquerading as if it were scientific." They noted, for example, that it did not require biochemical or toxicological tests and hence served to "discourage and inhibit informative scientific research" (Millstone *et al.* 1999: 526).

In contrast to the USA, the EU has consistently strengthened its regional GMO governance architecture through its directives on deliberate release, traceability, and labeling of GMOs and their products (Pollack and Shaffer 2005; Levidow 2007). At the heart of the EU approach is a focus on the production process. Thus *use* of techniques of genetic engineering is sufficient to trigger regulation, regardless of the characteristics of the resultant product. Furthermore, the EU's approach institutionalizes reliance on precaution, insofar as (trade) restrictive actions can be used to avert potentially serious harm, even given lack of clear scientific evidence of harm (Murphy and Levidow 2006; Falkner 2007).

Both the USA and the EU have sought in the last decades to export their respective approaches to GMO regulation to the global arena, and bilaterally to developing countries. In its broad contours, the WTO-SPS Agreement's science-based harmonization approach is consistent with a US sound-science based regulatory approach; while the EU's precautionary approach is perceived by many to have been institutionalized within the Cartagena Protocol. Beyond this, the consequences of the transatlantic divide in GMO regulatory approaches, in particular for developing countries, are much debated. Some scholars argue that the transatlantic EU–USA conflict constrains developing country biosafety policy choices, insofar as it forces choice between the two (e.g. Bernauer and Aerni 2007), while others argue that developing countries do not necessarily have to ally themselves with the EU or US

biosafety model, but can, to greater or lesser extent, forge their own path in GMO regulation (e.g. Falkner and Gupta 2009). This debate relates directly to another strand of scholarly literature assessing global GMO policy, namely whether such policy promotes *harmonization or diversity* in national-level biosafety governance approaches, to which I turn next.

Global Biosafety Governance: Privileging Harmonization or Diversity?

With globalization as a catchword of the 1990s and beyond, a debate permeating scholarly analysis of global biosafety policy approaches relates to whether economic globalization and, in particular, globalized systems of food production and trade promote a *harmonization* of national policy choices or whether policy diversity persists. Harmonization is seen as desirable in a global trade context as a way to promote a level playing-field in the stringency and scope of national environmental policies, and hence to facilitate easy transfers of transgenic crops (Bernauer 2003; Drezner 2007; but see also Jasanoff 1998 for a different conceptualization of harmonization).

In the case of agricultural biotechnology and biosafety, the debate has focused on whether global policy will result in a "trading up," that is, an upward harmonization of national biosafety policies towards the more stringent level of the EU (e.g. Prakash and Kollman 2003; Young 2003). Evidence for such trading up remains inconsistent, however, and in recent years, attention has shifted to the persisting regulatory polarization between the USA and the EU and its consequences for national policy choices, particularly in the developing world (Bernauer 2003; Pollack and Shaffer 2009). Several prominent studies point to negative consequences of this transatlantic GMO conflict for developing country policy choices, arguing either that countries will be forced to choose one or the other pathway, that is, that there will be regulatory harmonization in the South along two nodes (Drezner 2007), or that the transatlantic conflict will have varied adverse impacts in the South, including the development of inconsistent regulatory approaches; impediments to public and private investment in agricultural biotechnology; and/or lack of public support (Paarlberg 2001; Bernauer 2003).

Others, however, provide alternative interpretations of whether globalization fuels harmonization, and with what implications for policy choices. In line with a long-standing literature that questions a view of globalization as a homogenizing force (e.g. Appadurai 1996), this strand of writing emphasizes the persistence of regulatory diversity. This is also because of the important mediating influence of domestic institutions and priorities, which fuel diverse national responses to globalization, also in the biosafety realm (Millstone and Van Zwanenburg 2003; Falkner and Gupta 2009; Pollack and Shaffer 2009). Recent studies propose typologies of domestic biosafety regulatory approaches that go beyond the EU–US regulatory dichotomy. For example, Kleinman *et al.* (2009) identify three regulatory models – which they term "liberal science-based"; "precautionary science-based"; and "social values-based" – that they claim different countries blend in distinctive ways to determine their specific policy approach.

