

## Research Articles

# The Influence of the Cartagena Protocol on Biosafety: Comparing Mexico, China and South Africa

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### Introduction

The introduction of genetic engineering to agriculture has produced a range of new governance challenges in the fields of environmental safety, human health, trade and development. The use of genetic engineering is rapidly expanding in key sectors of food production, particularly in globally traded commodity crops such as maize, canola, soybean and cotton. In the last decade, a growing web of global rules and institutions has been created to govern agricultural biotechnology. The most recent of these is the Cartagena Protocol on Biosafety negotiated under the auspices of the Convention on Biological Diversity (CBD), which regulates transboundary transfers of genetically modified organisms (GMOs).<sup>1</sup> It was negotiated from 1996–2000 and entered into force in 2003, and is now being implemented in a growing number of developing countries.

The Cartagena Protocol calls for the advance informed agreement of an importing country prior to trade in certain GMOs.<sup>2</sup> It was negotiated at the insistence of developing countries, most of whom were not yet participating in the GMO trade and feared the entry of novel transgenic products into their coun-

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1. GMOs are called “living modified organisms” (LMOs) in the Cartagena Protocol.
2. Advance informed agreement is the terminology used in the Protocol instead of the better known “prior informed consent” which underpins global treaties regulating trade in hazardous

tries without their knowledge. These countries pushed for a global agreement that would make biosafety information-sharing mandatory on GMO exporting countries and would legitimize an importing country's right to restrict GMO trade in the face of scientific uncertainty about risk or potential adverse socio-economic impacts. The Cartagena Protocol has, in fact, been hailed by its supporters as one of the key global environmental agreements to institutionalize a precautionary approach to risk governance.

Since its negotiation, there has been growing scholarly interest in this global biosafety regime. Much attention has been devoted, in particular, to potential conflict with world trade rules.<sup>3</sup> However, few analyses exist of whether and how the Cartagena Protocol is influencing domestic debates and policy choices, particularly in developing countries.<sup>4</sup> It is this dimension that we address here.

The impact of global regimes on domestic policy has long been the subject of scholarly study. In international relations, this is a well-established area of inquiry via analyses of regime implementation, compliance and effectiveness.<sup>5</sup> In our study, we use the term "influence" rather than implementation or compliance, which often refer more narrowly to a treaty's obligations and provisions alone. Under "influence," we can include discursive changes associated with global regime creation and implementation as well.

We also prefer to assess influence rather than "effectiveness" of a global regime. The concept of effectiveness necessarily presupposes certain shared and clear-cut regime objectives which, if complied with, can change actor behavior in a domestic context and ultimately contribute to improved governance of an environmental problem. In controversial areas such as agricultural biotechnology, however, key elements of a global regime may remain contested. If so, assessing regime effectiveness becomes normatively problematic, requiring as it does the analyst to judge which of a regime's contested provisions, if complied with, would make for an "effective" global regime.

Our goal instead is to assess influence, via analyzing domestic discursive and/or institutional changes stimulated by a regime, notwithstanding persisting global-level conflicts. By discursive change, we refer to changes in the normative context surrounding agricultural biotechnology policy, which can result in legitimizing diverse perspectives and empowering different actors than might otherwise be the case. Under institutional change, we include regulatory, administrative, institutional and/or procedural changes stimulated by domestic implementation of a global regime.<sup>6</sup>

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waste and chemicals. For an analysis of how this changed language reflects conflicts over the nature of the global regime, see Gupta 2000a.

3. Kim and Chambers forthcoming; Oberthür and Gehring 2006; Isaac and Kerr 2003; and Safrin 2002.
4. For an early analysis of the relevance of the Cartagena Protocol in India, see Gupta 2000b. For biosafety regulations in developing countries and their compatibility with the WTO, see Baumüller 2003.
5. Young 2001; Weiss and Jacobson 1998; and Victor, Raustiala, and Skolnikoff 1998.
6. Clearly, the two are interlinked in that institutional change is likely to include discursive change

In assessing the influence of the Cartagena Protocol, we identify three elements of this global regime that are likely to stimulate discursive and/or institutional change in a domestic context. While the Cartagena Protocol contains obligations for both GMO exporting and importing countries, we focus here on elements that are most likely to exert influence in a potential GMO importing country, given that most developing countries fall within this group.

These three elements—or avenues of influence, as we refer to them here—include: *enhanced choice* regarding GMO imports, via the Protocol's legitimization of a broad set of decision criteria underpinning regulatory choices (including scientific evidence of harm, a precautionary approach, and socio-economic concerns); *enhanced access to biosafety information* from exporting countries, required by the Protocol; and *enhanced capacity* to regulate and ensure biosafety domestically (via financial assistance, training, sharing experiences, and learning from other contexts etc.).

In considering whether these avenues of influence are contributing to discursive or institutional change in a domestic context, we focus on three prominent developing/emerging economies: China, Mexico and South Africa. Our case selection is guided by two criteria: (a) participation in the global biosafety regime creation process; and (b) established capacity and active encouragement of domestic biotechnology research and commercialization as well as current participation in the GMO trade as importers. In short, we have selected what are often described as biotechnological leaders in the developing world,<sup>7</sup> where agricultural biotechnology is a key economic, environmental, political and social issue.

Our three countries are similar in this important respect, yet they also exhibit key differences. They vary particularly in the nature of their domestic political system: Mexico and South Africa are (nascent) democracies with a market economy, whereas China is undergoing a profound and rapid process of economic transformation and liberalization, although without corresponding political reform. Mexico is strongly integrated into global and regional trade and safety regimes, and is linked to leading industrialized countries of North America through membership in the North American Free Trade Agreement (NAFTA). South Africa has, since its re-admission into the global community in the early 1990s, participated enthusiastically in global regimes. China's version of a "socialist market economy" embraces international economic links and is concerned with international competitiveness, most notably symbolized by the country's accession to the World Trade Organization (WTO). However, it

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as well. We make the distinction here in order to capture influences of a global regime that may not result in concrete institutional change but only in a more open discourse or debate.

7. Although Mexico is a member of the OECD, in areas of relevance for agricultural biotechnology, it exhibits key characteristics of a developing country. Observers note the existence of "two Mexicos"—an industrialized North and an impoverished South—in analyses of the ongoing devastation of the peasant sector, partly resulting from the neoliberal reforms associated with NAFTA. The country still has a relatively large proportion of the population engaged in agriculture, particularly subsistence farming, and is a center of origin and/or diversity of key crops subject to genetic engineering, such as maize and cotton.

still places high priority on policy autonomy and insulation from external influences.

Notwithstanding these differences, it is the similarities that guide our choice: all three countries prioritize and encourage domestic biotechnology development and commercialization and are current importers of transgenic crops. In all three countries, encouragement of new agricultural technologies is part of an overall effort to promote economic liberalization and greater competitiveness in international markets. A key motivation underlying agricultural biotechnology policy is fear of being left out of the next technological revolution, with consequences for international competitiveness. If so, we would expect the Cartagena Protocol—given its justification of a precautionary approach to GMO imports—to have relatively less influence in these countries.

Yet all three countries have also participated actively in negotiation of the Protocol and all have ratified and begun to implement it. If so, in the face of potentially competing trade, market access and competitiveness concerns, what influence is the Cartagena Protocol having in these countries, if any? Our country selection is thus guided by the “most difficult” cases approach: if we can ascertain influence of this global regime in countries where one would least expect it, we can extrapolate that such influence is likely to be present in smaller developing countries, which are only now beginning the processes of biotechnology research, commercialization or regulation.

We proceed as follows: Section two elaborates further on the Cartagena Protocol’s three avenues of influence and places this regime within the larger context of global GMO governance and trade conflicts. The following three sections present detailed contextual analyses of biosafety debates and decision-making in Mexico, China and South Africa. Our analysis is based on fieldwork in each country and interviews with policy-makers representing diverse interests, including agriculture, environment, health, economy, science and technology, foreign affairs and trade, as well as stakeholder representatives including scientists, NGOs (where they exist) and the private sector. In the last, concluding section, we compare our findings and assess their relevance for other developing countries.

