Chapter 26
Cartagena Protocol on Biosafety

LIM LI LIN
THIRD WORLD NETWORK

This chapter will address and highlight some of the key substantive principles and provisions of the Cartagena Protocol on Biosafety. It does not comprehensively cover all aspects of the Protocol, and is not meant to provide legal interpretation of the Protocol. It will, however, underscore some of the rights and obligations of Parties under the Protocol, and address its interpretation and implementation at the national level.

1. Introduction

The Cartagena Protocol on Biosafety entered into force on 11 September 2003. It is a legally binding international agreement under the United Nations' Convention on Biological Diversity (CBD) (see Box 26.1).

Box 26.1. What is a protocol? (adapted from Mackenzie et al. 2003)

A protocol is a binding international instrument, separate from, but related to, another treaty. It is a separate instrument: a protocol must be individually negotiated, signed and eventually ratified. It is only binding on States that become Parties to it. It thus has its own Parties, and creates separate rights and obligations for them, as any other treaty.

The unique characteristic of a protocol is that it is related to a 'parent' treaty, through substantive, procedural, and institutional links. Most importantly, a protocol under a specific treaty must comply with the parent treaty's provisions authorizing and regulating the adoption of protocols under its auspices. Any protocol adopted as a result of these 'enabling' provisions in the parent treaty must comply with them. In particular, it may not deal with subjects which are beyond the purview of these provisions, or if these provisions are not restrictive in this regard, with subjects which are beyond the purview of the parent instrument. Such enabling provisions usually restrict (as is the case for the Cartagena Protocol) participation in a protocol to Parties to the parent treaty.
In addition, the parent treaty usually defines basic institutional and procedural links between the two instruments, for example it may indicate that provisions in the treaty itself (e.g. related to dispute settlement) will also apply to any protocol adopted under it.

The protocol itself may, however, add further links to the parent treaty, for example by designating mechanisms existing under the treaty (e.g. the Conference of the Parties) also to serve the protocol. This is the case for the Cartagena Protocol.

The Cartagena Protocol on Biosafety is the first international law to specifically regulate genetic engineering, and this largely reflects the global climate of concern about the safety, health and environmental risks of genetically modified organisms (GMOs), along with the wider political and socio-economic implications of this technology. For the first time in international law, there is an implicit recognition that GMOs are inherently different from naturally occurring organisms, and carry special risks and hazards, hence the need to have a legally binding international instrument. The Protocol recognizes that GMOs may have biodiversity, human health and socio-economic impacts, and that these impacts should be risk assessed or taken into account when making decisions on GMOs. Precaution is the basis for the Protocol itself, and is operationalized in decision-making and risk assessment.

The entry into force of the Protocol was an important defining moment in global biosafety regulation. It followed years of negotiations, from when the need for a biosafety protocol to address the risks of genetic engineering was first articulated in Article 19(3) of the CBD in 1992, to its adoption by more than 130 countries in the year 2000 in Montreal.

The Protocol's entry into force means that it is legally binding in the international legal system and in the legal systems of countries that have ratified, approved, accepted, or acceded to it (depending on a country's legal system). As of March 2007, there are 140 Parties to the Protocol. The Protocol enters into force in a country 90 days after it deposits its instrument of ratification, approval, acceptance, or accession with the United Nations Secretary General.

The first Conference of the Parties serving as the Meeting of the Parties to the Protocol (COP-MOP 1) was held in Kuala Lumpur, Malaysia, 23–27 February 2004. COP-MOP 2 was held in Montreal, Canada, 30 May–3 June 2005, and COP-MOP 3 was held in Curitiba, Brazil 13–17 March 2006. The COP-MOP is the Protocol's supreme decision-making body, which negotiates and adopts decisions that take forward the development, interpretation and implementation of the Protocol. COP-MOP decisions are binding on the Parties. Subsequent COP-MOPs will be held every two years, back to back with the Conferences of the Parties (COPs) of the CBD. The next COP-MOP will be held in Bonn, Germany in May 2008.

Prior to the Protocol's coming into force, the Intergovernmental Committee of the Cartagena Protocol (ICCP) met three times to move forward the work of the Protocol in the interim.