In this, the role of the Cartagena Protocol is also noted. Analysts have focused on how the Cartagena Protocol's privileging of importing country choice in relation to the GMO trade permits context-specific differences to persist in biosafety regulatory

choices, in contrast to the harmonization imperative of the global trade regime (Jaffe 2005; Gupta and Falkner 2006). Millstone and Van Zwanenberg (2003) note, for example, that rather than a convergence of policies across jurisdictions, the persisting scientific conflicts over GMO safety provide leeway to countries in the South to pursue divergent policy choices, and in this they are bolstered by the Cartagena Protocol's privileging of importer choice and precaution. Others concur with the existence of diverse rather than harmonized biosafety policies in the South, yet attribute this diversity to conflicting trade imperatives rather than to scientific uncertainty over GMO safety, arguing that policy diversity is related to differential needs to access US and/or EU markets (Clapp 2006). Yet others highlight a variety of domestic political imperatives, extending beyond scientifically assessable harm, in shaping policy choices (Jaffe 2005; Falkner 2006; Gupta and Falkner 2006; Falkner and Gupta 2009).

This body of work has also highlighted that domestic biosafety policy choices transcend science-based decisions. Analyses of various national-level biosafety rules reveal that domestic biosafety decisions are based on myriad criteria that include, but go beyond, scientifically assessable ecological and human health risks. The influence of so-called "socio-economic considerations" in GMO decision-making was an important axis of conflict during the global negotiations of the Cartagena Protocol as well. Developing countries pushed to have such considerations included as a legitimate basis for national GMO regulatory choices, even those which would have resulted in a restriction of trade. The Protocol allows, as a result, for countries to "take into account, consistent with their international obligations, socioeconomic considerations arising from the impact of [genetically modified organisms] on the conservation and sustainable use of biological diversity" (Cartagena Protocol 2000: Article 26).

This, however, can be interpreted in a manner that is similar to the WTO-SPS Agreement's (limited) provisions on relevant socio-economic factors to be taken into account in domestic risk decisions. The WTO-SPS Agreement permits consideration of "relevant economic factors" in a risk assessment that is to form the basis for national decisions. Such considerations include

> the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risk (SPS Agreement 1994: Article 5.3).

Thus, socio-economic factors that can be considered under this Agreement relate to potential economic damages *arising from* sanitary or phytosanitary harm.

The Cartagena Protocol's provisions on socio-economic considerations can also be interpreted as restricted to those impacts arising from adverse impacts on biodiversity. Furthermore, the explicit stipulation that such considerations be "consistent with international obligations" implies deference to the WTO-SPS Agreement's provisions, in particular its call for science-based national decisions and (limited) inclusion of "relevant" economic factors. This appears to exclude considerations such as disruption to traditional livelihoods or undue dependence on patented seed as legitimate socio-economic bases for restricting GMO trade, concerns voiced by

developing countries during negotiation of the Cartagena Protocol. While such rationales to restrict trade appear to clearly run afoul of WTO rules, a more open question is whether public acceptability or consumer opposition to transgenic crops; lack of capacity to segregate modified from non-modified varieties of key crops; and/or lack of capacity to monitor safe handling and use in diverse contexts should be seen as legitimate socio-economic considerations influencing domestic biosafety policy choices (see e.g. Stabinsky 2000; Gupta 2002; Kleinman and Kinchy 2007).

As with most instances of global policy implementation, the key test lies in how criteria for domestic biosafety choices – whether those advanced by the Cartagena Protocol or the WTO-SPS Agreement – are interpreted and applied in diverse national contexts. A recent analysis of how "socio-economic considerations" permitted by the Protocol are being transposed into domestic legislation in developing countries shows that relatively few countries formally and systematically include such considerations in their biosafety assessment and approval processes (Falck-Zepeda and Zambrano 2011). Furthermore, what "socio-economic factors" include is open to multiple interpretations, with implications for what constitutes legitimate biosafety governance outcomes.

Whether and how to systematically include socio-economic factors in domestic decision-making is related, more broadly, to debates about democratic modes of risk governance as a way to lend legitimacy to contested risk and safety decisions (Jasanoff 2004, 2005; Lövbrand *et al.* 2011). In a recent analysis of the evolving domestic biosafety regime in India, Gupta (2011), for example, identifies two contrasting (and contradictory) sources of legitimacy that the Indian governance architecture has relied upon in reaching contested biosafety decisions: objective science versus democratic deliberation.

