Regulating biotech trade: the Cartagena Protocol on Biosafety

ROBERT FALKNER*

It has long been recognized that any successful sustainable development strategy has to strike a balance between the interests of trade and concern for the environment. However, these sometimes conflicting imperatives have been, and remain, a potential source of conflict in international political economy. The World Trade Organization (WTO), often accused of insensitivity to environmental problems and the new reality of global environmental governance, has for many years been investigating ways of reconciling trade and the environment. However, failure to introduce a formal environmental mandate into the international trade regime and the collapse of the 1999 WTO ministerial meeting in Seattle could hardly have highlighted more sharply, or more publicly, the contentious nature of the trade–environment relationship.

One area in which environmental concerns have recently clashed with the trading interests of states and corporations is that of biotechnology. The burgeoning trade in genetically modified organisms (GMOs) has been met with growing consumer and regulatory resistance in a number of countries, most notably in Europe, where stringent rules on the release of GMOs into the environment have led to accusations by GMO-exporting countries of unfair trade restrictions. The United States, the world's largest exporter of biotechnological products, has repeatedly attacked the European Commission for its reliance on the precautionary principle in regulating GMOs, seeing it as in direct conflict with the WTO's science-based risk-assessment methods.

In the light of these developments, the adoption of the Cartagena Protocol on Biosafety earlier this year, only two months after the debacle of Seattle, represents a significant achievement in trying to reconcile the respective needs of trade and the environment. The Protocol establishes international rules for trade in genetically modified organisms and reinforces the right of importing nations to reject GMO imports on environmental or health grounds. While recognizing the

* Research towards this article was made possible by financial support from the European Commission (DG Environment) and the UK's Department for International Development and Department for Trade and Industry. The author would like to thank Duncan Brack, Les Levidow, Ruth Mackenzie and Désirée McGraw for their comments on an earlier draft of this article, and the participants in the Montreal talks who provided briefings despite pressure of time.

potential benefits of biotechnology trade, the treaty strengthens the application of the precautionary principle in this area and explicitly states that trade and environment agreements 'should be mutually supportive'.

However, in many ways the Protocol represents an inconclusive compromise between the interests of GMO exporters and importers, as was to be expected after the acrimonious collapse of the biosafety talks in early 1999. The agreement is unlikely to prevent future tension over some important issues that remain unresolved: the precautionary principle has been defined only insufficiently; and the provisions on trade and the environment, relegated to the preambular text, leave considerable room for interpretation. Moreover, environmentalists fear that rapid progress in biotechnological innovation will soon call into question some of the Protocol's exemptions. While the Cartagena Protocol marks a significant step forward in regulating biotech trade, its effectiveness with regard to protecting biodiversity and human health will depend on its future ability to adapt to, and catch up with, rapid change in biotechnological research and commercialization.

The political controversy over biotechnology

Over the last 20 years modern biotechnology has moved from scientific research and experimentation to worldwide commercialization in a number of industries, ranging from agriculture and food production to chemicals and pharmaceuticals. The rapidly expanding number of biotechnological applications and products has been met with increasing scepticism and fears among consumers and public authorities alike, although some societies, especially in North America, have shown higher levels of acceptance towards the new technology. In Britain and in continental Europe, however, genetically modified (GM) crops and food products have become the new *cause célèbre* of environmentalists and consumer protesters.

Among the reasons for bio-agriculture's lack of popular support in parts of the world, the environmental and health risks associated with GMOs constitute the most important factor. What the biotech industry and its supporters describe as ill-informed alarmism and a 'Luddite' anti-science attitude is, in the view of environmentalists, an expression of the popular distrust in scientific and corporate self-regulation. Previous food scares revolving around Salmonella-infected eggs, Bovine Spongiform Encephalopathy (BSE)—mad cow disease—and hormone-treated beef are seen as an indication of the inadequacy of the safety systems that govern modern industrial agriculture.

There is also a political dimension to the public's hostility towards biotechnological developments. Environmentalists claim that political institutions have responded only slowly and inadequately to the perceived risks of biotechnology. Regulations in industrial countries have not always assured the public of the safety of biotechnology, and many developing countries lack even minimal regulatory frameworks. The perception of a growing gap between biotechnological

innovation and political responses is further accentuated by the fact that, until recently, no comprehensive regulatory system existed that could deal with the transboundary aspects of the global biotechnology business.

