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## The Cartagena Protocol on Biosafety and Domestic Implementation: Comparing Mexico, China and South Africa

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### Summary

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- During its brief lifetime, the Cartagena Protocol has asserted itself as the pre-eminent global regime on agri-biotechnology, but there are limits to its impact.
- The Protocol has influenced and informed biosafety policy debates and developments in developing countries and emerging economies, but has not always been decisive in resolving key controversies.
- The country studies here highlight that national biosafety policy is influenced as much by domestic agricultural priorities and international trade concerns as by safety debates centred on risk assessment, science and precaution.
- Our case studies show that, in line with the Protocol's objective to allow countries to make autonomous choices about import and safe use of genetically modified organisms (GMOs), its implementation has been accompanied by persisting regulatory diversity, rather than harmonization.
- Notwithstanding certain gaps and unresolved issues in the Protocol, this tendency to support domestic regulatory diversity and choice is promising.

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### Introduction

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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. 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, which regulates the transboundary transfer and use of genetically modified organisms (GMOs). The Protocol seeks to facilitate informed decision-making by GMO importing countries about whether or not to permit entry of particular GM seeds and food. It entered into force in September 2003 and had been ratified by 129 countries and the European Community as of December 2005.

We find ourselves at a critical moment in global biotechnology governance. With the Cartagena Protocol now in force, its implementation will reveal whether international governance of biosafety can keep up with the rapid pace of technological change and globalization in genetic engineering. Important challenges lie ahead, especially in the developing world: will the biosafety protocol be implemented on the ground, despite often severe capacity constraints? And will implementation lead to an internationally harmonized science-based approach to GMO regulation (as hoped for by GMO producer countries and industry) or will it allow for a diversity of regulatory models and practices to co-exist? How might the ongoing transatlantic GMO trade conflict between the US and the EU affect developing-country regulatory choices? We address these questions through comparative analysis of biosafety policy in selected developing/emerging economies which are currently both producers and importers of transgenic crops – Mexico, China and South Africa. In doing so, we explore how global biosafety governance and global trade–safety conflicts influence domestic choices about powerful new technologies such as genetic engineering.

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### Background: global biotechnology and the governance of biosafety

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The use of genetic engineering techniques is rapidly expanding in key sectors of food production, particularly in globally traded commodity crops such as maize, canola, soybean and cotton. Producers of these transgenic crops, which have been genetically engineered largely to be herbicide-tolerant or insect-resistant, claim a range of benefits to farmers and

consumers, including higher yields, lower pesticide use and nutritional improvements. But all such claims about benefits remain disputed and stand in contrast to human health, environmental, agro-ecological and social concerns.

Although data about the spread of GM crops worldwide are difficult to come by, statistics 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 in 1996 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 Argentina (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 ha each.<sup>1</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, the rest 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 biotech 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.

The Cartagena Protocol is the centrepiece of an emerging global architecture designed to govern uptake of genetic engineering in agriculture. Other key elements of this architecture include the World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and Agreement on Technical Barriers to Trade (TBT Agreement). The Codex Alimentarius Commission, a global food safety standard-setting body, is also 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 the use of genetic engineering in agriculture. The governance challenge is made more complex by the fact that the nature and manageability of risks associated with modern biotechnology remain 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. 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 national implementation. It is also, however, because of the potential for conflict between norms and rules contained in the Cartagena Protocol and WTO agreements.

The Cartagena Protocol was negotiated to ensure the 'informed agreement' of an importing country prior to trade in certain GMOs. In operationalizing 'advance informed agreement', the Protocol lays out certain criteria and procedures for national decision-making. It mandates, first and foremost, that importer decisions about GMO trade should be based upon a scientific risk assessment. This reflects the desire of producer countries and industry to have a science-based approach to GMO regulation. The Protocol also, however, permits precautionary decisions in the face of scientific uncertainty about risks posed by a traded GMO – a significant victory for those arguing for caution in uptake of GMOs in agriculture. Finally, the Protocol also permits consideration of certain non-scientific socio-economic factors in national decisions – a demand from developing countries and NGOs – but only insofar as such factors are linked to impacts on a country's biodiversity and are consistent with other international obligations (such as those of the WTO).