India has so far approved only genetically modified varieties of cotton for commercial use. This looked set to change in 2010/2011, when a nation-wide controversy erupted over granting commercial approval to a variety of eggplant (or brinjal, as it known as in India) modified to be pest resistant. Brinjal is a widely consumed vegetable in India and such approval would have resulted in the first transgenic food crop being approved for commercial use in India. In this instance, the then Minister of Environment and Forests launched an innovative experiment in deliberative democracy as a means to reach *and* legitimize a decision. He did this by organizing a nation-wide series of open public meetings to debate the risks and benefits of this particular transgenic crop. Following this, he announced a moratorium on approval of the modified brinjal variety, yet simultaneously held out the hope that better scientific information about risks and benefits could, in the future, help guide decisions on these contested issues. This was notwithstanding the fact that his own decision to impose a moratorium evoked concerns going well beyond scientifically assessable harm.

This paradoxical outcome – namely relying on democratic deliberation as a way to legitimize risk-related decisions, but nonetheless calling on objective science to serve as ultimate arbiter of conflicting views – highlights the continued deference to science as a way to legitimize contested risk decisions. Yet, as Gupta (2011) concludes, the brinjal experience makes clear that biosafety governance in India will *perforce* have to engage with (potentially messy) democratic decision-making processes, even if these are seen as ad hoc in a global context. The challenge lies in

how to institutionalize deliberative processes so as to rely on them in a systematic manner in making risk-related societal choices.

In line with this, research has also examined the role of global regimes, such as the Cartagena Protocol, in contributing to a democratization of debate and broadening of domestic biosafety policy agendas. Global obligations under the Protocol, for example, have been embraced by local and/or translocal protest movements as a means to contest global neoliberal or expert-driven discourses and practices of risk governance. Scoones (2008), for example, focuses on how anti-GMO mobilization and protest movements in countries such as India, South Africa, and Brazil shape domestic biosafety policy choices. He documents how such local and translocal mobilizations make "an important contribution to democratic debate in context(s) where, because of the forces of neo-liberalism, alternatives have little space" (Scoones 2008: 317). Nonetheless, the policy space for domestic biosafety regulatory choices is not without limits. Newell (2007) highlights, for example, the "bounded autonomy" of developing countries, particularly least developed countries, in selecting preferred biosafety regulatory pathways, given multiple global-national-local nexus of influences, both public and private, that need to be negotiated in making such policy choices (see also Pollack and Shaffer 2009).

Notwithstanding this, a relocalization of globally negotiated norms in given domestic contexts appears inevitable in practice. Global governance arenas such as the Cartagena Protocol are best viewed, then, as sites for negotiating shared understanding of concepts such as biosafety, rather than as vehicles for the global diffusion of consensual or universally valid decision criteria (Jasanoff 1998; Gupta 2004; see also Alemanno 2011). Such negotiated understandings are apt to rely, furthermore, on ambiguity and interpretative flexibility, rather than standardization on the basis of technical precision or scientific objectivity. If so, global policy arenas such as the Cartagena Protocol are themselves arenas for the generation of local – that is, context-specific – knowledge, which then inevitably requires relocalization to be relevant to other (local) contexts (Gupta 2004).

Global Biosafety Governance: Norm Conflicts or Collusion?

If global policy forums can be conceptualized as sites for deliberating and generating shared understandings of contested concepts, such a lens can also be brought to bear on analyzing *inter-linkages between global forums*, such as the Cartagena Protocol and world trade agreements. Analyses of such linkages have been another key strand of scholarly research in global environmental and biosafety governance (for a comprehensive overview, see Young *et al.* 2008). A concern with so-called "regime interplay" dates back to the mid-1990s, with a proliferation ever since of typologies of different types, sources, and consequences of regime interplay (e.g. Gehring and Oberthür 2006). Much scholarly attention has focused on whether there are synergies or conflicts among global policy forums. Capping this is a recent interest in interplay management (Oberthür and Stokke 2011).