1.1 The different perspectives and interests

The Protocol negotiations were very difficult and divisive; although scheduled to conclude after six meetings of the Working Group on Biosafety (1995–1999) in February 1999 in Cartagena, Colombia, the talks collapsed (see Chapter 25). The United States-led Miami Group (comprising also Canada, Australia, Argentina, Chile, and Uruguay – the major producers of GMOs and their allies) could not agree to provisions on the transboundary movement of genetically engineered commodities. The provisions would

have required the prior informed consent of the importing Party before the GMOs are shipped to the respective countries. These commodities are the bulk of traded GMOs, and the Miami Group was determined that they should be excluded from the Protocol. On the other hand, developing countries felt very keenly the need to have an internationally binding legal instrument on biosafety, based on the principle of precaution, which would regulate the movement of *all* GMOs between countries.

During the negotiations, the overwhelming majority of these countries forged a negotiating bloc known as the Like-Minded Group of Developing Countries. As importers of GMOs, and as countries most vulnerable to their ecological and socio-economic impacts, they presented a united front.

At that time, most developing countries had no laws or regulations on biosafety and lacked the capacity, and technological and financial resources to regulate genetic engineering (this is still the case in many developing countries). As public rejection of GMOs in Europe and other parts of the world gathered momentum, the fear of becoming a dumping ground for GMOs was real.

It was thus imperative to place the onus on exporting countries to seek the prior informed consent of importing countries, instead of simply allowing GMOs to pass unregulated through the global market and across national boundaries. Furthermore, the lack of scientific certainty and gaps in scientific knowledge, mounting scientific evidence of hazards, and revelations of flawed approval systems in producer countries highlighted the urgent need for international regulation. The Protocol establishes the foundations of international law on the regulation – primarily of the transboundary movement – of GMOs. While many aspects of biosafety regulation are best addressed by national legislation, aspects relating to transboundary movement are difficult to regulate domestically. An international law is therefore necessary.

None of the Miami Group countries have so far become Parties to the Protocol. The United States is the leading producer of GMOs in the world but it is not even a Party to the CBD, and cannot become a Party to the Protocol unless it first becomes a Party to the CBD. Nevertheless, a number of significant GMO producing countries, such as Brazil, China, India, and South Africa, have become Parties.

2. Objective of the Cartagena Protocol on Biosafety

> 'In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human heath, and specifically focusing on transboundary movements'.
>
> Article 1, Cartagena Protocol on Biosafety

A number of points can be made with regard to the objective of the Protocol.

First, the precautionary approach as contained in the Rio Declaration is clearly identified to be the basis of the Protocol, and the objective of the Protocol is taken to be in accordance with the precautionary approach in Principle 15. (The preamble of the Protocol also reaffirms the precautionary approach contained in Principle 15.):

> 'In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'
>
> Principle 15 of the Rio Declaration

Thus, precaution is the basis for the international regulation of GMOs. A full discussion of the Precautionary Principle in GMO regulations, and in the Protocol, is contained in Chapters 29 and 30 respectively.

The idea is to ensure that there is an adequate level of protection in the undertaking of all activities, in particular, the transboundary movement of living modified organisms (LMOs). Protection against adverse effects on biological diversity, 'taking also into account risks to human health', is the objective of the Protocol.

Clearly, protection from risks to human health is part of the objective of the Protocol. The Protocol always uses this language formulation whenever making reference to impacts on human health. This reflects the compromise that was reached on this issue, between the majority of developing countries that wanted the protection of human health to be included as an objective of the Protocol and those that only wanted the Protocol to ensure protection of biological diversity. It is clear from this formulation that impacts on human health as a result of adverse effects on biological diversity are captured, while direct impacts on human health (e.g. from consuming a GMO) may also arguably be captured.

2.1 'Living modified organisms' ('LMOs')

The term 'living modified organism' ('LMO') is used in the Protocol to mean 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology' (Article 3 (g)). This means that only living organisms that contain novel combinations of genetic material, and which have been produced using the techniques of modern biotechnology are defined as 'LMOs', and are within the scope of the Protocol. (See Chapter 23 on 'Definitions of GMO/LMO and modern biotechnology' for a discussion on possible similarities and differences in interpretation and understanding of GMOs/LMOs. For a thorough discussion on whether an organism is an LMO under the Protocol see Mackenzie et al. 2003).