The incomplete and fragmented framework of biotechnology regulation stands in sharp contrast with the fast expansion of the agribiotech sector around the world. The global area of GM crop production (e.g. soybean, maize, canola, corn and cotton) is estimated to have grown from 1.7 million hectares in 1996 to 39.9 million hectares in 1999, with an increase of 44 per cent between 1998 and 1999 alone. The sales volume of GM crops has increased approximately 30-fold in the period 1995–9, and the global market for GM crops is projected to reach $8 billion in 2005, and $25 billion in 2010.[1]

International discussions on the need for a global biosafety standard initially focused on the need for developing countries to strengthen their regulatory powers with regard to trade in GMOs. Most countries in Asia, Africa and Latin America lacked the necessary scientific or regulatory capacities in the field of biotechnology, and therefore placed their hopes for international legal, financial and technological support in an international biosafety agreement.

The decision to consider aspects of international biosafety in the context of the Convention on Biological Diversity helped to frame the biosafety talks in terms of a North–South issue. This focus on the needs of developing countries was supported by a number of developed countries that had already established their own regulatory systems, most notably the countries of the European Union. However, the growth of commercial GM applications and trade in GM crops in the second half of the 1990s brought the EU into more direct conflict with the United States, the world's largest GMO exporter. What had started out as a North–South issue soon developed into a conflict among Northern countries over the potential implications of biotech regulation for international trade rules and obligations.[2]

At the heart of this dispute was the conflict between the EU's insistence on a precautionary approach in regulating GMO releases into the environment, which takes into account the uncertain potential environmental threats posed by GMOs, and the 'science-based' methods of risk assessment prevailing in the United States. The EU issued two directives in 1990 concerning the contained use of GMOs and their release into the environment. They require environmental evaluation and step-by-step approval for the dissemination of GMOs, giving extensive rights to member states to participate in the evaluation process. These procedures, and the EU's strengthening resolve to apply the precautionary principle, have been criticized by the biotech industry and Washington for producing an over-complex and unpredictable approval process which gives

[1] Clive James, 'Global status of commercialized transgenic crops: 1999', *ISAAA Briefs* no. 12: Preview (Ithaca, NY: ISAAA, 1999).

[2] On the US–EU and North–South dimensions of the GM trade conflict, see Robert Falkner, 'International trade conflicts over agricultural biotechnology', in Alan Russell and John Vogler, eds, *The international politics of biotechnology: investigating global futures* (Manchester: Manchester University Press, forthcoming).

priority to political over scientific considerations. In contrast, the United States' more streamlined and depoliticized evaluation procedure has allowed industry to promote the rapid commercialization of biotechnological research.

Although the US government has not yet sought a settlement of the GMO dispute within the WTO, it has consistently argued that the EU's regulations are in violation of WTO disciplines. The United States has stressed that the WTO Agreement on Sanitary and Phytosanitary Measures (SPS), which governs aspects of human health and food safety (as in the dispute over hormone-treated beef), assigns the burden of scientific proof to the nation imposing trade restrictions.

Against this background of an intensifying transatlantic trade dispute, the parties to the Convention on Biological Diversity initiated in the mid-1990s international talks to consider the safety aspects of trade in GMOs. What began as an extension of the environmental biodiversity agenda to the field of biotechnology soon developed into a prominent example of the growing tensions between trade and environmental interests.

The history of international biosafety negotiations

Facing the regulatory gap at international level

The issue of an international biosafety standard was first raised at the diplomatic level in the 1980s. In the run-up to the 1992 United Nations Conference on Environment and Development (UNCED), questions of biosafety emerged within the context of the preparations for the Convention on Biological Diversity (CBD). At that time, advances in biotechnology had given rise to concerns about the ecological impact of GMO releases into the environment. Although the new technology had not yet been introduced to agricultural production on a commercial scale, it became clear that it was only a matter of time before genetic engineering would be adopted by the global agriculture and food industries.

A number of international organizations began to address aspects of international biosafety, although none of them was able to go beyond non-binding standards or codes of conduct. Within the Food and Agriculture Organization (FAO) the Commission on Plant Genetic Resources (CPGR) produced in the early 1990s a Draft Code of Conduct on Biotechnology, which aims at promoting the use of biotechnology for the 'conservation and sustainable utilization of plant genetic resources' as well as their 'safe, equitable and responsible use' (Article 1.1).[3] It decided later to concentrate on the biosafety talks under the CBD umbrella and offered its Draft Code of Conduct as input into these talks.[4]

[3] Commission on Plant Genetic Resources (CPGR), Fifth Session, Rome, April 1993, 'Preliminary Draft International Code of Conduct on Plant Biotechnology', Annex to CPGR/93/9, agenda items.