In addition to decision criteria, a central element of the Protocol's advance informed agreement obligation revolves around biosafety information-sharing between countries, including via a global biosafety clearing house. These information-sharing obligations are seen as critical to making transboundary transfers of GMOs more transparent – and hence are of key relevance for developing countries. One contentious issue is the nature of information-sharing obligations for the agricultural commodity trade. The Protocol calls for explicit identification of agricultural commodity shipments that 'may contain' GMO varieties – a compromise reached in the last hours of the biosafety negotiations. This statement is to be further elaborated in future negotiations, with greater specificity about the form of accompanying documentation, the extent of information to be supplied by exporters, and the thresholds to apply in identifying GMO content in commodity shipments.<sup>2</sup> The relationship between these provisions of the

Cartagena Protocol and WTO rules was a key stumbling block on the way to agreement on the biosafety protocol. Even today, it remains one of the most controversial aspects of implementing the Protocol. The potential for conflict centres around how countries will interpret the Protocol's provisions on precautionary and socioeconomic factors in making GMO trade decisions, and whether these interpretations will conflict with the WTO-SPS Agreement's more narrowly circumscribed – 'scientifically sound' – approach to domestic decision-making. Developing countries and the EU have been concerned about the possibility of WTO disciplines trumping biosafety measures based on the Cartagena Protocol and are 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.

The long-standing trade conflict between the United States, Canada, and Argentina against the European Union over the EU's GMO-import restrictions, which led to a WTO complaint by the United States in 2003 and is to be decided by a WTO panel in 2006, looms ominously in the background to these debates.<sup>3</sup> This transatlantic GMO conflict underlines the fact that no uniform global approach for biosafety regulation currently exists. In fact, two dominant regulatory approaches persist, one serving as a model for comprehensive and precautionary safety regulation (the EU model), the other seeking a more deregulatory approach to biosafety and biotechnology development (the US model). These approaches differ on questions such as process- versus product-based regulation and substantial equivalence of GMOs, the role for precautionary action within (and beyond) science-based risk assessment, and information, labelling, traceability and threshold requirements for authorized GMOs. There are no signs that these two models are converging towards one consensual regulatory model.

In fact, the biosafety protocol remains contested by leading GMO-exporting countries, none of which have ratified it so far. And despite establishing procedures and criteria for decision-making, the Protocol's obligations either remain open to interpretation or deliberately permit considerable room for domestic policy choice when it comes to such decision-making.<sup>4</sup> While much controversy has centred around its decision-criteria in a global negotiating context, little is currently known about whether, in formulating domestic biosafety regulations in developing countries, such decision-criteria are indeed the most disputed elements, or whether other

considerations (such as access to information, labelling or R&D capacity) dominate debate and discussion.

The Cartagena Protocol calls for capacity-building to help countries develop national biosafety frameworks and install scientific, regulatory and administrative capacity. A range of such capacity-building initiatives is currently under way, led by United Nations agencies, bilateral aid agencies or the private sector in collaboration with international organizations. However, this decentralized capacity-building has allowed different interests and regulatory approaches to be promoted, with the jury still out on which, if any, of the currently contested biosafety governance approaches might be spread to the developing world. In recent years, there has been a strong push to support capacity-building in Africa by the biotechnology industry and the US Agency for International Development (USAID), which has raised concerns amongst those advocating a more cautionary approach to GMO uptake in African agriculture.

In sum, the Cartagena Protocol can be seen as a multilateral agreement that strengthens national prerogative in regulatory matters, with only a loose global framework directing national decision-making. At the same time, the current transatlantic conflict suggests that GMO-importing countries may not be able to apply precautionary measures without repercussions from producer/exporter countries, notwithstanding the Protocol. In the following section, we investigate the evolution of domestic biosafety policy in three developing/emerging economies, and the biosafety protocol's impact on such policy.

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### Comparing biotechnology regulation in Mexico, China and South Africa

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Mexico, China and South Africa are among the leading developing countries that have actively sought to build biotechnological research capacity and have faced the dilemmas of creating biosafety regulation while engaging in the commercial application of biotechnology. All three countries have important agricultural sectors, making agricultural biotechnology a key economic, environmental, political and social issue. Although Mexico is a member of the OECD, in areas of relevance to agricultural biotechnology it exhibits important characteristics of a developing country: a relatively large proportion of the population is engaged in agriculture, particularly subsistence farming; and the country is a centre of origin and diversity of key crops subject to genetic engineering, such as maize.