Many countries use the terms 'LMO' and 'GMO' interchangeably, and consider that the terms refer to the same thing. A number of countries use the term 'GMO' in their national laws, and interpret the definition of LMO in the Protocol to be consistent with the definition of GMO in their national laws. Laws in the European Union and a number of other countries use the term 'GMO' to refer to LMOs covered by the Protocol. Malaysia, for example, made a written declaration on signing the CBD that the term 'LMO' would be understood as meaning 'GMO'. The definition of LMO in the Protocol is instructive

on this point.

What are clearly excluded from the definition of LMO, and by using the term 'living organism', are products from LMOs, which are not living, and which are therefore not covered by the scope of the Protocol. This includes, for example, oil produced from genetically modified (GM) canola or meat from GM animals.

3. General scope of the Protocol

A key fight during the course of the Protocol negotiations was for the inclusion of 'products thereof' in the general scope of the Protocol. This was strongly advocated by the Like-Minded Group of Developing Countries. 'Products thereof' include products derived from LMOs such as processed foods containing GM soya, cotton clothing made from GM cotton, etc. However, 'products thereof' are excluded from the scope of the Protocol and, as such, remain largely unregulated internationally.

However, there are two references to 'products thereof' in the Protocol. First, in the Risk Assessment Annex (Annex III) of the Protocol 'Risks associated with LMOs or products thereof, namely, processed materials that are of LMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment', and in Article 20.3 (c) which requires relevant information on 'products thereof' in the context of risk assessments or environmental reviews to be made available to the Biosafety Clearing House, where appropriate.

The Protocol's scope applies to the 'transboundary movement, transit, handling, and use of all 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' (Article 4). The terms 'transboundary movement, transit, handling and use' are wide enough to include all activities related to LMOs under the scope of the Protocol.
The general scope of the Protocol in Article 4 provides for a comprehensive scope, covering all LMOs, and does not specifically exclude any category of LMOs.

3.1 GM pharmaceuticals: Within the scope of the Protocol?

Article 5 states that, 'Notwithstanding Article 4 and without prejudice to the right of a Party to subject all LMOs to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of LMOs which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations'.

Clearly, LMOs that are pharmaceuticals for animals are within the scope of the Protocol. Less clear is whether or not biopharm crops and animals (e.g. edible vaccines or plant/animal 'factories' that produce pharmaceutical compounds) are considered 'LMOs which are pharmaceuticals for humans'. In any case, these biopharm crops are clearly LMOs as defined by the Protocol, and Article 5 does not explicitly exclude biopharm

crops and animals.

The Protocol does not apply to only the transboundary movement of LMOs which are pharmaceuticals for humans and which must also be 'addressed by other relevant international agreements or organizations'. All three elements (there must be transboundary movement, involving LMOs which are pharmaceuticals for humans, and the LMOs in question must be addressed by other relevant international agreements or organizations) must be satisfied for the exemption from the general scope of the Protocol to apply.

In other words, the transboundary movement of some LMOs which are pharmaceuticals for humans may be excluded from the scope of the Protocol depending on whether or not they are addressed by other international agreements or organizations. However, a lot depends on the interpretation of the terms used in this provision, such as for example, 'addressed', 'relevant' and what would constitute an international agreement or organization for the purposes of this provision.

With regard to 'other international agreements', the Protocol allows for Parties to enter into bilateral, regional and multilateral agreements, and arrangements regarding the intentional transboundary movements of LMOs, but these must be consistent with the objective of the Protocol, and must not result in a lower level of protection than that provided for by the Protocol.

It is envisaged that 'other relevant international organizations' is meant to refer to the World Health Organization (WHO). However, WHO does not 'address' GM pharmaceuticals as such, to take into account the special hazards and risks of GMOs. Furthermore, it only sets standards for human health and safety and does not take into account impacts on the environment and biological diversity, which is the main focus of the Protocol.

Nevertheless, the Protocol explicitly preserves the right of Parties to subject all LMOs, including those that are pharmaceuticals for humans, to risk assessment prior to the making of decisions on import.

4. Main principles and provisions

A number of key principles underpin the Protocol. The principle of prior informed consent applies and there should be no transboundary movement without the prior knowledge and authorization of the importing Party. The onus is on the exporters and exporting Parties to notify and furnish relevant information to the importing Party before an LMO crosses national boundaries. An importing Party makes its own decision based on risk assessment and applying precaution, and national sovereignty in decision making is therefore one of the principles that the Protocol establishes. The right to say 'no' is also clearly established.