[4] See Abby Munson, 'Should a Biosafety Protocol be negotiated as part of the Biodiversity Convention?', *Global Environmental Change* 5: 1, 1995, p. 14.

The Organization for Economic Cooperation and Development (OECD), concerned primarily with the promotion of economic growth and technological innovation through market and trade liberalization, had achieved more progress in developing the OECD Safety Considerations for Biotechnology, published in 1992. These did not, however, constitute a binding agreement and were not concerned with aspects of the transboundary movement of GMOs. Other bodies, such as UNEP, UNIDO, the International Plant Protection Convention and the Codex Alimentarius Commission, each had international agreements in place which covered certain aspects of genetic engineering, with the UNEP International Technical Guidelines for Safety in Biotechnology (1995) serving as an interim mechanism prior to an international biosafety treaty. And yet, as a study by the CBD Secretariat concluded, none of these regimes was able to fill the regulatory gap that had emerged in the early 1990s with regard to the rapid expansion of GM technologies in commercial agriculture.[5]

These various efforts to create international biosafety standards demonstrated three important aspects of the new biotechnology agenda: first, the wide range of policy issues and areas affected, including environmental safety, human health, international trade, food security, technological innovation and industrial policy; second, the considerable difficulties involved in reaching international agreement on a comprehensive and universal biosafety standard; and third, the growing gap between economic and technological innovation, on the one hand, and international regulatory responses, on the other. It is against this background that the parties to the CBD began to consider the need for, and modalities of, an international agreement on biosafety.

The start and collapse of international biosafety talks, 1996–1999

Negotiations on the Biosafety Protocol began a year after an exploratory group of experts met in 1995 to define the issue area to be covered by a potential biosafety protocol to the Convention. An open-ended ad hoc Working Group on Biosafety (BSWG) was formed to act as the negotiating body and was given the task of producing a final draft treaty by 1998. The Working Group met five times between 1996 and 1998, but failed to create sufficient common ground among the parties to open final negotiations within the original schedule. The BSWG therefore reconvened for a sixth time in Cartagena, Colombia, in February 1999, to pave the way for the adoption of the Biosafety Protocol at an Extraordinary Conference of Parties following immediately from the Working Group meeting.[6]

[5] The CBD Secretariat was given the task of identifying gaps in the existing regulatory system of international biosafety. It concluded that 'no such system exists' (Background Document on Existing International Agreements, UNEP/CBD/BSWG/2/3, 7 March 1997, p. 25).

[6] The BSWG meetings are well documented by the *Earth Negotiations Bulletin*. Electronic versions of the *Bulletin* can be found at the Linkages WWW server at <http://www.iisd.ca/linkages/>. For an analysis of the biosafety talks up to 1999 see Aarti Gupta, *Framing 'biosafety' in an international context: the Biosafety Protocol negotiations*, ENRP Discussion Paper E-99-10 (Harvard, MA: Kennedy School of Government, Harvard University, 1999); John Vogler and Désirée McGraw, 'An international environmental regime for biotechnology', in Russell and Vogler, eds, *The international politics of biotechnology: investigating global futures*.

Despite a continuous presence at the BSWG meetings of observers from industry and environmental NGOs, the negotiations proceeded up to 1999 without attracting much international publicity. The issues discussed were often of a highly technical nature, and some of the key political differences between the parties, although manifest throughout the process, were left unresolved until the last round of negotiations in Cartagena. Here, the intensity of the looming conflict over biosafety finally broke out into the open. By this time, in early 1999, the issue of biosafety had been sufficiently politicized to arouse greater interest in the biosafety talks. This was particularly the case in Europe, where the public grew increasingly hostile towards GM foods and began to realize the wider international trade implications of agricultural biotechnology.

The heavily bracketed draft treaty that formed the basis of the Cartagena Conference in February 1999 contained a number of contentious issues that eventually eluded agreement. Some of them had been on the agenda from the start of negotiations; some had arisen as the parties developed a clearer view of the emerging Protocol.