## **Cartagena Protocol: Avenues of Influence and Global Context**

### *Global Context: The Governance Challenge*

Although data about the spread of genetically modified (GM) crops worldwide is difficult to come by, figures compiled by the International Service for the Acquisition of Agri-biotech Applications (ISAAA) claim that, from 1996, when genetically modified varieties were first grown commercially, the global area planted to such crops has increased over 50-fold, from 1.7 million hectares to 90.0 million hectares in 2005. Biotech crops are now grown in 21 countries. Of these, the leader is the United States, with 49.8 million hectares, followed by Ar-

gentina (17.1 million ha), Brazil (9.4 million ha), Canada (5.8 million ha), China (3.3 million ha), Paraguay (1.8 million ha), India (1.3 million ha) and South Africa (0.5 million ha). Mexico and twelve other countries make up the rest, with less than 0.3 million hectares each.<sup>8</sup> It is important to note that, although both developed and developing countries are growing transgenic crops, the United States alone accounts for over half of the total area devoted to such crops.

Apart from the few developing countries growing transgenic crops in commercial quantities, others are still carrying out field testing and experimental research, if they participate in the process at all. However, irrespective of whether countries grow transgenic crops, most have to contend with an increasingly global trade in agricultural commodities and food containing genetically modified material. The growth of a globalized biotechnology industry and of trade in biotech crops requires countries to develop regulatory systems, forcing them to consider the impact that the spread of GM seed and crops to their countries might have on the sustainability of their agricultural systems, on the prospects for biosafety and food security, and on their current and future position in global agricultural trade.<sup>9</sup>

The need for global governance of genetic engineering has thus been recognized since the late 1980s, when the first calls were made for an international biosafety treaty. It took until January 2000 for an agreement to be reached on the Cartagena Protocol on Biosafety, after nearly four years of increasingly contentious negotiations.<sup>10</sup> The Protocol is the center-piece of the emerging global governance architecture for genetic engineering in agriculture. Other key elements of this governance architecture include the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and Agreement on Technical Barriers to Trade (TBT Agreement). Furthermore, the Codex Alimentarius Commission, a global food safety standard-setting body, is debating global safety standards for food produced via use of genetic engineering.

This emerging governance framework has to contend with a wide range of concerns (including ecological, human health, social and ethical) associated with genetic engineering in agriculture. The governance challenge is made more complex by the fact that the existence, nature and manageability of risks remain deeply contested. Moreover, the emerging system of rules and institutions is far from coherent or consistent. Instead, it remains unclear how components of this rapidly expanding set of global rules interact with and influence one another.<sup>11</sup> This is partly because these regimes are still evolving, and their obligations are still being interpreted or expanded within global fora, as well as via na-

8. James 2005. Given the difficulty of obtaining data on transgenic crop expansion in developing countries, a recent report questions the ubiquitous ISAAA statistics. See FOEI 2006.

9. For business and biotechnology, see Newell and Glover 2004; for agribusiness in general, Jansen and Vellema 2004.

10. For a detailed history of these negotiations and the range of issues covered by the Cartagena Protocol on Biosafety, see Falkner 2002, 2006; and Gupta 2000a.

11. See Kim and Chambers forthcoming, for an analysis of global biosafety regime inter-linkages.

tional interpretation and implementation.<sup>12</sup> It is also because of the potential for conflict between the Cartagena Protocol's obligations and WTO agreements.<sup>13</sup>

This biotechnology governance challenge is rendered yet more complex by the long-standing trade conflict between the United States and the European Union over the EU's policy towards GMO imports. The conflict was fuelled by a *de facto* EU moratorium since 1999 on approvals of transgenic crops, while it debated amendments to its regional GMO directives. Although recently lifted, this moratorium led to a WTO complaint by the US in 2003 and a WTO Panel decision in favor of the US in 2006.<sup>14</sup>

This transatlantic GMO conflict underlines the fact that no shared global approach to biosafety regulation currently exists, which might be diffused to different domestic contexts via a global governance regime. Instead, two dominant regulatory approaches persist, one serving as a model for comprehensive and precautionary biosafety regulation (the EU model), the other emphasizing a "sound science" approach to biosafety, whereby restrictive regulatory action is justified only in the face of scientific evidence of harm (the US model).<sup>15</sup> In the absence of such evidence, the US model assumes the "substantial equivalence" of GM and non-GM varieties of seed and food crops.

The two regulatory approaches also differ with regard to labeling, segregation, traceability and threshold requirements for domestically authorized GMOs (all of which are either mandatory or more stringent in the EU, as compared to the US). There are no signs of these two models converging towards one consensual regulatory model. Instead, negotiation of the Cartagena Protocol has provided one more site where these conflicts have played out, and its influence must therefore be considered within this larger context.

### *The Cartagena Protocol: Avenues of Influence*

The Cartagena Protocol was negotiated to allow for the "advance informed agreement" of an importing country prior to trade in certain GMOs. In assessing its influence in a domestic context, we identify three avenues through which such influence might be felt: *enhanced domestic choice* about GMO imports, via the Protocol's legitimization of a broad set of domestic decision-criteria; *enhanced access to information* from GMO exporting countries about transgenic crops in international trade; and *enhanced capacity* to regulate and ensure biosafety domestically (via the Protocol's encouragement of financial assistance,

12. For an analysis of the decisions taken at the first Meeting of the Parties to the Cartagena Protocol in February 2004, see Falkner and Gupta 2004; and Falkner 2004.

13. Winham 2003; Isaac and Kerr 2003; Koester 2001; and Kim and Chambers forthcoming. For a general analysis of trade-environment linkages in the WTO, see Biermann 2001.

14. Brack, Falkner, and Goll 2003; and *Financial Times* 2006.

15. Young 2003.

training, sharing experiences, and learning from other contexts etc.). We elaborate on these avenues of influence below.

*Enhanced Choice via Broad Decision-Making Criteria*

In operationalizing “advance informed agreement,” the Cartagena Protocol mandates that importer decisions about GMO trade should be based upon a scientific risk assessment. This decision-criterion has been designated “sound science” by its proponents, which include leading biotechnology and GMO-exporting countries. These groups have argued that it should be the only basis for decision-making about GMO imports, with the hope that the Protocol will become a vehicle to diffuse such a regulatory approach to developing countries and harmonize regulatory outcomes relating to GMO trade.

However, at the insistence of the European Union and developing countries, the Protocol also allows for precautionary (trade restrictive) decisions in the face of scientific uncertainty about harm posed by a traded GMO. Finally, as a third criterion, the Protocol permits consideration of socio-economic factors in decision-making about GMO imports, a demand from developing countries. However, it restricts such considerations to impacts on biodiversity and consistency with other international obligations (such as the WTO).

The relationship between these decision-criteria and WTO rules was a key stumbling block during Protocol negotiation, and remains one of the most controversial aspects of regime evolution and implementation today. Developing countries and the European Union are concerned that WTO disciplines will trump domestic biosafety measures based on the Cartagena Protocol, and have been keen to ensure that the Protocol’s inconclusive language on this issue—the preamble speaks of “mutual supportiveness” between the Protocol and other international agreements—cannot be interpreted as subordinating the Protocol to the WTO.

Areas of conflict with the WTO exist, in particular, with regard to precautionary trade restrictions under conditions of scientific uncertainty. The Cartagena Protocol’s language on precaution has been interpreted by some as going beyond what the WTO-SPS Agreement calls for, although this remains an issue of much debate and controversy.<sup>16</sup> The SPS agreement allows precautionary measures to be taken only on a preliminary basis with the aim of generating scientific evidence about risks. This can be seen as more restrictive than the Cartagena Protocol’s implicit recognition that scientific uncertainty is a pervasive aspect of biosafety regulation, making precaution legitimate in this area. Furthermore, the Protocol puts no limitation on the duration of precautionary measures and there is no explicit requirement that a review of the scientific basis for decisions be undertaken.

Consistency with the WTO relating to socio-economic factors as a

16. Gupta 2002; and Kim and Chambers forthcoming.

decision-criterion also remains disputed. Some socio-economic concerns voiced by developing countries, such as adverse impacts of traded GMOs on traditional livelihoods or increased dependence on GM seed, may well run afoul of world trade rules, if used as a justification to restrict imports. However, it remains contested and unclear whether such key socio-economic concerns as the lack of domestic capacity to monitor, segregate or label imported GMOs would be acceptable reasons to restrict imports.

Although much debate has centered around the Protocol's decision-criteria and potential conflicts with WTO, little is currently known about whether similar debates about science, precaution and/or socio-economic concerns are at the center of conflict and controversy in a domestic context, or how such criteria are interpreted by countries in formulating biosafety regulations. We analyze whether the decision-criteria legitimized by the Protocol are leading to institutional and/or discursive change in a domestic context.