Precaution is operationalized in the decision-making procedures:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a LMO on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the LMO … in order to avoid or minimize such potential adverse effects.

Precaution is also established as a principle in risk assessment:

> Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

4.1 Advance informed agreement (AIA) procedure

The Protocol has a special focus on transboundary movements. The procedure by which transboundary movements of LMOs are regulated is known as the advance informed agreement (AIA) procedure which involves a few steps. Firstly, the Party of export notifies or requires its exporters to notify the Party of import if there is an intention to export a LMO. The notification must include at least the information required in Annex I (Information Required in Notifications under Articles 8, 10 and 13) of the Protocol. The notification is then acknowledged by the Party of import. The Party of import may make a decision on the notification according to its domestic regulatory framework, which must be consistent with the Protocol or proceed according to the decision procedure in the Protocol.

The decision by the Party of import is based on risk assessment and precaution, and the Party of import may take into account socio-economic considerations when making its decision. A Party is obliged to consult its public in the decision-making process, and must make the results of such decisions available to the public. A Party may make the following decisions: unconditional approval, approval with conditions, prohibition of the import, request for additional relevant information, or extension of the time period for making a decision.

There are time periods specified in the AIA procedure. The Party of import is required to acknowledge receipt of the notification within 90 days, and has a total of 270 days from the time it receives the notification to communicate its decision on the transboundary movement.

However, the issue of time frames was very contentious during the Protocol negotiations and a number of flexibilities have been built into the provisions. The Party of import may make its decision according to its domestic regulatory framework, which may not necessarily strictly adhere to the time periods specified in the Protocol, but which must be ‘consistent with’ the Protocol. Moreover, the clock stops (i.e. the time keeping is suspended) once the Party of import has requested for additional relevant information. The decision by the Party of import may also be to extend the time period.
A failure to acknowledge receipt of the notification does not imply the consent of the Party of import. Neither does a failure by the Party of import to communicate its decision within the specified time period imply that it has consented to the transboundary movement.

COP-MOP 1 adopted a decision on procedures and mechanisms for facilitating decision-making by importing Parties, which provides some guidelines and procedures to assist importing Parties.

4.1.1 Applicability of the AIA procedure

The AIA procedure under the Protocol does not apply to all LMOs. It applies only to the first intentional transboundary movement of LMOs for intentional introduction into the environment (e.g. planting and field testing) of the Party of import. Under the Protocol, subsequent exports will not be subject to the AIA procedure.

Under the Protocol, LMOs in transit (i.e. that are passing through the territory of a third party) are excluded from the AIA procedure. This simply means that the AIA procedure under the Protocol does not apply between the Party of export and the Party of transit. The AIA procedure will still apply between the Party of export and the Party of import for that shipment.

However, the right of a Party to regulate LMOs in transit is explicitly preserved under the Protocol. It must be noted that it is only the AIA procedure that does not apply to LMOs in transit, and all other provisions in the Protocol still apply.

Under the Protocol, the transboundary movement of LMOs destined for contained use (defined as specific measures that limit the contact and impact of LMOs on the external environment) undertaken in accordance with the standards of the Party of import are also excluded from the AIA procedure.

Article 6 (2) on contained use states:

> Notwithstanding Article 4 and without prejudice to any right of a Party to subject all LMOs to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the AIA procedure shall not apply to the transboundary movement of LMOs destined for contained use undertaken in accordance with the standards of the Party of import.

This means that if there is transboundary movement of a LMO that is destined for contained use, and the contained use is undertaken in accordance with the standards of the Party of import, only then can this category of LMO be exempted from the AIA procedure.

The right of Parties to subject all LMOs to risk assessment prior to decisions on import and to set standards for contained use within their jurisdiction is explicitly preserved. As with transit, all other provisions in the Protocol, apart from the provisions relating to the AIA procedure, will still apply.

4.2 Procedure for LMO-FFPs

LMOs intended for direct use as food or feed, or for processing (LMO-FFPs) are also excluded from the AIA procedure. These LMOs make up the bulk of traded GMOs, but they are not subject to the AIA procedure. These LMOs include, for example, GM foods, GM animal feed and GM microbes used in industrial production. For this category, an alternative system, based on information sharing via the Biosafety Clearing House (BCH)

(a website database administered by the CBD Secretariat in Montreal) applies.