Among the fundamental disagreements between the parties that burdened the whole negotiation process was the scope of the Protocol, i.e. whether regulation should apply only to trade in 'living modified organisms' (e.g. seeds) or also to products made with the help of genetic engineering or containing GM ingredients (e.g. food, animal feed). The GM-exporting nations, fearful of the potential repercussions for the burgeoning trade in GM foods and pharmaceutical products, insisted on a narrow definition of the Protocol's scope. The developing countries and environmental pressure groups, on the other hand, wanted to have all biotechnological products covered by the treaty. Another area of intractable disagreement concerned the purpose and nature of the Protocol: was it primarily to facilitate trade in biotechnology by harmonizing biosafety standards, or to strengthen the regulatory interests of GM-importing nations, and especially developing countries, against the interests of the global agribiotech industry? These and many other controversial issues defied the efforts of the negotiating parties at resolution in Cartagena. The GM-exporting nations would accept only a narrowly defined Protocol that was subject to the WTO's legal order, while the EU and the developing countries argued in favour of a document with more extensive scope and clearly defined exemptions from existing WTO obligations. In the end, the position of the American delegation—that 'no deal is better than a bad one'[7]—

[7] US delegation member Tim Galvin reiterated this position in the run-up to the Montreal talks ('Montreal GML talks likely to be difficult—USDA', Reuters News Service, 10 Jan. 2000). The United States never ratified the CBD, owing mainly to resistance in Congress, but was granted observer status at the biosafety talks. In recognition of the United States' dominant position in the global agribiotech business and its leadership role within the group of GM-exporting, the US delegation played an active role in the talks and was admitted to informal negotiations. Despite fundamental opposition to stringent international biosafety rules, both the government and biotech industry groups in the United States advocated US participation in the biosafety talks, hoping to have greater influence over the outcome than was the case when the US flatly rejected the CBD in 1992. On the evolution of US policy on biodiversity and biosafety, see Robert Falkner, 'Business conflict and American foreign environmental policy', in Paul G. Harris, ed., *The environment and American foreign policy* (Washington DC: Georgetown University Press, forthcoming).

prevailed and the talks were suspended with the aim of reconvening the conference and concluding negotiations by May 2000.

The resumed Extraordinary Conference of the Parties (ExCOP), Montreal, January 2000

Notwithstanding the mutual recriminations that followed the breakdown of the Cartagena Conference, the parties pledged to work towards a resumption of the talks. In informal consultations, held in July and September 1999 and again immediately before the January 2000 Montreal ExCOP, some progress was made in further narrowing down the remaining contentious areas and clarifying the positions of the parties. The talks were conducted both within and among the five groups of countries that had emerged in Cartagena: the Miami Group of GMO-exporting nations (Argentina, Australia, Canada, Chile, the United States and Uruguay); the European Union; the Central and East European countries (CEE); the Compromise Group (Japan, Mexico, Norway, South Korea and Switzerland); and the Like-Minded Group, representing the majority of developing countries.

While a more upbeat atmosphere among negotiators developed after the Vienna meeting in July 1999,[8] events on the international trade agenda cast a new shadow over the future of the biosafety talks. In the run-up to the WTO's ministerial conference in Seattle, two controversial proposals had been made to introduce trade in biotechnology to the WTO as a separate issue area. Canada and Japan suggested a WTO working group on biotechnology, while the United States wanted to see new disciplines introduced for trade in GM products.[9] Both proposals raised the spectre of a shift in the institutional context within which biosafety issues would be debated, away from the CBD's emphasis on biodiversity protection and towards the WTO's objective of trade liberalization. The developing countries strongly objected to these initiatives, while the EU's General Affairs Council rebuked the Commission's trade representative, Pascal Lamy, who had reached a bilateral agreement with the United States at Seattle to establish a WTO working group on biotechnology.

The controversy over the unsuccessful attempt to create a WTO working group on biotechnology highlighted the stakes involved in the Montreal biosafety talks, although it was not clear whether it would enhance or reduce the chances of an agreement. On the one hand, the WTO proposals signalled to the parties, and especially to those who wanted a strong Protocol, that if they failed to reach an agreement at Montreal GM trade issues might resurface in the WTO context. On the other hand, however, some delegates argued that the Protocol's cause could only be strengthened by the outcome of the Seattle conference.[10] Once again, the relationship between trade and the environment promised to be a thorny issue in the negotiations.

[8] UNEP, 'Informal consultations on Biosafety Protocol held in Vienna from 15 to 19 September 1999' (UNEP/CBD/ExCOP/1/INF/3, 20 Oct. 1999).
[9] World Trade Organization: WTI/GCI/WI/288, 4 August 1999; WTI/GCI/WI/359, 12 October 1999.
[10] *Earth Negotiations Bulletin* 9: 132, 24 Jan. 2000, p. 2.