#### *Enhanced Access to Information from GMO Exporters*

Another key avenue of Protocol influence relates to its obligation to share biosafety information between countries. GMO-exporting countries are required to provide biosafety information to potential importing countries, either directly or via a global information clearing house. The nature and extent of information to be shared depends upon intended use of a GMO in a domestic context. This right to information is seen as critical in making the GMO trade more transparent—and hence is of key relevance for potential GMO importing countries.

One particularly contentious issue has been the extent of information to be shared about GM varieties in the bulk agricultural commodity trade.<sup>17</sup> Following protracted negotiations, the Protocol calls for bulk agricultural commodity shipments to state only that they “may contain” GMO varieties (rather than specifying which ones), a compromise reached in the last hours prior to Protocol adoption.

This general statement is to be elaborated in future meetings, with greater specificity to be negotiated regarding the form of documentation, the extent of information to be shared about particular GM varieties, and the thresholds to apply in identifying GMO content in bulk commodity shipments. Most developing countries and the European Union are demanding clear identification and detailed information sharing about specific GMO varieties in the commodity trade. Exporting countries and producers strongly resist these demands, arguing that they pose an unfair burden on trade.

The issue has been a bone of contention at each meeting of the Parties to the Cartagena Protocol since its adoption and coming into force (the third such meeting was held in March 2006). This last meeting was also unable fully to re-

17. Falkner and Gupta 2004.



solve differences or to replace the “may contain” language in this key category of GMO trade.<sup>18</sup> Whether and how global disputes over biosafety information-sharing are influencing domestic discursive and/or institutional change is addressed via our case analyses.

#### *Enhanced Capacity to Regulate and Ensure Biosafety*

The Cartagena Protocol also calls for capacity-building to help countries develop national biosafety frameworks and expand scientific, regulatory and administrative capacity. In particular, the Global Environment Facility (GEF) has been mandated, together with its hosting agencies, the World Bank, the United Nations Development Programme (UNDP) and the United Nations Environment Programme (UNEP), to support biosafety capacity building activities in developing countries. The Protocol also encourages private sector involvement in capacity building.

A range of biosafety capacity-building initiatives are thus currently underway in the developing world, led by United Nations agencies, bilateral aid agencies or the private sector in collaboration with international organizations. However, this decentralized approach to capacity-building has allowed different interests and regulatory approaches to be promoted. The jury is still out on which of the currently contested biosafety governance approaches might be spread to the developing world via such efforts.

In recent years, there has been a strong push by the biotechnology industry and the United States Agency for International Development (USAID) to support capacity building in Africa, which has raised concerns amongst those advocating a more cautionary approach to GMO uptake in African agriculture. We examine whether and how capacity building initiatives stimulated by the Protocol are influencing discursive and/or institutional change in our three countries.

#### *Regime Influence: Harmonization or Regulatory Diversity?*

On the face of it, then, the Cartagena Protocol is a multilateral agreement that seeks to strengthen national prerogative in biosafety decision-making for GMO importing countries. It does so via emphasizing enhanced choice, access to information and capacity in domestic decision-making processes. At the same time, however, market access and trade competitiveness concerns are a strong counterforce (and hence a key source of influence on domestic policy), especially in countries at the leading edge of agricultural biotechnology. In analyzing Protocol influence in a domestic context, we consider the interactions between its avenues of influence and trade/market pressures.

18. See the *Earth Negotiations Bulletin* reports on the third Meeting of the Parties to the Cartagena Protocol at <http://www.iisd.ca/biodiv/bs-copmop3/>.

In particular, the transatlantic trade conflict between the US and the EU is likely to shape the influence that the Cartagena Protocol might exert in countries. This conflict raises legitimate fears among GMO-importing countries that they may not be able to apply precautionary trade restrictive measures without repercussions from GMO producer/exporter countries, notwithstanding the Protocol.

In fact, no GMO-exporting country, including the US, Canada and Argentina, has to date ratified the Protocol. At the same time, these countries continue to participate in further regime negotiation and evolution, in an on-going effort to steer its avenues of influence towards science-based harmonization of domestic regulatory policies, instead of a strengthening of national prerogative and persistence of regulatory diversity. Via our analysis, we thus also comment on whether the Protocol's influence in a domestic context is, indeed, strengthening national prerogative, or whether such influence is steering countries in the direction of science-based harmonization of regulatory policy.

We turn next to our case analyses of agricultural biotechnology and biosafety policy evolution in three countries and the influence of the Cartagena Protocol therein.

### 3. Domestic GMO Governance: The Experience of Mexico

Mexico is often held up as a dramatic example of a country that has moved in a relatively short period of time from being a closed and protected economy to one of those most closely integrated into regional and global markets, including in agriculture. Until the 1970s, Mexico prioritized (and largely attained) self-sufficiency in the production of basic food grains. The 1982 debt crisis changed this long-standing agricultural policy, with the country embracing trade liberalization and privatization, and scaling back long-established programs of state-led price supports and direct subsidies to the small-scale agricultural sector. Mexico acceded to the General Agreement on Tariffs and Trade (GATT) in 1986, became part of NAFTA in 1992, and the Organization for Economic Cooperation and Development (OECD) in 1994. Biotechnology policy in Mexico is inextricably tied into this thrust towards trade liberalization and integration into world markets.

#### *Trade Policy Dimensions*

The use of genetic engineering in agriculture remains a hotly contested issue in the country, as is evident from recent conflicts over genetically modified maize, a crop which is at the center of the national diet and is thus of overwhelming importance in Mexico. Imports of transgenic maize from the United States (for the animal feed and food processing industry) have, in particular, become a lightning rod for conflict. The first manifestation of this conflict was a moratorium on release of transgenic maize into the environment, declared by executive

decree in 1998 but lifted in mid-2004 (since its lifting, however, no new transgenic maize varieties have been approved for field-testing). Transgenic maize in Mexico received worldwide attention in 2001 following an article in *Nature* magazine by David Quist and Ignacio Chapela, alleging transgene ingression into indigenous maize varieties in the Chiapas region of Mexico.<sup>19</sup>

The conflicts over imports of transgenic maize reflect, indeed, a more fundamental conflict over the neo-liberal model of economic development embraced since the late 1980s and through the 1990s by a succession of Mexican governments. Mexico's appetite for bilateral and regional free trade agreements is also evident from the fact that it became the first country in Latin America to sign a free trade agreement with the European Union—its second most important trading partner after the United States. In addition, the country has also participated actively in negotiating the Cartagena Protocol on Biosafety, which it ratified in 2003.

#### *Participation in Cartagena Protocol Negotiations*

Mexico participated in Protocol negotiations as part of the so-called Compromise Group of countries (consisting of OECD countries that were neither part of the European Union, nor the Miami Group of GMO-exporting countries largely opposed to a stringent global biosafety regime).<sup>20</sup> Given that its NAFTA partners, the US and Canada, were vocal members of the Miami Group and neither has since ratified the Protocol, it can appear puzzling why Mexico chose to ratify. One key reason, as acknowledged by diverse actors, was to give domestic policy-makers the option to withstand NAFTA and trade imperatives through reference to their global biosafety rights and obligations, should the need to do so arise. Ratification was also stimulated by the newfound potential to influence Mexican legislators during parliamentary debates about whether to ratify the agreement, which environment ministry representatives pushing for ratification were able to successfully do.<sup>21</sup>

Mexico's obligations under NAFTA and WTO Agreements, together with its ratification of the Cartagena Protocol, and the continuing controversy over maize, have shaped on-going efforts to develop a domestic policy on agricultural biotechnology.

#### *An Evolving Regulatory Framework*

Mexico has permitted field-testing of transgenic crops since 1988, when the first government approval was issued to Monsanto for its transgenic (Bt) cotton.

19. Quist and Chapela 2001.

20. The compromise group comprised of Japan, Mexico, New Zealand, Norway, Singapore, South Korea and Switzerland. The Miami Group consisted of Argentina, Australia, Canada, the United States and Uruguay.

21. Interviews.

Since then various transgenic crops, produced primarily by the private sector, have been approved for field-testing. While the private sector has concentrated on the same crops in Mexico that are the focus of genetic manipulation elsewhere, such as corn, canola, cotton and soybean, biotechnology crop development is also under way in the public sector.<sup>22</sup>

This research trajectory dating back to 1988 has necessitated the development of an institutional and regulatory framework for biosafety oversight. The first law governing transgenic crops in Mexico was a set of standards (the Mexican Official Standard NOM-056-FITO-1995, or NOM-056 for short) developed under the jurisdiction of the Ministry of Agriculture and in force since 1995.<sup>23</sup> The Ministry of Agriculture was the key locus for regulatory oversight for transgenic crops throughout the 1990s, with other government representatives, including from the Ministry of Environment, only seeking a more active voice from 1998 onwards. This greater attention to biosafety issues domestically coincided with the escalation in global GMO conflicts and their reverberation in negotiations of the Cartagena Protocol.