The three countries also exhibit certain important differences. They vary, in particular, with regard to the nature of their domestic political system: Mexico and

South Africa are (nascent) democracies with a market economy, whereas China has only recently emerged out of socialist isolation, and 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 the leading industrialized countries of North America through membership of the North American Free Trade Agreement (NAFTA). South Africa has, since its readmission 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 global competitiveness, most notably symbolized by the country's accession to the WTO, but it still places high priority on policy autonomy and insulation from external influences. Importantly, all three countries have ratified the Cartagena Protocol; China did so most recently, in 2005.

Below we present detailed contextual analyses of the dynamics of domestic biotechnology governance in the three countries. Our analysis is based on fieldwork in the countries and interviews with policy-makers representing diverse state interests (including agriculture, health, environment, economy, science and technology policy, foreign affairs and trade), as well as stakeholder representatives including scientists, NGOs (where they exist), and the private sector.

#### *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 programmes 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, 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.

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 centre 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 ingressions into indigenous maize varieties in the Chiapas region of Mexico.<sup>5</sup> The resultant controversy, together with global and regional developments, have spurred institutional and regulatory change in Mexican biotechnology policy.

### *Trade policy dimensions*

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 and continued by current President Vicente Fox. 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. Mexico has also participated actively in negotiating the Cartagena Protocol on Biosafety. It is the only NAFTA country to have ratified the Cartagena Protocol.

Mexico's obligations under NAFTA and WTO Agreements, and its ratification of the Cartagena Protocol, together with the continuing controversy over maize, have shaped on-going efforts to develop a domestic policy on genetic engineering in agriculture. Elements of such a policy predate some recent developments, given that Mexico has permitted field-testing of transgenic crops since 1988, when the first government approval was issued to Monsanto for its transgenic (Bt) cotton. Since then a range of transgenic crops, produced primarily by the private sector, has 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.

### *An evolving regulatory framework*

This research trajectory dating back to 1988 has necessitated the development of an institutional and

regulatory framework for biosafety oversight. The first – and until recently only existing – 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>6</sup> The Ministry of Agriculture was, in fact, the key locus for regulatory oversight for transgenic crops throughout the 1990s; other government representatives, including from the Ministry of Environment, only sought more of a 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 set of regulatory standards, 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 NOM-056 to portray large areas (even exceeding 10,000 hectares) as experimental fields (and hence still requiring 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 centres of diversity for cotton, and hence has generated less controversy domestically.

Sentiments and controversies over transgenic maize have been much more intense. Fears about transgene ingressions 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 the likelihood of a shut-down of biotechnology research in Mexico.

Such a biosafety law was recently approved 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, and the key drafters are two prominent Mexican scientists. It is fairly unprecedented that the scientific community should develop a politically fraught piece of legislation. This points to the influence on regulation of those with specialized knowledge, who are also 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 ratified the Cartagena Protocol in 2003 and hence took on the legal obligation to develop a 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 even as it seeks to regulate its safe use.

In general, however, a view shared by almost all stakeholders is that a biosafety law, although flawed, is better than having no regulation at all. Most groups have thus supported its passage into law. In particular, the Ministry of Environment gains in a significant way from the passage of the new law, in that it now has equal say (with the Ministry of Agriculture) in approving transgenic crops for deliberate release. Under the earlier NOM-056, the Ministry of Environment had merely an advisory role; the final decision rested with the Ministry of Agriculture.

Another key institutional development in Mexican biosafety governance has been the establishment of an inter-agency commission for biotechnology to coordinate and develop biotechnology policy for Mexico. 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 action is desired'.

CIBIOGEM's involvement is less than substantive in another significant outcome of Mexico's ratification of the Cartagena Protocol – the signing of a controversial 'Trilateral Arrangement' between Mexico and its NAFTA partners, the US and Canada. The arrangement is intended to implement the Cartagena Protocol's requirement that bulk commodity shipments state that they 'may contain' transgenic varieties. This trilateral agreement was negotiated, by many accounts, by the Ministry of Agriculture without sufficient consultation

and it does not enjoy the unequivocal support of all branches of government, much less civil society.

A key reason is the arrangement's controversial clause stating that the Cartagena Protocol's obligation to declare that agricultural commodity imports 'may contain' transgenic varieties is only to be triggered in cases where transgenic material is above a minimum 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. Ironically, 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.