The resumed ExCOP in Montreal opened on 24 January 2000 to consider the remaining bracketed text in the draft treaty and the compromise paper produced by the chair of the conference, Colombia's environment minister Juan Mayr, which reflected the discussions of the Vienna meeting in September 1999.[11] The parties had agreed that the Montreal talks should focus only on the most contentious issues, and that the preliminary agreements reached on other parts of the Protocol would not be reopened.

Early progress was made on the question of which procedures for informed consent should apply to so-called 'commodities' (GMOs intended for food, feed or processing). Defining the scope of the Protocol, that is the range of GMOs and products made with the help of biotechnology to be covered by the biosafety treaty, proved more difficult. Equally, the application and definition of the precautionary principle, as compared to full scientific proof, as well as the relationship of the Protocol with the international trade regime, led to protracted negotiations which were resolved only at the end of the conference, when many of the delegations had been joined by ministerial representatives.

The atmosphere of the talks was significantly better than at the Cartagena meeting, as many participants noted. But despite the declared intention of all delegations to work towards an agreement, a successful outcome was not guaranteed. On the penultimate day of the conference the Miami Group announced its intention to reopen some of the previously agreed articles in the draft treaty, thus threatening the talks with collapse. This move was strongly rejected by all other negotiating groups, and last-minute efforts by the chair and the main delegation leaders secured an agreement on the Cartagena Protocol in the early hours of 29 January.[12]

The provisions of the Cartegana Protocol on Biosafety[13]

The scope of the Protocol

The fundamental question of which aspects of modern biotechnology should be covered by the Protocol proved to be one of the most contentious issues in the negotiations. Defining the potential scope of international biosafety rules had already taken up considerable time in the pre-negotiation period of 1996–8,[14] and had played a major role in the breakdown of the Cartagena Conference.

[11] The draft Protocol is contained in Annex V of UNEP, 'Draft Report of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity' (UNEP/CBD/ExCOP/1/L.2/Rev.1, 23 Feb. 1999).

[12] Over 130 governments were represented at the Montreal talks. The agreed text of the Cartagena Protocol will be opened for signature at UNEP headquarters in Nairobi, Kenya, from 15–26 May 2000, on the occasion of the Fifth Session of the Conference of the Parties to the CBD. The Protocol will enter into force after 50 countries have ratified it.

[13] In the following, the provisions of the Cartagena Protocol are cited according to the final draft text submitted by the Legal Drafting Group of the Montreal conference (UNEP/CBD/ExCOP/1/L.5, 28 Jan. 2000), which was adopted by the parties on 29 January.

[14] Gupta, *Framing 'biosafety' in an international context*, p. 9.

The ExCOP Draft Report of February 1999 proposed an inclusion in the Protocol of all living modified organisms (LMOs),[15] except: those that the parties would list in an annex as environmentally safe; the transit and contained use of LMOs; and pharmaceutical LMOs for humans. In Cartagena, the developing countries had failed in their attempt to have all products deriving from LMOs (so-called 'products thereof') included, whether they contained GM ingredients or not. The rationale behind their demand was that the environmental effects of such derivative products remained uncertain. But the industrial countries and business groups denied the potential hazards for biodiversity and argued forcefully that the rapid proliferation of products derived from GMOs throughout the global economy would render the Protocol's informed consent procedure impossible to apply, and would at worst lead to massive trade disruption. The industrial countries were particularly keen to exclude pharmaceuticals from the Cartagena Protocol, in order not to draw a biotechnology sector hitherto relatively unaffected by the political controversy over genetic engineering into the biosafety agenda.

Given that the all-inclusive definition of the Protocol's scope was anathema not only to the Miami Group but also to the EU, Chair Juan Mayr in his compromise paper did not suggest altering the existing text on scope. It therefore came as a surprise to negotiators and industrial lobbyists that the Like-Minded Group brought the issue of the Protocol's scope back onto the agenda in Montreal, insisting that no exemptions should be made. Some observers argued that this move served mainly to strengthen the developing countries' bargaining position in other areas.

In the end, a compromise definition of the scope of the Protocol, including minor concessions to the Like-Minded Group, was achieved only towards the end of the negotiations. Article 4 states that the protocol 'shall apply to the transboundary movement, transit, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health'. Entirely exempted are LMOs 'which are pharmaceuticals for humans that are addressed by other relevant international agreements', such as those of the World Health Organization (Article 5). Transit and contained use of LMOs are included in the Protocol, although Article 6 states that the provisions with regard to the Advance Informed Agreement procedure, the regulatory heart of the Protocol, shall not apply to them.