Inter-linkages between the WTO-SPS Agreement and the Cartagena Protocol on Biosafety remain one of the most analyzed examples of such phenomena (e.g. Safrin 2002; Eckersley 2004; Oberthür and Gehring 2006; Gupta 2008). One concern has been with the existence and nature of (what are mostly assumed to be

undesirable) *conflicts* across these global regimes. A related focus is on the practice of so-called "forum-shopping" by key actors, who search for a favorable international institutional environment to further their specific political interests and globalize their preferred GMO regulatory approaches (for a detailed analysis, see Pollack and Shaffer 2009). Much literature on inter-linkages has also noted the consequences of what Eckersley (2004) has termed the "big chill" or the shadow cast by the WTO over negotiation and evolution of multilateral environmental agreements that address trade-related environmental issues.

In a recent analysis that compares institutional interactions across global climate, biodiversity and trade regimes, Zelli *et al.* (2012) argue that, in addition to analyzing dyadic relations between two regimes, the broader normative context shaping inter-regime interactions is also crucial to understand. They point, for example, to the overarching normative dominance of market liberalism in shaping regime interactions, even as this dominance is incomplete and contested in specific instances by key actors. Market liberalism privileges economic efficiency, unfettered markets, deregulation, and privatization in governance, a configuration that Steven Bernstein has labeled the "compromise of liberal environmentalism" (Bernstein 2001). Building on this, Zelli *et al.* (2012) argue that liberal environmental norms not only shape the provisions and practices of individual global regimes, but also their interactions with each other. In such a view, if the WTO casts a shadow over global environmental regimes, it is because the overarching normative context supports such an outcome. As such, these authors suggest that institutional interactions in the global environmental domain might be characterized more by a problematic normative *collusion* (that is, a homogeneity or similarity) rather than the more frequently assumed *conflict* between regimes.

Whether there is normative conflict between the two regimes in practice remains open to interpretation. Political conflicts over the appropriate relationship between the Cartagena Protocol and the multilateral trade regime led to the near-collapse of protocol negotiations in 1999, before an agreement was finally concluded in 2000. Reaching an agreement hinged on the inclusion and formulation of a so-called "savings clause" in the Protocol, a legal term for a provision that makes explicit its relationship to a prior and related treaty, in this case WTO Agreements (Gupta 2000; Bail *et al.* 2002).

The preamble of the Protocol contains this savings clause, which begins with a shared ideal that "trade and environment agreements should be mutually supportive." It goes on to state, however, that "this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements," a sentence that was inserted at the insistence of GMO producer countries and seen as vital to securing agreement of the USA and other GMO producers to a protocol. A final sentence, insisted on by the EU as a way to counter the preceding one, notes that "the above recital is not intended to subordinate this Protocol to other international agreements" (Cartagena Protocol 2000: Preamble). The outcome is that these two almost contradictory statements can be differently interpreted to suit specific needs.

With the Protocol in force since 2003, scholarly and practitioner attention has shifted to how the relationship between it and global trade agreements is, for example, being interpreted in judicial decisions and dispute settlement processes. Here,

a 2003 WTO a case brought by the United States against the EU's GMO regulatory approach has proved instructive. In this case, the USA, supported by Australia and Canada, asserted that the EU was violating its WTO-SPS obligations, given its restrictive approach to GMO imports and the *de facto* moratorium in place on new approvals of transgenic crops (WTO 2003; see also Isaac and Kerr 2003). In its defense, the EU invoked, *inter alia*, its rights and obligations under the Cartagena Protocol on Biosafety. As a result, the highly anticipated outcome of the dispute was expected to shed light on how the WTO interpreted its relationship to the Cartagena Protocol (Isaac and Kerr 2003).

The WTO ruling, when it finally came in May 2006, found largely in favor of the United States, arguing that the European Union was partially in violation of its WTO-SPS obligations. It is noteworthy, however, that the panel did not rule on the substantive elements of EU GMO regulation, including the reliance on precaution therein. Instead, the finding highlighted the failure of the EU to conduct the needed risk assessments prior to imposing restrictions on trade. In reaching this conclusion, moreover, the dispute settlement panel did not take global obligations under the Cartagena Protocol into account (Lieberman and Gray 2008). A rationale was that the two regimes do not share similar (relevant) membership, given that the USA – as the major GMO producer and exporter – is not a party to the Cartagena Protocol. More importantly, the Cartagena Protocol was not yet in force when the EU GMO restrictions were introduced.