The NOM-056 established procedures for field-testing of transgenic crops but was silent about large-scale planting and commercialization. This gap in the regulatory framework was addressed by creatively interpreting the law to portray large areas (even exceeding 10,000 hectares) as experimental fields, which still required biosafety measures. This was the approach used to permit large-scale planting of Bt cotton, the only transgenic crop currently being grown in commercial quantities in Mexico. Bt cotton is confined to the industrialized north of the country, relatively far removed from centers of diversity for cotton, and hence has generated less controversy domestically.

Sentiments and controversies over transgenic maize have been much more intense.<sup>24</sup> Fears about transgene ingression into indigenous maize varieties resulted, for example, in an unusual regulatory step: an amendment, apparently without much debate or consultation, to the Mexican Penal Code in 2002, making it a criminal offence to store or release transgenic crops into the environment. This scared the country's leading public-sector biotechnologists into action, converting some of them into active proponents of a comprehensive biosafety law which would clarify permissible from impermissible activity and prevent what they perceived as "a shut-down of biotechnology research" in Mexico.<sup>25</sup>

Such a biosafety law was passed in March 2005 and is the most important regulatory development in biotechnology policy in Mexico in recent years. The main architect of the biosafety law, which replaces NOM-056, is the Mexican Academy of Science, with two prominent Mexican scientists playing a key role

22. Herrera-Estrella 1999; see also Massieu et al. 2000 for a more critical perspective.

23. For an overview of biosafety-related legislation, see also Chauvet and Galvez 2005.

24. See, for example, ETC Group 2002.

25. Interviews.

in its drafting.<sup>26</sup> It is fairly unprecedented that the scientific community should take the lead in developing a politically fraught piece of legislation. This highlights the sometimes controversial role played by scientific experts in normatively contested areas of domestic policy-making such as biotechnology, especially if such experts are themselves producers of the regulated technology.

### *Influence of the Cartagena Protocol*

The architects of the biosafety law have not, however, been able to ignore a key global development occurring at the same time—the negotiation and coming into force of the Cartagena Protocol. Mexico's ratification of the Protocol in 2003 obliged it to implement the agreement via its national biosafety framework. The scientific drafters of the new biosafety law claim that it meets Mexico's obligations under the Protocol. Its critics within the NGO community allege, however, that it does not include basic elements necessary to implement the Protocol, such as advance informed agreement prior to imports of certain GMOs. The biosafety law is also criticized for promoting biotechnology rather than operationalizing a precautionary approach—as legitimized by the Protocol—to transgenic crop use in the country. This remains disputed, since the law also calls for a special regimen for transgenic maize, to prevent release into areas of the country which are centers of origin. This could require demarcation of GMO-free zones, which supporters of the law see as a clear manifestation of a precautionary approach.

Despite quite severe criticism of the law, a view shared by almost all stakeholders is that having a domestic biosafety law, although flawed, is better than having no regulation at all. Significantly, the Ministry of Environment gains from passage of the new law, in that it now has (together with the Ministry of Agriculture) a stronger voice in approving transgenic crops for deliberate release. Under the earlier NOM-056, the Ministry of Environment had merely an advisory role, with the final decision resting with the Ministry of Agriculture.

Another key institutional development in Mexican biosafety governance has been the establishment of an inter-agency commission to coordinate and develop biotechnology policy. This commission, La Comisión Intersecretarial de Bioseguridad y Organismos Genéticamente Modificados—the Inter-Sectoral Commission on Biosafety and Genetically Modified Organisms—(CIBIOGEM), was created in 1999, partly in response to the temporary collapse of the biosafety protocol negotiations in Cartagena in the same year. However, CIBIOGEM has had a chequered existence, with critics alleging that it has missed an important opportunity to outline a vision for appropriate use of biotechnology in Mexican agriculture. This contributes to the somewhat cynical assessment of CIBIOGEM by some critics that “a commission is set up when no

26. Interviews.

action is desired."<sup>27</sup> Nonetheless, it has to date provided a site for the airing of diverse state and nonstate actor views, and is now responsible for administering the new biosafety law.

Another significant outcome of Mexico's ratification of the Cartagena Protocol has been the signing of a controversial "Trilateral Arrangement" between Mexico and its NAFTA partners, the US and Canada. The arrangement is intended to implement the Protocol's requirement that bulk commodity shipments state that they "may contain" transgenic varieties. This trilateral agreement was negotiated by a representative of the Ministry of Agriculture without sufficient consultation and it does not enjoy the unequivocal support of all branches of government, much less civil society.<sup>28</sup>

A key reason is the trilateral arrangement's controversial clause stating that the "may contain" declaration is only to be triggered in cases where the content of transgenic material is above a threshold of 5%. This threshold level is seen as too high by those advocating caution and is criticized by civil society groups as counter to the spirit, if not (yet) the letter of the Cartagena Protocol (given that the debate about thresholds is yet to take place in the global context). A technical annex to the Trilateral Arrangement is, notwithstanding its "technical" label, more politically useful in its demand for specific information from exporters about traded GM varieties that might be entering Mexico. Ironically, Mexican negotiators have sought via this annex to obtain precisely the kind of information about traded agricultural commodities that developing countries were demanding during a Meeting of the Parties to the Protocol in Kuala Lumpur in February 2004, but which Mexico blocked under pressure from its NAFTA trading partners.

It is important to note, however, that Mexico's membership in NAFTA has also been used by indigenous groups and environmental NGOs to press their case for caution relating to transgenic maize imports into Mexico. These groups successfully petitioned NAFTA's Commission on Environmental Cooperation in 2002 to undertake a comprehensive analysis of the impacts of transgenic maize on Mexican biodiversity, health and socio-economic practices. This resulted in an influential and controversial study released by the CEC in 2004, which recommends, among other things, that the current moratorium on commercial planting of transgenic maize be maintained, and even strengthened via minimizing transgenic maize imports into the country.<sup>29</sup> In doing so, the report also makes reference to Mexico's obligations under the Cartagena Protocol, in addition to mentioning its NAFTA and WTO-SPS obligations relating to trade.

A number of other domestic institutional developments have been directly stimulated by the Cartagena Protocol. One is the development of a do-

27. Interviews.

28. Interviews.

29. CEC 2004. Whether these recommendations have been or will be taken up remains a matter of constant domestic controversy and vigilance by NGOs.

mestic roster of experts in biosafety, modeled along the Protocol's global roster of experts, which can be drawn upon to evaluate and advise on transgenic crop approvals as necessary. The other is the launching of a project on capacity-building for biosafety regulation.

Mexico is one of twelve countries where a model UNDP-GEF project on capacity building for national biosafety frameworks is being implemented. Despite the *raison d'être* of such a project to assist with development and implementation of domestic biosafety frameworks, the GEF project in Mexico has not had this impact. While it is credited with bringing various members of government together to discuss approaches to biosafety and of playing an important role in training personnel to undertake biosafety assessments, it has not exerted discernible influence over the development and content of the new biosafety law, which has been mired in a messy domestic political process.

### Outlook

In Mexico, then, an overall promotional approach to biotechnology at the highest political levels and a general neo-liberal economic stance (whose most vocal adherents are the Ministry of Agriculture and Ministry of Economy, supported by high-profile public-sector scientists) has most influenced the direction of biotechnology policy. This coalition has, however, encountered resistance from those advocating a more restricted approach. Organizations such as Greenpeace, as well as peasant and labor unions, exercise considerable influence over the hearts and minds of the general public, especially in rural areas and particularly in relation to the cultural, social and political significance of maize. The Ministry of Environment, with its mandate for biodiversity conservation and sustainable use, has continued to emphasize the need for caution.

Equally important, Mexican legislators are discovering that they can actually debate legislation and are not required to rubber-stamp executive decisions, as earlier. However, the transition to (a functioning) democracy and public accountability is recent in Mexico, with the sentiment expressed that while previous regimes were authoritarian and corrupt, the administration of Vicente Fox was well-meaning but inept, with adverse consequences for a coherent biotechnology policy.