A number of other domestic institutional developments have been directly stimulated by the Cartagena Protocol. The first of these is the launching of a project on capacity-building for biosafety regulation. Mexico is one of 12 countries to have launched a model Global Environmental Facility (GEF) project on national biosafety frameworks. The GEF project 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, however, influenced the development of the recently passed biosafety law. Another direct outcome of the Protocol is the development of a domestic roster of experts in biosafety, modelled along the Protocol's global roster of experts. Both the GEF project and the biosafety roster of experts are portrayed, however, as apolitical technical interventions. They have not necessarily influenced the direction and content of biosafety policy in Mexico.

### *Outlook*

In Mexico, then, an overall promotional approach to biotechnology at the highest political levels and a general neo-liberal economic stance (the most vocal adherents of which are the Ministry of Agriculture and Ministry of Economy, supported by high-profile public-sector scientists) have most influenced the direction of biotechnology policy. This coalition has, however, encountered resistance from those who advocate a more restricted approach. Organizations such as Greenpeace, as well as peasant and labour unions, exercise considerable influence over the hearts and minds of the general public, especially in rural areas and especially 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 the previous regimes were authoritarian and corrupt, the present administration is 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 and, 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, at the very least, provided additional justification and has given greater visibility to those advocating a cautionary approach.

### **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 programme 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. Despite some waste in public research funding and lack of private investment, China had managed to produce 141 different types of GM crops by 2002, of which 65 have entered the stage of field trials.<sup>7</sup>

The absence of any biosafety regulation during the 1980s played into the hands of Chinese researchers, who, late in that decade, were the first worldwide to grow a GM crop in commercial quantities, a virus-resistant tobacco plant. 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. 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>8</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 Ministry 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 – 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 favour the rapid commercialization of GM crops.

### **Participation in biosafety 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. 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 treaty 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.

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 the United Nations Environment Programme (UNEP) and GEF, which gave SEPA a lead role in the drafting process and promoted a more comprehensive approach to GMO regulation. The impact of the framework was of a more limited nature, however: it 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.

### *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 signalled 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 regulations more in line with the emerging international system of biosafety governance.

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 labelling. 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 favoured by the leading biotech country, the United States, towards a more process-based approach as practised in the EU. These acts 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 the one side of the debate are advocates of agri-biotechnology 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 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 United States, rejected the transgenic variety. 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.

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>9</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 assessment. 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.

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 time-frame 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. 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 to 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. China has adopted important elements of the Cartagena Protocol, but is still some way from creating an effective system of domestic biosafety regulation. Environmentalists point 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>10</sup>

The future direction of China's biosafety policy remains uncertain. While its 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 are tipped to enter the market in the near future. Whether this will 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 interests, besides 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.

### *South Africa*

The direction taken by biotechnology in South Africa holds a 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 in various spheres. In the 1980s, with support from the government, new biotechnology research centres were established. Beginning in the 1990s, South Africa was 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. Unlike in China, in South Africa (as in Mexico) this 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. While the public sector is involved with transgenic research, its products have yet to reach the commercialization phase. The focus of public-sector research has been on, *inter alia*, transgenic potato, sugar cane, maize and strawberries. South Africa is also the first country to commercialize transgenic white maize, a staple food crop of its population. Even though the bulk of research and development is under way 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. The first general release of transgenics occurred in South Africa in 1997. This coincided with adoption of a separate biosafety law, also pushed for by SAGENE members, many of whom were engaged in biotechnology research themselves. 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. 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).

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 some other countries where the Ministry of Environment, for example, has less final authority over approvals than the Ministry of Agriculture. Critics note, however, that the capacity to raise relevant concerns in the Executive Committee varies greatly between government departments, and can depend partly on the personalities involved and their background and training.

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 mandates creation of regional innovation centres, with Rand 400 million (\$60 million) committed to their establishment. The strategy also notes the need for regulatory systems to permit South Africa's participation in GMO trade, both as an exporter and importer.<sup>11</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>12</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 played a relatively smaller role in influencing domestic

regulatory developments in South Africa. Where international influences have been important is in the debate in South Africa and neighbouring countries over food aid with genetically modified varieties, particularly from the US. In the food aid crisis in 2002, it was South 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>13</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 distinct varieties of cotton, three varieties of maize and one variety of soybean) have received general release approval (which permits import/export, commercial planting and use as food or feed) with another eight varieties of maize approved for commodity clearance, i.e. importation for use as food/feed.