[15] The CBD parties chose the phrase 'living modified organism' (LMO) over the more commonly used 'genetically modified organism' (GMO) in order to defuse a conflict over the question as to whether only genetic engineering, or all traditional techniques of breeding, posed a potential threat. See Gupta, *Framing 'biosafety' in an international context*, pp. 4–6.

Advance Informed Agreement (AIA), the treatment of 'commodities' and the precautionary principle

The Cartagena Protocol's major provision for regulating GM trade is the so-called AIA procedure which, as laid down in Article 7, applies 'prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import'. The central principle that informs the AIA procedure is the right of the importing nation to refuse the transboundary movement of regulated goods, on the basis of a system of risk assessment which takes into account threats to biodiversity and human health.[16] As in the case of the Prior Informed Consent (PIC) principle of the Basle Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal,[17] the AIA procedure effectively reinforces national autonomy in environmental and health regulation against the erosive forces of economic globalization.

The AIA procedure is intended primarily to strengthen the regulatory powers of importing nations in the developing world, and as such was uncontroversial during the negotiations. It requires the exporter to provide detailed information about GMO exports and obtain an importing nation's approval for initial shipments of GMOs (Article 8 and Annex I). The importing nation is under the obligation to inform the exporter of its decision based on risk assessment, in accordance with the procedures set out in the Protocol (Articles 10–13 and 15; Annex II).

Two aspects of the AIA procedure, however, caused considerable difficulties in the negotiations: the role and definition of the precautionary principle within risk assessment; and the scope of the procedure, especially whether it would apply to LMOs intended for direct use as food or feed, or for processing ('commodities'). Both issues had been identified in the run-up to the Montreal negotiations as crucial points that needed to be resolved if the Protocol was to be adopted.

The inclusion of commodities was strongly rejected by the Miami Group on the grounds that they did not pose any significant environmental threat, and that the requirements for notification and informed consent would severely disrupt the fast-growing multi-billion-dollar trade in crops and food products. The procedure would, in particular, require a costly overhaul of the existing crop production, distribution and storage system in the major GM-exporting countries, as GM crops would have to be segregated from non-GM crops. On the other hand, excluding commodities altogether from biosafety provisions would drastically reduce the significance of the Cartagena Protocol, given that trade in commodities makes up the vast majority of transboundary movement of GMOs.

[16] The developing countries also extracted the concession that 'socio-economic considerations', especially with regard to 'the value of biological diversity to indigenous and local communities', can be taken into account when making decisions on GMO imports (Article 26).

[17] Jonathan Krueger, *International trade and the Basel Convention* (London: Earthscan/RIIA, 1999).

The compromise reached in Montreal exempts commodities from the AIA procedure. It creates a separate notification procedure (Article 11, Annex III) which requires notification of domestic approvals for marketing of commodities to the Protocol's Clearing-House, and the exporter to declare that commodity exports 'may contain' GMOs. Importing nations retain the right to reject such GM commodities, and the Conference of the Parties is to decide on more detailed labelling requirements within two years after the Protocol has come into effect.

The Miami Group also objected to the EU's insistence on the precautionary principle as the cornerstone of the AIA procedure. The EU was keen to have the biosafety protocol adopt its own system of risk assessment and raised the stakes in the final part of the negotiations to achieve this goal. The Miami Group eventually agreed to include references to the precautionary principle not only in the preamble but also in the main text of the treaty, which stated in Article 10.6 that 'lack of scientific certainty due to insufficient relevant scientific information and knowledge … shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question.' However, neither the term 'precautionary principle' nor the Miami Group's preferred term 'precautionary approach' were mentioned in the treaty text.

Relationship with other international agreements

One of the thorniest issues in the negotiations was the relationship between the Cartagena Protocol and other international agreements, and the existing international trade order in particular. Although in the past multilateral environmental agreements did not usually address themselves to the question of trade implications, it was recognized by the parties to the CBD that this issue had to be resolved if an overall compromise was to be found. It was unlikely that the experience of the Montreal Protocol on Ozone Layer Protection, where the major signatories all supported the *raison d'être* of the trade restrictions, would be repeated.[18] This time, the GM-exporting countries had set out from the beginning their fundamental objections to a biosafety regime that would weaken or even annul existing obligations under the WTO's trading order.