This mix of actors and influences has resulted in a domestic policy towards transgenics that is both open as well as, in certain ways, restrictive and cautionary. The moratorium on environmental releases of transgenic maize is a reflection of the latter, although it is seen, even by its supporters, as "having failed," since imports of transgenic maize from the US continue unabated, with few oversight systems in place to ensure that imported transgenic maize will not inadvertently enter the food chain or farmers fields. Elements of the new biosafety law, when implemented, may well introduce some cautionary elements into biosafety governance. However, this will depend upon the extent to

which, for example, the Ministry of Environment and its associated research and assessment institutions are willing (through their authority over approvals) to slow down the impetus from higher echelons of power to encourage use of agricultural biotechnology. In such a scenario, the Cartagena Protocol has provided additional justification and has given greater visibility to those advocating a cautionary approach.

#### 4. Domestic GMO Governance: The Experience of China

Genetic engineering has been an integral element of China's agricultural strategy since the mid-1980s. In an effort to boost agricultural productivity and scientific capacity, the Chinese state has expended the largest public spending program on biotechnology in the developing world and is now in a leading position in advanced biotech research outside the industrialized world. Over 150 national and local research laboratories are in operation today, and 2,690 scientists were estimated to be working in the field of plant biotechnology in 2003, up from 740 in 1986.<sup>30</sup> Despite some waste in public research funding and lack of private investment, China has managed to produce 141 different types of GM crops by 2002, of which 65 have entered the stage of field trials.<sup>31</sup>

The absence of any biosafety regulation during the 1980s played into the hands of Chinese researchers, who in the late 1980s were the first worldwide to grow a GM crop in commercial quantities, a virus-resistant tobacco plant.<sup>32</sup> After the introduction of China's first safety rules for GMOs in the mid-1990s, 12 GM crops were approved for large-scale field trials, of which three (cotton, tomato, petunia) passed the safety tests for commercial planting in 1997. Of the GM crops approved for introduction to the market, only GM cotton has since been grown on a large scale, accounting for 58 per cent of the total cotton production in 2003. An estimated 5 million farmers are now using Bt cotton, including also varieties developed by Monsanto, the first and so far only multinational to sell GM seeds through a joint venture with a Chinese firm.<sup>33</sup> New GM crop developments (e.g. rice, potatoes) have since entered the regulatory approval process, but an informal moratorium on GMO authorizations, imposed in 1999, has so far held back efforts to expand the use of genetic engineering in Chinese agriculture.<sup>34</sup>

China's headlong rush into modern biotechnology proceeded largely unencumbered by any regulatory burden. In 1993, the Ministry of Science of Technology (MOST), as the then lead agency in the field of biotechnology, established the Safety Administration Regulation on Genetic Engineering, a set of general safety rules drafted largely by scientists for scientists. In 1996, the Minis-

30. Huang and Wang 2002; and Huang, Hu, Pray, and Rozelle 2004, 7.

31. Huang and Wang 2003.

32. Paarlberg 2001, 128.

33. Huang and Wang 2003.

34. Paarlberg 2001.



try of Agriculture (MOA) followed this up with Implementation Guidelines and became the lead agency in the regulatory process. The MOA guidelines were equally informed by a desire to promote biotechnology and concentrated on scientifically demonstrated risks<sup>35</sup>—a position that, as critics argue, tended to downgrade the importance of long-term and uncertain threats from GMOs to human health and environment. Given its close links with the agricultural and biotech sectors, MOA is widely seen to favor the rapid commercialization of GM crops.<sup>36</sup>

### *Participation in Cartagena Protocol Negotiations*

China's participation in the negotiations on the Cartagena Protocol provided an important external stimulus for the creation of a domestic biosafety agenda. Because the negotiations were held under the auspices of the Convention on Biological Diversity, China's equivalent to an environmental ministry, the State Environmental Protection Agency (SEPA), became the lead agency in the biosafety talks. This ensured that greater weight was given to environmental concerns in developing China's position and allowed SEPA to move out of its relative marginalization in domestic biotechnology regulation.

In keeping with diplomatic tradition, China sided with the group of developing countries that was the key *demandeur* for stringent international biosafety rules. Although maintaining a low profile in the talks and appearing to be more conciliatory than others, China sided with the Like-Minded Group of developing countries (formed in 1999) in pushing for a comprehensive and precautionary system of international GMO regulation.<sup>37</sup> China signed the Protocol in August 2000 but did not ratify the agreement until June 2005, owing in part to intensive domestic debates about the impact of the Protocol on China's biotechnology policy.

The creation of the international biosafety regime had an important effect on China's biosafety policy. Chinese scientists and regulatory experts participating in the biosafety talks were able to tap into the rapidly expanding global biosafety agenda and became key agents for domestic policy change, importing international biosafety concerns and risk assessment and management approaches into the domestic context.<sup>38</sup>

The biosafety negotiations also led to a range of international capacity-building initiatives, of which China became the biggest recipient country in the late 1990s. These efforts included the creation of a national biosafety framework in China, funded by UNEP and GEF, which gave SEPA a lead role in the drafting process and promoted a more comprehensive approach to GMO regulation.<sup>39</sup> The impact of the framework was of a more limited nature, however: it

35. Paarlberg 2001, 129.

36. Interviews.

37. Lijie 2002.

38. Wang 2004, 902.

failed to change the existing regulatory framework, largely owing to resistance by MOA and MOST officials, but further strengthened regulatory debates about the need for comprehensive and precautionary GMO regulation. Efforts are now under way to create the first comprehensive biosafety law in China, which would replace the existing system of regulations.<sup>40</sup>

### *Shift Towards Greater Precaution*

The shift in China's domestic biosafety debate came to be felt for the first time in 1999, when a *de facto* moratorium on new GMO releases was imposed. The timing of this move—shortly after the introduction of the European Union's moratorium in October 1998 and shortly before the adoption of the Cartagena Protocol in January 2000—is highly significant. It signaled the growing impact that the international GMO debate and the biosafety negotiations were having on regulatory developments in China. For the first time, Chinese authorities implicitly acknowledged shortcomings in the existing regulatory framework and quickly moved to create new domestic regulations.

With the adoption of a new national seed law in 2000, the final managerial authority over all new GM crop varieties passed to the State Council, a central decision-making body at cabinet-level. The State Council's new Regulation on Safety Administration of Agricultural GMOs of 2001 was followed in 2002 by three implementing regulations issued by MOA, covering the areas of biosafety evaluation, import safety administration and GM food labeling. These new acts provided a more comprehensive system of risk management, for the first time regulating imported GMOs and providing consumers with some degree of choice over GM food content. They signified a shift away from the previous product-based risk assessment of GMOs, as favored by the leading biotech country, the United States, towards a more process-based approach as practiced in the EU. They also adopted key approaches and methodologies of risk assessment and management from the Cartagena Protocol and thus provided the basis for its domestic implementation.

### *Trade Policy Dimensions*

The move towards a more comprehensive and precautionary approach to biosafety regulation has been heavily contested and provoked debates on its impact on China's trade policy. On one side of the debate are advocates of agribiotechnology and importer interests who fear that the new emphasis on biosafety would slow down the future adoption of GM crops and impede agricultural trade liberalization. On the other side are agricultural exporters to markets with GMO restrictions (e.g. Europe, Japan and South Korea), who consider

39. Interviews.

40. Interviews.

stricter biosafety rules necessary to preserve China's GM-free status in key areas of trade. As in other developing countries, the balance of influence between exporter and importer interests has become a critical factor in the evolution of China's biotechnology policy.