### *An evolving regulatory process*

In this process, 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 domestic NGO community. Most recently, a court case brought by the environmental organization BioWatch against the government demanded access to information about transgenic crop approvals. BioWatch won the case; the Registrar of the GMO Act (the main repository of information within the Department of Agriculture) is now required to make such information available. Despite being a significant victory, this 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 to date the domestic NGO community in South Africa has played this role with aplomb, filing detailed objections to an ever-increasing body of transgenic crop permit applications.<sup>14</sup>

One concrete outcome of these objections and legal challenges by domestic NGOs has been that they have provided an important impetus to amend the 1997 GMO Act. An important additional motivation for the amendment process has been South Africa's ratification of the Cartagena Protocol in August 2003. With an overall political environment that supports rapid development of the biotechnology sector, it can appear puzzling why South Africa ratified the Cartagena Protocol – which is seen as a potential hurdle to rapid biotechnology uptake by supporters of the technology. The ratification is explained by observers, however, as politically unavoidable, given

South Africa's emphasis on multilateralism and its desire to show solidarity with other African countries, most of which strongly support the Protocol.

### *Influence of the Cartagena Protocol*

Ratification of the Cartagena Protocol has resulted, at the very least, in procedural adjustments to time-frames in the current regulatory approval process. Discussions are also under way about how to meet the country's obligations to provide information about domestic GMO approvals to the Protocol's Biosafety Clearing House. Furthermore, as stated above, ratification of the Cartagena Protocol has also provided a 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 NGOs both for failing to address environmental and social concerns around transgenic crop use in South Africa and for failing to adequately implement the Cartagena Protocol.

Where unable to introduce desired changes into the GMO bill, the domestic NGO community, partly emboldened by ratification of the Cartagena Protocol, 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 is often a desk-top study undertaken elsewhere. Although it remains disputed whether this is indeed a far-reaching regulatory change, the requirement for an EIA is seen by supporters as in keeping with the Cartagena Protocol, and its inclusion in the Biodiversity Bill as a victory for those seeking to draw attention to environmental impacts of GMO releases.

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 an NGO that exists to serve as a source of objective information about the use of genetic engineering in agriculture. 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 USAID. The influence of the US is prominent in such regional capacity-building initiatives, which has raised 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 labelling legislation under the Ministry of Health, which subscribes to the notion of the substantial equivalence of GM food with non-GM food. This permissive approach may 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 was unaware or unconcerned about transgenic foods, a finding that subsequent government-initiated surveys claim to confirm as well. This could be because, unlike maize in Mexico, for example, no single crop subject to genetic engineering has the cultural resonance around which public debate can be or has rallied so far. Maize is South Africa's most important crop as well, and commercialization of transgenic white maize may well lead to future heated debates, 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 South Africa's agricultural imports or exports, it is a small but vocal domestic pro- and anti-GM lobby within the country that is driving domestic regulatory developments. In a recent development in late 2005, however, 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 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. Both proponents and critics, however, have drawn upon the Cartagena Protocol (or at least its call for capacity-building) to bolster their positions and influence developments within the country and regionally. With many countries in Africa now at a key juncture in developing biosafety regulations, outcomes in South Africa remain critical to watch.

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## Conclusion: domestic implementation of the Cartagena Protocol

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The analysis shows that the Cartagena Protocol is indeed influencing policy debates and developments in the countries we examine. Although it has only been in force for a few years, the process of its negotiation and implementation has created greater awareness of biosafety concerns and has strengthened domestic constituencies pushing for greater caution in testing and commercialization of biotech products. By empowering such domestic actors, both within the core state and in civil society, the Protocol has demonstrated the potential to augment more inclusive, participatory and democratic decision-making around biosafety policies in a domestic context.

However, our analysis also emphasizes that the degree to which the Cartagena Protocol can have such an impact is tied up with international trade imperatives and domestic politics, which vary from country to country. 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 overall approach to transgenic crop development and uptake. This is evident from the fact that, although existing biosafety laws are being amended in our three countries in response to the Cartagena Protocol, considerations shaping this process go beyond the Protocol's focus on scientific risk assessment, advance informed agreement for certain GMO transfers, and information-sharing.