Recognizing the difficulty of resolving this conflict, chair Juan Mayr decided not to address the trade aspect until some progress had been made in other contentious areas. After a compromise on the question of commodities appeared on the horizon, a separate contact group on trade-related issues was formed under the chairmanship of Ambassador Philémon Yang of Cameroon. It soon became clear that the Like-Minded group and the EU would not agree to the text of the ExCOP Draft Report, which they regarded as subordinating

[18] See Duncan Brack, *International trade and the Montreal Protocol* (London: Earthscan/RIIA, 1996), on the trade provisions of the ozone regime.

the Biosafety Protocol to the WTO's legal system.[19] On the other hand, the Miami Group sought to avoid a formulation, as suggested in chair Mayr's compromise paper,[20] which they feared would provide *carte blanche* for parties to cancel their obligations under the WTO.

The negotiations in this contact group proved particularly difficult and were brought to a close only in a last-minute effort to save the Protocol by agreeing on a compromise text that does not resolve the underlying differences. The compromise adopted by the parties follows Mayr's recommendation to defuse the conflict by removing the controversial subordination clause from the main treaty text. Instead, a preambular text was included setting out that 'trade and environment agreements should be mutually supportive with a view to achieving sustainable development'. On the insistence of the Miami Group, it was further stated that 'this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements'; but the Preamble's third provision stated that 'the above recital is not intended to subordinate this Protocol to other international agreements'.

Capacity-building and financial mechanisms

The main beneficiaries of the Cartagena Protocol are the developing countries, whose regulatory powers it is designed to strengthen. If they are to make full use of the Protocol's provisions, however, many developing countries will need first to create their own scientific and regulatory capacity. Though a small number of southern states have long-standing national biotechnology strategies (e.g. India, Brazil, China), many are only beginning to develop indigenous biotechnology expertise, and most will depend on external support, in the form of financial and technical aid, technology transfer and institution-building, in doing so.

The parties to the Cartagena Protocol recognized the particular problems of developing countries and included in the treaty text several provisions that deal with supportive measures. But, as with other multilateral environmental agreements (on, for example, ozone layer protection and climate change), the Cartagena Protocol only creates a framework for facilitating future international aid and technology transfer mechanisms. Most of the detailed institutional arrangements for aid will have to be decided by subsequent meetings of the conference of the parties.

The most important institutional development to emerge from the Protocol is the Biosafety Clearing-House. Apart from facilitating 'the exchange of scientific, technical, environmental and legal information on, and experience

[19] Article 31 of the ExCOP Draft Report stated: 'The provisions of this Protocol shall not affect the rights and obligations of any Party to the Protocol deriving from any existing international agreement to which it is also a Party, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity' (UNEP/CBD/ExCOP/1/L.2/Rev.1, 23 Feb. 1999).

[20] The chair's compromise paper spoke of the protocol and other international agreements as being 'of equal status'.

with, living modified organisms', its task is to assist developing countries and countries with economies in transition to implement the Protocol (Article 20).

With regard to financial and technological aid, the parties did not consider any specific commitment by the industrial countries, apart from stating that the CBD's institutional structure will be entrusted with the operation of the Cartagena Protocol's financial mechanism (Article 28). The Northern nations committed themselves to 'cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol' (Article 22). The careful wording of these provisions, as well as experience with existing international environmental aid institutions,[21] suggest that the donor countries will want to ensure that the Cartagena Protocol does not lead to open-ended financial obligations, and that the required financial aid and technology transfer are strictly limited to helping southern countries with the implementation of the Protocol's control measures.

Conclusion: the outlook for biosafety

The adoption of the Cartagena Protocol represents a significant milestone in reconciling trade and environmental interests. The outcome of the Montreal negotiations was welcomed by environmentalists who claimed victory for the inclusion of the precautionary principle. At the same time, business representatives expressed their satisfaction with the Protocol's provisions, hoping that the international treaty would harmonize international biosafety rules and legitimize trade in GMOs.[22]

The Cartagena Protocol does not establish a global standard by which to judge the environmental impact of agricultural biotechnology as such. Recognizing that modern biotechnology has 'great potential for human well-being' (Preamble), the Protocol instead aims to empower nation-states and regional organizations with internationally sanctioned regulatory instruments for assessing the biosafety of GM trade. Importing nations may choose to promote biotech trade or to err on the side of caution, and these decisions will reflect the differences in societal values regarding the proper balance between environmental risks and economic opportunities.