The fear of being shut out of markets with GMO import restrictions first surfaced in the early 1990s. At that time, the country's first experiments with introducing GM tobacco plants were scaled down as soon as international buyers, mainly from the USA, rejected the transgenic variety.<sup>41</sup> The experience with GM tobacco did not in itself put an end to GMO commercialization but provided a first example of how international market reactions could influence domestic biotechnology strategy. China concentrated instead on a new range of GM crops. In 1997, insect-resistant GM cotton varieties passed regulatory hurdles and were introduced in four provinces (Hebei, Henan, Shanxi, Shandong), including the first and so far only foreign-owned GM plant variety, Monsanto's Bt cotton. Because cotton was primarily grown for the domestic market and did not enter international trade, trade concerns did not stand in the way of rapid commercial introduction of the GM varieties, which were grown on 3.7 million hectares and accounted for 66 per cent of China's cotton area in 2004.<sup>42</sup>

The threat of exclusion from export markets resurfaced, however, when in 2000 GM content was detected in Chinese shipments of soy sauce, leading to a temporary ban on such shipments to the EU. Although soybean production was officially GM-free, China had been importing transgenic soybeans from the United States, mainly for animal feed and processed food production, and was testing domestically developed GM soybean varieties for market introduction. The suspicion was that either imported or illegally planted domestic varieties of GM soybeans were spreading into the major soybean-producing areas in Northern China, calling into question the domestic regulatory system. The experience with the temporary EU trade ban is widely cited to have contributed to the continuing moratorium on authorizations of GM soybean and other GM crops.<sup>43</sup>

Whereas the threat of exclusion from international markets was a driving force behind the tightening of China's biosafety regime, domestic demand for agricultural imports was pulling in the opposite direction. Owing to rapidly growing domestic consumption and the liberalization of agricultural trade, China has now become the world's largest importer of GM soybeans, mainly from the United States. The introduction of new biosafety rules in 2002, however, threatened the continuous import of soybean shipments on which many domestic operators of crushing and processing plants, mainly in the Southern ports of China, had come to rely. The new biosafety rules, which entered into force in early 2002, only months after China entered the WTO, stipulated that every shipment of GM crops had to be issued a safety certificate based on risk as-

41. Paarlberg 2001, 128–129.

42. Huang and Wang 2003, 11.

43. O'Neill 2001; and interviews.

essment. Owing to the short time-frame within which the rules were introduced, US shipments of soybeans were held up temporarily, leading to a noticeable fall in US soybean exports.<sup>44</sup>

The US government accused China of “back-door” protectionism aimed at manipulating the burgeoning trade in soybeans and complained about the uncertain nature of the new biosafety rules, which in their view failed to give clear guidance to traders on the documentation requirements and allowed Chinese authorities to delay a decision for up to 270 days (the timeframe given in the Cartagena Protocol). China eventually gave in to sustained diplomatic pressure from Washington and issued interim safety certificates to facilitate uninterrupted imports of soybeans before issuing formal three-year certificates in February 2004.<sup>45</sup> The climb-down by the Chinese authorities underlined the difficulties involved in implementing the provisions of the Cartagena Protocol, which at that time had not yet entered into force but served as a blueprint for regulating GMO imports. The significance of this episode for the biosafety efforts of less powerful trading partners was widely noted in the developing world.

### *Outlook*

The experience of GMO regulation in China has shown that the Cartagena Protocol has had an important impact on domestic biosafety governance. International biosafety debates and participation in the negotiations have helped to upgrade biosafety concerns on the domestic agenda. This has been further amplified by the spread of GMO import restrictions in key export markets for Chinese agricultural products. While China has adopted important elements of the Cartagena Protocol, environmentalists point, however, to the many failings of the system in preventing unauthorized releases of GMOs into the environment and the central role played by pro-biotech scientists and regulators in the GMO approval process.<sup>46</sup>

The future direction of China’s biosafety policy remains to be seen. While China’s regulatory approach has evolved from being largely promotional and product-based in the 1990s to a more comprehensive, precautionary and process-based model that is closer to that of the European Union than the United States, support for basic and applied research in agricultural biotechnology has not ceased and new GM crop developments (e.g. rice) are tipped to enter the market in the near future. Whether this will actually happen any time soon depends on a cost-benefit calculation that many observers expect to be undertaken at a high political level, and that will take into account the conflicting imperatives of technological innovation, agricultural growth and impact on export in-

44. Rugaber 2002.

45. *China Daily* 2004.

46. Keeley 2003; and interviews.

terests, in addition to environmental risk assessment. The often conflicting international influences that have shaped China's regulatory policy have thus been employed by domestic interest groups—within and outside the core state—to shape GMO policy. The Cartagena Protocol has helped to shift domestic policy in the direction of greater caution but domestic battles continue over the precise direction of China's biotechnology strategy.

## 5. Domestic GMO Governance: The Experience of South Africa

The direction that biotechnology policy takes in South Africa holds significance that goes beyond that country's own borders. Policy developments in South Africa are often seen, whether legitimately or not, as the litmus test for how things may develop in the African continent as a whole. Its potential to be a "gateway" to the rest of Africa for transgenics, as well as for biosafety regulations, makes developments in South Africa of particular interest to both proponents and opponents of the technology alike.

Biotechnology and its use in agriculture receive strong support from the highest echelons of the South African government. State encouragement of biotechnology goes back to 1978, when a South African Committee for Genetic Experimentation (SAGENE) was constituted to encourage research in molecular biology and biotechnology.<sup>47</sup> In the 1980s, with support from the government, new biotechnology research centers were established. Beginning in the 1990s, South Africa became one of the first countries to undertake field trials and environmental releases of transgenic crops. Government support of modern biotechnology remained strong through the dramatic political changes in South Africa in the early 1990s, with the fall of apartheid and the coming to power of the African National Congress. South Africa is now one of the few developing countries, and the only one in Africa, to grow transgenic crops commercially.

### *Participation in Cartagena Protocol Negotiations*

With an overall political environment that supports rapid development of the biotechnology sector, it can appear puzzling why South Africa has chosen to ratify the Cartagena Protocol—which is seen as a potential hurdle to rapid biotechnology uptake by supporters of the technology. South Africa participated in Protocol negotiations as part of the so-called Like-Minded group of developing countries. In initial stages of the negotiations, tensions were evident between its domestic priorities and the negotiating positions put forward by the Like-Minded Group, and particularly by the African Group of countries within it, who were calling for a stringent global biosafety regime.

That South Africa remained a part of the Like-Minded Group throughout the negotiations and subsequently ratified the agreement is explained by ob-

47. Sasson 2000.

servers as politically unavoidable, given the country's emphasis on multilateralism since the early 1990s, and its desire to show solidarity with other African countries. The timing of ratification, August 2003, is also linked to the then-upcoming Johannesburg Earth Summit. With South Africa playing host to the key sustainability event of the decade, it was yet more important to demonstrate support of multilateral environmental processes.<sup>48</sup>

### *An Evolving Regulatory Process*

Unlike in China, in South Africa (as in Mexico) development and commercialization of transgenics remains largely the domain of the private sector. Crops approved for commercialization since 1997 include insect-resistant and herbicide-tolerant varieties of maize, cotton, and soybeans, with all but one developed by Monsanto.<sup>49</sup> South Africa is also the first country to commercialize transgenic white maize, a staple food crop of its population. While the public sector is involved with transgenic research (focusing on crops such as transgenic potato, sugar cane, maize and strawberries), its products have yet to reach the commercialization phase. Even though the bulk of research and development is underway within the private sector, public-sector scientists remain influential players, primarily via their participation in the biosafety regulatory process.

This regulatory process dates back to the late 1980s. At the time, with no biosafety law in place, research and field testing of transgenics was regulated under the 1983 Agricultural Pests Act, with a reconstituted SAGENE serving as the scientific advisory body on environmental releases of GMOs.<sup>50</sup> The first general release of transgenics occurred in South Africa in 1997.<sup>51</sup> This coincided with adoption of a separate biosafety law, also pushed for by SAGENE members, many of whom were engaged in biotechnology research themselves.<sup>52</sup> This is in keeping with the trend seen elsewhere, notably in Mexico, where scientists engaged in biotechnological research have felt the need for biosafety laws and have led the way in developing them.

The Genetically Modified Organisms Act (henceforth GMO Act) was passed in 1997 and implemented in 1999.<sup>53</sup> The GMO Act is administered by the Ministry of Agriculture and establishes procedures and an institutional structure for regulating transgenics in South Africa. This includes an Executive Committee consisting of representatives of agriculture, health, environment, science and technology and trade, as well as a Scientific Advisory Council (which replaced SAGENE, although some members remained the same).