In some cases (e.g. China), trade interests in favour of maintaining GM-free status have, for the moment, reinforced the shift towards more restrictive biosafety policies, whereas in others (e.g. Mexico), pressures for trade liberalization have served to counteract such a trend. By comparison, South Africa's regulatory path to date has more closely followed a domestic logic. Thus, the complex interplay of state strategies, domestic interests and trade patterns creates country specific conditions for the way in which the Cartagena Protocol impacts on domestic biosafety policy.

While the Cartagena Protocol is being implemented across the developing world, including in our three cases, this process has not yet resulted in a harmonization of regulatory policies. Hence, the hope of some GMO producer countries and industry that the Cartagena Protocol might result in a narrow harmonized set of science-based domestic biosafety regulations has not been fulfilled. Instead, the analysis here suggests that the absence of a uniform global approach to GMO regulation, combined with disunity among leading agricultural trading partners in Europe

and North America, has the effect of widening the space for autonomous decision-making in developing countries struggling with the challenges of domestic biosafety regulation.

Of course, this widened space for autonomous policy-making varies across the developing world, depending not least on a country's economic size and political clout. In implementing global biosafety rules, leading developing countries/emerging economies are choosing different combinations of promotional and cautionary elements, reflecting their position in global agricultural trade and the domestic balance of interests. All three countries examined here are encouraging new agricultural technologies as part of an effort to promote economic liberalization and greater competitiveness in international markets. A key motivation underlying their biotechnology policy is fear of being left out of the next technological revolution, with consequences for international competitiveness. This concern does not carry the same weight across the developing world. Hence, the directions of biosafety policy elsewhere, also in response to the Cartagena Protocol, may well differ significantly.

This also applies to the role of capacity-building in influencing domestic biosafety frameworks. In our three cases, capacity-building initiatives launched under the aegis of the Cartagena Protocol have not necessarily influenced the nature of domestic biosafety regulations. Instead, they have merely

supported and complemented such frameworks. However, this may not be the case for other developing countries, where regulatory frameworks do not yet exist or where concerns around transgenics are related less to international competitiveness and more to regulatory capacity to manage potential risks. Here, capacity-building initiatives are likely to exert greater influence, requiring additional analysis and international scrutiny.

Nonetheless, our analysis suggests that the prospects for countries to choose their own paths in biosafety policy, shaped by domestic priorities and imperatives, are not necessarily 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 crop transfers on their domestic ecological, health and agricultural systems. Our case studies support the view that the globalization of biotechnology currently coexists with regulatory diversity in key developing countries. 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, the persistence of domestic regulatory diversity and choice thus far is a promising result of the implementation of the Cartagena Protocol.

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<sup>2</sup> For a detailed analysis of this and other challenges facing countries in further elaborating Protocol rules, see Robert Falkner and Aarti Gupta, *Implementing the Cartagena Protocol: Key Challenges*, SDP Briefing Paper No. 4 (London: Chatham House), November 2004

<sup>3</sup> Although the WTO conflict does not directly challenge Cartagena Protocol provisions, the WTO panel's decision, which is expected in early 2006, will have broader ramifications for the interpretation of the Protocol. Cf. Duncan Brack, Robert Falkner, and Judith Goll, *The Next Trade War? GM Products, the Cartagena Protocol and the WTO*, Briefing Paper No. 8 (London: Chatham House), September 2003.

<sup>4</sup> For a discussion of the need for local reinterpretation of global obligations, see Aarti Gupta, 'When Global is Local: Negotiating Safe Use of Biotechnology', in Sheila Jasanoff and Marybeth Long-Martello (eds), *Earthly Politics: Local and Global in Environmental Governance* (Cambridge, MA: MIT Press, 2004), pp. 127–48.

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<sup>11</sup> National Biotechnology Strategy, South Africa. 2001. Department of Science and Technology, available at <http://www.dst.gov.za/programmes/biodiversity/biotechstrategy.pdf>.

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<sup>13</sup> Noah Zerbe, 'Feeding the famine? American food aid and the GMO debate in Southern Africa', *Food Policy*, 29 (2004), pp. 593–608.

<sup>14</sup> See, for example, detailed objections by the African Center for Biosafety at [www.biosafetyafrica.net](http://www.biosafetyafrica.net).

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