This WTO panel finding has been interpreted in multiple ways, with one issue being whether the transatlantic GMO conflict is amenable to juridical resolution. Alemanno (2011: 2) asserts, for example, that the WTO case proved important not so much in what it decided but "in constraining the conflict by channelling it into a legal process, so as to deflect pressure within the US to retaliate aggressively against the EU." Cho (2010: 12) argues, in contrast, that resorting to a WTO dispute settlement mechanism aggravates conflict. As he puts it, "the adversarial legalism entrenched in the WTO adjudicative mechanism tends to judicialize science" with "duelling experts" (Pollack and Schaffer 2009: 172) seeking to mediate between uncertainties and conflicts over whose science is sound. A conclusion stressed by these authors, then, is that the WTO dispute settlement's procedural emphasis on "reason-giving and deliberation" among parties may be a better vehicle for generating shared understandings than (misguided) attempts to adjudicate whose science is valid or better aligned with WTO obligations.

A procedural focus on transparency and deliberation also underpins the final strand of debates about global policy examined here, reliance on information disclosure as key to a right to know and choose in anticipatory risk governance.

Global Biosafety Governance: The Trials and Triumphs of Disclosure?

A more recent strand of research on global policy approaches to biosafety has emphasized the focus on information disclosure as an anticipatory risk governance strategy in a global context. The Cartagena Protocol's call for "advance informed agreement" can, in this view, be seen as an example of "governance by disclosure," whereby disclosure of information is relied upon to further normative, procedural, and substantive governance aims. These include furthering a right to know and the

exercise of choice by GMO importing countries, so as to facilitate risk mitigation (Gupta 2010a, 2010b).

Advance informed agreement as a way to govern GMO trade derives from the longer-established notion of prior informed consent (PIC). PIC has its origins in medical ethics as a risk–benefit balancing strategy for individuals participating in potentially risky clinical trials. Since the mid-1980s, prior informed consent has also underpinned voluntary guidelines and globally negotiated legally binding regimes governing trade in hazardous waste and restricted chemicals (Mehri 1988; Wolf 2000). The choice of prior informed consent as a governance mechanism is a compromise between the two extremes of an outright *ban* on trade in potentially hazardous substances, versus *caveat emptor* ("let the buyer beware"), whereby it is left to the market to govern potentially risky trade (Mehri 1988; Gupta 2010b). This compromise is reflected in the Cartagena Protocol as well, which privileges importing country *choice* based on mandatory information disclosure relating to GMOs in trade, rather than either calling for restrictions on such trade itself or leaving disclosure requirements or restrictions solely to the dictates of markets.

The current limited disclosure obligations institutionalized within this global regime, however, ensure that a norm of *caveat emptor* prevails in practice. This holds at least for GMO varieties contained in the bulk agricultural commodity trade of crops such as maize, canola, or cotton (Gupta 2010b). In documentation accompanying such trade, exporters are required only to disclose that shipments "may contain" GMOs. This requirement does not require existing market practices, such as current lack of segregation between GM and non-GM crop varieties, to change. As a result, governance by disclosure in this case is market following rather than market forcing. Furthermore, in order for importing countries to put the limited disclosed information to use in risk decisions, the onus remains on them to undertake sampling, testing, and verification of such disclosed information.

Debates in the global context of the Cartagena Protocol have now shifted to standardization of sampling criteria, appropriate detection methods, and availability of testing protocols, where again divergent EU–US approaches to such issues come to the fore. The Protocol's disclosure obligations for the GMO commodity trade are thus another global arena where the transatlantic conflict plays out (see Gupta 2010b for a detailed analysis of these dynamics). Given the many hurdles (capacity- and cost-related) to implementing such a disclosure, testing, verification, and labeling approach to domestic biosafety governance, it is noteworthy that some smaller or poorer developing countries are now imposing bans or moratoria on entry of GMOs, notwithstanding the existence of the Cartagena Protocol and its privileging of importer choice (Falck-Zepeda 2006).