48. Interviews.

49. Morris et al. 2005.

50. Sasson 2000.

51. Morris et al. 2005.

52. Interviews.

53. GMO Act 1997.

Decisions on approvals of transgenics are to be taken by consensus within the Executive Committee—which ensures that all represented government departments can, in theory, veto particular transgenic crop approvals. This is distinct from countries where the Ministry of Environment, for example, has less final authority than the Ministry of Agriculture over approvals. Critics note, however, that the capacity to raise relevant concerns in the Executive Committee varies greatly between government departments.<sup>54</sup>

This regulatory process has been accompanied by efforts to develop a coherent overall strategy for biotechnology development, as reflected in a 2001 National Biotechnology Strategy, which outlines a vision for biotechnology's role in ensuring South Africa's technological leadership in the 21st century. The strategy is a response, as stated in its executive summary, to an alleged failing to "extract value" from the third generation of genetics and genomic sciences in South Africa, and is designed to "make up for lost ground." It mandates creation of regional innovation centers, with Rand 400 million (\$60 million) committed to their establishment. It also calls for "suitable regulatory systems in order to participate as exporters and importers in the international trade in biotechnology products."<sup>55</sup> Yet, as noted by critics, it leaves unclear how use of biotechnology in South Africa will address pressing rural development and food security needs.<sup>56</sup>

### *Trade Policy Dimensions*

South Africa is a net agricultural exporter, although it currently both exports and imports certain commodity crops subject to genetic manipulation. The United States and Argentina are key exporters of transgenic maize and soybean to South Africa, and transgenic varieties of these two crops, once approved in these exporting countries, have also largely received approval in South Africa (often, as critics point out, on the basis of risk assessments generated elsewhere). Although Europe is South Africa's most important agricultural trading partner, this is not the case for crops subject to genetic modification. Of the transgenic crops approved for general release in South Africa that may enter international trade, only cotton is exported to Europe.<sup>57</sup>

Unlike in China, and to lesser extent Mexico, the transatlantic GMO trade conflict between the US and the EU, and trade imperatives in general, have thus been less of an influence on domestic regulatory developments in South Africa. Where international influences have been important is in the debate in South Africa and neighboring countries over food aid containing genetically modified varieties, particularly from the US. In the food aid crisis in 2002, it was South

54. Interviews.

55. National Biotechnology Strategy (South Africa) 2001, ii and v.

56. See, for example, Aerni 2001.

57. Wolson 2005.

Africa's offer to mill maize in food aid (to prevent planting as seed) at its ports of entry before it was sent onto other countries that defused the crisis to some extent.<sup>58</sup>

Without strong trade pressures exerting a pull either way, the half decade since the GMO Act has been in force has been a period of intense activity in research, development and approvals of transgenics in the country. An ever-growing number of transgenics (including three varieties of cotton and maize and one variety of soybean) have received general release approval, with another eight varieties of maize approved for commodity clearance, i.e. importation for use as food/feed.<sup>59</sup>

### *Influence of the Cartagena Protocol*

Hand in hand with this, the domestic regulatory framework has been put to the test and has evolved, stimulated also by a series of high-profile legal challenges by an active NGO community, who have also drawn upon the government's ratification of the Cartagena Protocol to justify demands for greater accountability and transparency in decision-making about transgenic crop approvals.

Most recently, a court case brought by the environmental organization BioWatch against the government demanded access to a wide variety of information about domestic transgenic crop approvals. BioWatch won the case, with the Registrar of the GMO Act (the main repository of such information within the Department of Agriculture) now required to make such information available.<sup>60</sup>

Although a significant victory, this has also raised the question of whether civil society groups in developing countries have the capacity to sift through vast quantities of biosafety information in an attempt to hold the government accountable—although the domestic NGO community in South Africa has played this role to date with aplomb, filing detailed objections to an ever-increasing body of transgenic crop permit applications.<sup>61</sup> This focus on transparency is very much in line with the spirit of the Cartagena Protocol, as envisaged by its supporters and potential importing countries.

Ratification of the Protocol has also provided an important additional stimulus to amend the existing GMO Act. A draft amended bill is now under consideration in parliament, yet it has come under sustained criticism from civil society groups for failing to address environmental and social concerns around transgenic crop use in South Africa and for failing to institutionalize a precautionary approach.<sup>62</sup> To the extent currently discernible, changes to the act directly stimulated by the Protocol include only certain procedural adjustments to

58. Zerbe 2004

59. Morris et al. 2005.

60. Dunn 2005.

61. See, e.g., the detailed objections by the African Center for Biosafety at [www.biosafetyafrica.net](http://www.biosafetyafrica.net).



time frames in the current GMO approval process. Discussions are also underway about how best to meet the country's obligations to provide information about domestic GMO approvals to the Protocol's biosafety clearing house.<sup>63</sup>

Where unable to introduce desired changes into the GMO bill, the domestic NGO community has sought to influence other related domestic regulations. Particularly noteworthy is recent passage of the Biodiversity Bill, which permits the Minister of Environment to require an environmental impact assessment (EIA) for particular transgenic crops prior to approval, if he/she is convinced of the need for it.

Such an EIA is distinct from the risk assessment called for by the GMO Act, which can sometimes remain a desk-top study. Although it remains disputed whether this is indeed a far-reaching regulatory change, the requirement for an EIA is also seen by supporters as in keeping with the Cartagena Protocol, and its inclusion in the Biodiversity Bill as a victory for those seeking attention to environmental impacts of GMO releases. It also strengthens the hand of the Ministry of Environment in regulatory decisions.

While the NGO community's actions are contributing to regulatory change in South Africa, supporters of genetic engineering are not silent observers—far from it. The dominant pro-biotechnology group, AfricaBIO, sees itself as a source of objective information about the use of genetic engineering in agriculture for the African continent as a whole. Most members are private sector companies involved with production of transgenics. The group plays an active role in capacity-building initiatives in the Southern African region, often in conjunction with the USAID.<sup>64</sup> US influence is prominent in such regional capacity-building initiatives, raising concerns in the NGO community.

In its broadest contours, South African biosafety legislation has tended to follow the permissive regulatory approach of the United States. This is also reflected in the recently passed labeling legislation under the Ministry of Health, which subscribes to the notion of the substantial equivalence of GM food with non-GM food.<sup>65</sup> This permissive approach to GMO regulation in South Africa may also be politically feasible in part because there is currently little widespread public knowledge or concern about transgenics. A recent survey carried out on behalf of AfricaBIO claimed that a substantial majority of the population is unaware or unconcerned about transgenic foods, a finding that subsequent government surveys claim to confirm as well.<sup>66</sup>

This could be because, unlike maize in Mexico, no single crop subject to genetic engineering has the cultural resonance around which public debate can rally. However, maize is South Africa's most important crop as well, and com-

62. See, for example, Mayet 2004.

63. Interviews.

64. Wolson 2005.

65. Interviews.

66. AfricaBIO undated.

mercialization of transgenic white maize may well lead to future heated debates<sup>67</sup> also in conjunction with the food aid debate, since most South African maize exports go to other African countries.

### *Outlook*

For now, without immediate threats to its agricultural imports or exports, it is a small but vocal domestic pro- and anti- GM lobby within South Africa that is driving domestic regulatory developments. In an important development in late 2005, a policy decision was taken to halt approvals of applications for GMO commodity imports, pending the outcome of a study by the Department of Trade and Industry about the impacts of such imports on South African agriculture and trade. Whether this signals a shift towards precaution or a temporary aberration will only become clearer with time.

In general, however, the domestic coalition supportive of biotechnology in South Africa is very similar to that in Mexico and China—it includes the biotechnology industry, the Ministry of Agriculture, and public-sector biotechnologists as key players. Critics, including vocal environmental and public interest NGOs, see the biosafety regulatory structure as crafted by this “coalition of the supportive” and intended solely to facilitate quick approvals of transgenics.

In seeking to contest this, they have drawn upon the Cartagena Protocol to bolster their positions and influence developments within the country and regionally. Furthermore, as in both China and Mexico, the position of the Ministry of Environment in South Africa has been strengthened because of existence of the Protocol, partly because of its role in regime negotiation and evolution, and partly because of the increased legitimacy conferred upon a precautionary discourse around biosafety.

For critics of the current biosafety policy direction in South Africa, what the country needs, also in order to implement its obligations under the Cartagena Protocol, is the African Model Law on Biosafety, which is seen as suitably precautionary.<sup>68</sup> This Model Law has been developed by the African Union as a template for domestic biosafety regulations. Such a position is dismissed as untenable by supporters of the technology, such as AfricaBIO. With many countries in Africa now at a key juncture in developing biosafety regulations, outcomes in South Africa remain critical to watch.

## **6. Conclusion: Influence of the Cartagena Protocol**

Our analysis of biotechnology policy evolution in Mexico, China and South Af-

67. For a view that sees this as a positive development for small farmers, see Gouse et al. 2005. For an opposing view, see Biowatch at <http://www.biowatch.org.za/docs/booklets/gebk4/chapt3.pdf>.