The Protocol's system of decentralized risk assessment serves to strengthen the nation-state as the primary source of environmental governance. Yet newly established procedures of international information-sharing within the institutional framework of the Biosafety Clearing-House may create within limits a tendency towards convergence of biosafety standards, particularly in the

[21] See Robert O. Keohane and Marc A. Levy, eds, *Institutions for environmental aid: pitfalls and promise* (Cambridge, MA: MIT Press, 1996).

[22] 'US accepts trade agreement for altered food', *Washington Post*, 30 Jan. 2000; 'Greens and free-traders join to cheer GM crop deal', *Financial Times*, 31 Jan. 2000; 'Weltweites Lob für neues Gentechnik-Protokoll', *Neue Zürcher Zeitung,* 31 Jan. 2000.

developing world. Most of the Southern states depend on the Protocol's institutions and aid to create regulatory capacities to enable them to benefit from the biosafety treaty, and donor countries may want to promote their own risk assessment approaches in the South. But as regulatory standards and procedures in the North remain contentious, the information-sharing mechanism is likely to bring out into the open the conflict between different types of regulatory approaches.

The Protocol is neither a pure environmental nor a pure trade agreement. At its heart is the realization that for importing nations to be able to safeguard their natural biodiversity and human health they need to have satisfactory information about the environmental aspects of GMO imports. The agreement will therefore strengthen existing market pressures on farmers, agricultural exporters and food retailers clearly to identify genetically modified crops and foods. The segregation of GM and non-GM products will most likely lead to the completion of the emerging trend towards a two-tier agricultural market, but whether the growth and trade prospects of agribiotechnology will be dampened by the treaty is far from clear. A more likely scenario is that national and regional differences with regard to take-up of GM products will persist. Societal and market forces will decide the future of the agribiotech market, leaving open the possibility of a continuing expansion of international GMO trade.

The Cartagena Protocol contains a number of compromises, exemptions and omissions that may adversely affect its effectiveness in safeguarding biosafety. Among the unresolved issues are the labelling of commodities, liability and the provision of aid for capacity-building and technology transfer, and the parties will need to establish international rules on these matters. It was the shelving of these issues that made the initial agreement possible, and the parties will now have to enter into difficult negotiations to complete the international framework for biosafety regulation in order to make the Cartagena Protocol a reality.

Moreover, the Protocol's exemptions for pharmaceuticals and the contained use of GMOs have given rise to criticism by environmentalists that they do not reflect the rapidly changing reality of commercial biotechnology. Current biotechnological research may soon lead to the commercialization of GMOs for pharmaceutical purposes that could pose environmental risks similar to those of agricultural GMOs. And current practice in the contained commercial use of GMOs already calls into question its exemption from the Protocol on grounds of negligible environmental impact.[23] As in the case of other multilateral environmental agreements, the effectiveness of the biosafety regime will depend on the ability of the parties to broaden the Protocol's scope and strengthen its control mechanisms in future revisions of the regime.

Despite the progress made in reconciling biotech trade and environmental safety, the Cartagena Protocol, in common with all other multilateral

[23] See Jan van Aken, *Genetically engineered fish: swimming against the tide of reason*, Greenpeace Background Briefing (Berlin: Greenpeace International, 1999).

environmental agreements, failed to resolve the underlying conflict between international environmental regulation and the WTO's trade rules. The room for interpretation left by the preambular compromise text on the relationship between the Protocol and other international agreements could see the US–EU trade dispute resurface within the WTO, not least because the United States is unlikely to become a party to the CBD and the Biosafety Protocol in the near future. While US and Canadian efforts to create a WTO working group on biotechnology are off the agenda for the moment, the Protocol does not prevent the GMO-exporting countries from using the WTO dispute settlement procedure to clarify existing obligations under the trade regime.

The biosafety agreement has, however, reduced the likelihood of an open trade conflict over GMOs within the WTO. The EU's position has been strengthened by the Protocol: while the treaty does not add significantly to the EU's existing regulatory system, it does provide it with greater international legitimacy. The establishment of the precautionary principle within the Protocol's AIA procedure, despite its imprecise definition, serves to challenge the United States' insistence on full scientific proof as the basis for risk assessment, as is customary in WTO dispute settlement cases.

The Cartagena Protocol on Biosafety does not fully reconcile the conflicting interests of trade and the environment; but it marks an important step in that direction. It serves as a potent reminder of the complexity of the 'new' trade agenda, as reflected in the growing influence of societal values and preferences with regard to environmental and human health concerns.