A market-following rather than market-shaping outcome of disclosure is also discernible in the Protocol's requirement that parties disclose certain risk and biosafety-related information to its online Biosafety Clearing House (BCH). Information to be disclosed to the BCH includes the genetically modified varieties approved for commercialization in GMO producer countries (as demanded by potential importers); but also domestic biosafety laws and contact persons responsible for import decisions in GMO importing countries (CBD 2008). Given, however, that most GMO producer countries have not ratified the Protocol, the burden of disclosure has fallen, ironically, on importing countries who are parties to the Protocol. Disclosure of information

such as contact persons for GMO import decisions can, however, be trade facilitating, given that such information is necessary for trade to occur (Gupta 2010a).

In sum, as this line of research suggests, it is not clear that a biosafety governance approach based on disclosure and choice (and an associated need for segregation, labeling, and extensive infrastructures for sampling, detection, and verification) is an appropriate governance pathway for all countries. Given persisting political conflicts, technical complexities, and high costs of such routes to governance, it is noteworthy that bans and moratoria are becoming a fallback option for some of the poorest countries faced with the challenge of managing entry and safe use of GMOs within their borders. This is likely to remain the case as long as the veil of unknowability continues to hang over future normative and political developments in (global) GMO use, trade, and governance.

Conclusions and Global Policy Implications

This chapter has highlighted normative disagreements over the nature of the biosafety problem, and the implications of such disagreements for evolution and implementation of multilevel biosafety policy approaches. Various strands of research suggest that biosafety policy is shaped by an overall market-liberal bent to (global) environmental governance. This is evident, for example, in how a market-enabling global policy environment appears to have curtailed the evolution of stringent disclosure obligations in the Cartagena Protocol. It is also reflected in the rise and spread of corporate voluntary biosafety approaches in recent years, and their influence in shaping domestic biosafety trajectories (see e.g. Newell 2003; Glover and Newell 2004; Clapp 2007).

Yet a dominance of market liberalism in shaping biosafety trajectories is neither predetermined nor static, but is consistently challenged at multiple levels and by multiple actors (Zelli *et al.* 2012). This is evident, not least, from the policy evolution continually underway within the global context of the Cartagena Protocol. Two aspects now on the global biosafety agenda that may shift the normative balance include, first, a recently concluded agreement on GMO-related liability (Jungcurt and Schabus 2010) and, second, a much-awaited strengthening of trade-related disclosure obligations on GMO exporters, still to be negotiated.

Notwithstanding how these developments will proceed, a key issue remains how to conceptualize *and* institutionalize socially appropriate and democratically legitimate pathways for GMO governance that vary across contexts. Jasanoff (2005) analyzes, for example, the distinctive evolution of biotechnology and biosafety trajectories across OECD countries, and the role of distinct risk rationalities and political cultures therein. Building on this, a future global biosafety research agenda requires further delineation of what democratizing risk governance *can mean* in diverse global and national contexts (Jasanoff 2004, 2006; Gupta 2011; Lövbrand *et al.* 2011) and how it might be linked to imperatives of sovereignty and markets that shape technological trajectories.

Such a research agenda also has to engage with the anticipatory nature of the biosafety governance challenge and the veil of uncertainty over how markets for GM and non-GM crops will develop, which crops will be approved and win acceptance (or not) in key markets, and how understandings of risks will evolve. The challenge

remains selecting appropriate governance pathways in the absence of such knowledge and in the presence of epistemological uncertainties relating to risk and harm. The economic, political, and normative stakes are high for all, but particularly for the poorest countries, who might be recipients of (unwanted) GMOs (on "unplanned exposure" to transgenic crops in the South, see Clapp 2006).

Ultimately, anticipatory governance of biosafety remains contested because different governance pathways implicate different (and contested) visions of a desirable future (Jansen and Gupta 2009). Pro-poor biotechnology writings evoke a vision of a future *without* biotechnology as threatening and a future *with* biotechnology as beckoning and promising (on this, see also de Wilde 2000). Either way, the message is that if we do not embrace agricultural biotechnology and are too circumspect about safety, we will run out of time, and the future (at least for some) will be bleak. However, not all share such depictions of the future. The anticipatory governance challenge requires engaging with such diverse views in a legitimate manner; and in democratically agreeing upon appropriate decision parameters and sources of (policy) legitimacy.

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