68. Mayet undated.

rica suggests that market and trade dynamics and/or a general overarching concern with technological leadership and international competitiveness, are driving policy choices in the three countries. In a domestic environment largely supportive of the use of transgenic technology in agriculture, the Cartagena Protocol has, nonetheless, influenced policy debates and regulatory and institutional developments in these key countries. Their prominent role in agricultural biotechnology application makes them important reference points for how the Protocol might shape domestic policy choices. We highlight below our findings with regard to the Protocol's avenues of influence in these countries.

### *Avenues of Influence: Findings in Comparative Perspective*

#### *Enhanced Choice as an Avenue of Influence*

With regard to enhanced choice as an avenue of influence, we find that existing biosafety frameworks are being amended in all three countries partly in response to the Cartagena Protocol. However, the nature of such amendments are driven by domestic considerations that mediate how the Protocol's decision-criteria of scientific risk assessment, precaution and/or socio-economic factors are interpreted or institutionalized.

The evolving regulatory frameworks in each of the three countries all have scientific risk assessments at their center. Although a precautionary discourse has gained greater credence in general, its incorporation into amended biosafety laws remains disputed. This reflects on-going disagreements over the interpretation of precautionary actions in global fora as well. Furthermore, we find that socio-economic concerns over traded GMOs—a decision-criterion argued for by developing countries during Protocol negotiations—are not officially voiced as a reason to restrict trade or domestic GMO releases. At the same time, such concerns are constantly present as the backdrop to domestic application of scientific risk assessment processes and decisions about uptake.

They remain key in disputes over transgenic maize in Mexico, for example, and continue to be emphasized by civil society groups and within the larger discourse about agricultural biotechnology. In South Africa, it is noteworthy that consideration of transgenic crop applications was temporarily halted in order to consider the implications for the country's agricultural trade priorities. Likewise in China, the trade implications of any decision on GMO authorization, whether for import or domestic commercialization, is uppermost on the minds of state officials. Socio-economic, rather than scientifically assessable safety concerns alone, are thus never far from the surface of domestic biosafety decision-making.

In general, our findings suggest that the Protocol's influence is not discernible via direct or uniform translation of its (still disputed) regulatory decision-criteria into national biosafety frameworks. Instead, it is the flexible interpretation of its perceived overall precautionary thrust that is stimulating limited in-

stitutional and discursive change in diverse domestic contexts. As Jasanoff notes in a study of regime compliance, in areas of technological and scientific controversies, “policy agreement is maintained . . . by leaving room for locally variant interpretations of centrally articulated, but flexible, scientific concepts”.<sup>69</sup> In the case of biosafety, we find that domestic influence is contingent upon such interpretive flexibility.<sup>70</sup>

#### *Enhanced Access to Information as an Avenue of Influence*

Concerning access to biosafety information, we see from the case analyses that this avenue of influence has stimulated (or, in the case of South Africa, supported) certain domestic developments. China’s shift towards greater precaution has been bolstered by the participation of Chinese scientists in international biosafety debates, which has led to a kind of transnational “concern transfer” into a domestic context of technology promotion. In South Africa, access to information is a key aspect of domestic biosafety politics, mostly stimulated by that country’s constitution and right to information laws. This has, nonetheless, been given further impetus by ratification of the Cartagena Protocol. In Mexico, we find direct influence of the Protocol’s information-sharing obligations in the controversial Trilateral Agreement negotiated with NAFTA partners, which may result in greater access to information and associated policy change around transgenic maize imports in the future. These developments have, at the very least, contributed to greater visibility and debate over biosafety concerns domestically.

#### *Enhanced Capacity as an Avenue of Influence*

Capacity building projects stimulated by the Cartagena Protocol are intended primarily to facilitate development and implementation of domestic biosafety frameworks. In our cases, however, we find that the well-endowed capacity-building initiatives launched under the aegis of the Protocol have not significantly influenced the content of domestic biosafety regulations. As seen from the analyses, the projects have remained at the margins of political decision-making processes in both Mexico and China.

However, this is unlikely to be the case for developing countries where regulatory frameworks do not yet exist, or where concerns around transgenics are related less to market access and international competitiveness, and more to lack of capacity to manage potential risks. Here, the Protocol’s capacity-building initiatives are likely to exert greater influence.

This is particularly the case for those countries where the prospect of having an internationally funded capacity building project has served as a lure to ratify and implement the Protocol. In others, however, capacity building is be-

69. Jasanoff 1998, 81.

70. The term “interpretative flexibility” draws on work by scholars of science and technology such as Bijker et al. 1987. For the need for local reinterpretation of global biosafety obligations, see Gupta 2004.

ing supported by GMO exporting countries who have not ratified the Protocol and who oppose the spread of its precautionary thrust. Capacity building as a vehicle for diffusion of contested biosafety regulatory models thus requires additional analysis and international scrutiny.

*Regime Influence: Domestic Discursive and Institutional Change*

In sum, although the Protocol has only been in force for a few years, the process of its negotiation and domestic implementation has created greater awareness of biosafety concerns in each of the three countries, and has strengthened domestic constituencies pushing for greater caution in testing and commercializing transgenic products. By empowering such domestic actors, both within the core state and in civil society, the Protocol has demonstrated the potential to make domestic biosafety debates and decision-making more open and inclusive than might otherwise have been the case. This applies to Mexico and South Africa, with their present-day democratic polities, as well as to China, where environmental policy-making remains tightly controlled by the core state.

Our analyses also emphasize, however, that the influence of the Cartagena Protocol is intimately tied to international trade imperatives and is mediated by domestic politics. Concerns over competitiveness, technological innovation and international trade, as well as contestation among domestic interest groups, are shaping the nature of biosafety policy and the approach to transgenic crop uptake in each of these three countries. As seen, the Protocol's avenues of influence work within this larger context.

In fact, an important caveat arising from our analysis of Protocol influence is that the relationship between biosafety concerns and market pressure is more complex than might be commonly assumed. As seen in the case of China, trade interests in favor of maintaining transgenic-free status have, for the moment, reinforced a shift towards more restrictive import and biosafety policies. In others, such as Mexico, pressures for trade liberalization have served to counteract such a trend. By comparison, South Africa's regulatory path has to date followed more closely a domestic logic, without being shaped by international trade considerations to the same degree as the other two countries. Thus, the complex interplay of state strategies, domestic interests and trade patterns creates country specific conditions for the way in which the Protocol exercises influence, and for the way in which biosafety concerns interact with market pressures.

*Regime Influence: Harmonization versus Regulatory Diversity*

As is also evident from the analyses, even though the Cartagena Protocol is being implemented in all three countries examined here, this process has not resulted in a harmonization of domestic regulatory policies. Hence, the hope of some GMO producer countries and industry that the Cartagena Protocol might

result in diffusion of a narrow harmonized set of science-based domestic biosafety regulations has not come to pass.

Instead, our analysis suggests that the prospects for countries to choose their own paths in biosafety policy, shaped by domestic priorities and imperatives, are not diminishing. This is also in keeping with the original intent of the Cartagena Protocol, which is to empower GMO importing countries to make informed judgments about the impact of transgenic crops on their domestic ecological, health and agricultural systems.

In fact, we find that the absence of a shared global approach to GMO regulation, combined with disunity among leading agricultural trading partners in Europe and North America, has the potential to widen the policy space for autonomous decision-making in key developing countries. This is partly because such conflicts require countries which desire to trade with both sides to simultaneously combine openness and precaution towards transgenics in their domestic policy choices. While this is a key challenge for many developing countries, our analysis reveals that it can also have empowering consequences, by opening up political space for those who were earlier sidelined in a scenario where promotion of the technology was the dominant trend. This is a promising outcome in controversial areas of governance such as agricultural biotechnology.

Of course, widened space for autonomous policy-making, and the empowering consequences of the transatlantic trade conflict, vary across the developing world, depending not least on a country's economic size, key trading partners, and political clout. In interpreting global biosafety rules, leading developing countries are choosing different combinations of promotional and cautionary elements, reflecting their position in global agricultural trade and the domestic balance of interests. Where trade, market access and competitiveness are not driving the directions of biosafety policy, as in many smaller developing countries, the influence of the Protocol might be different, and in all likelihood more pronounced, insofar as visibility to biosafety concerns is concerned.

Notwithstanding the Protocol, the controversies around global and national GMO regulations are unlikely to diminish in the near future, and instead look set to escalate as the WTO weighs into the global debate via the transatlantic GMO dispute. Nonetheless, our case analyses support the view that the globalization of agricultural biotechnology currently coexists with regulatory diversity in key developing countries—not least because such globalization (and associated global regulation) itself remains heterogeneous.

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