When a Party makes a final domestic decision (e.g. for commercialization or placing on the market) on LMOs intended for direct use as food or feed, or for processing, that may be subject to transboundary movement, minimal information (specified in Annex II – Information Required Concerning LMO-FFPs under Article 11) must be posted on the BCH within fifteen days. This is the basically the extent of the obligation of the potential exporting Party.

A Party may take a decision on the import of LMO-FFPs under its domestic regulatory framework which must be consistent with the objective of the Protocol. This explicitly preserves the right of Parties to regulate LMO-FFPs in much the same way as other LMOs, according to an AIA-like procedure (bilateral notification and case-by-case decision making), at the national level.

How, to regulate LMO-FFPs, if at all, in the Protocol was the subject of much debate. It was argued by the majority of developing countries that the intended use of the LMO, even though for food, animal feed or for processing, would not ensure that the LMO did not end up being, for example, planted or released into the environment, which might entail risks to the environment and biological diversity. Hence, developing countries had wanted LMO-FFPs to be subject to the same AIA procedure as other kinds of LMOs. This was resisted by the Miami Group in particular, and the resulting procedure for LMO-FFPs, while preserving the rights of Parties to regulate LMO-FFPs according to their domestic regulatory framework, is a compromise.

Parties which are developing countries or which are economies in transition may, if they do not have a domestic regulatory framework, declare that their decision prior to the first import of LMO-FFPs will be taken according to a risk assessment in accordance with the risk assessment annex of the Protocol, and that the decision will be made within a predictable timeframe, which will not exceed 270 days.

Again, this allows for an AIA-like notification and decision-making procedure for countries without domestic regulatory frameworks. A potential importing Party that does not communicate this decision is not assumed to have agreed to or refused the import of LMO-FFPs. Precaution is also given operational meaning under this procedure.

The multilateral nature of the notification procedure for LMO-FFPs is vastly different from the bilateral nature of the AIA procedure for other LMOs. The burden is placed on potential importing Parties to constantly monitor the BCH for any notifications for domestic approvals in producer Parties. Potential importing Parties may have to initiate procedures for risk assessment and decision making without knowing whether a given LMO will ever be exported, or whether it will be exported to them. The burden of regulation of LMO-FFPs has thus been shifted from exporting Parties onto other Parties, and from international to domestic regulatory procedures.

5. Other key provisions in the Protocol

5.1 Risk assessment and risk management

Risk assessments are mandatory for decision making under the AIA procedure. It is the duty of the Party of import to ensure that risk assessments are conducted. The Party of import may also require the exporter to undertake the risk assessment as well as require the notifier (Party of export or exporter) to pay for the risk assessment. The rights of Parties to require risk assessment or to regulate LMOs according to their domestic regulatory frameworks which may require risk assessment is preserved for decision making for LMOs which fall outside the AIA procedure.

Risk assessments are carried out in order to identify and evaluate possible adverse effects on biological diversity and human health. In general, risk assessment includes identifying potential adverse effects, assessing the likelihood that the adverse effect may occur, and evaluating the magnitude of the consequences should the potential adverse effect occur. An adverse effect that is not very likely to occur may still carry a high risk if the consequences are severe and irreversible.

Under the Protocol, risk assessments must be carried out in a scientifically sound manner, taking into account recognized risk assessment techniques. Risk assessments are to be based, at a minimum, on the information provided in the notification, and other available scientific evidence, and carried out in accordance with the Risk Assessment Annex (Annex III) of the Protocol.

Risk management addresses the issue of how to regulate, manage and control the risks that may have been identified in the risk assessment process. Parties must establish and maintain appropriate mechanisms, measures and strategies for this purpose. These measures should be imposed to the extent necessary to prevent adverse effects on biological diversity and human health.

Parties must endeavour to ensure that LMOs have undergone an appropriate period of observation either corresponding with their life cycle or generation time, before the LMOs are utilized. Depending on the LMO concerned, the life-cycle time may vary from seconds to centuries. The generation time (from germination to producing progeny) would, in most cases, be shorter.

5.2 Socio-economic considerations

The Protocol recognizes that LMOs may have socio-economic impacts. Parties are entitled to take into account socio-economic considerations arising from the impact of LMOs on biological diversity when taking decisions on imports of all LMOs, as well as in decision making at the national level. This must, however, be consistent with Parties' other international obligations. In particular, the value of biological diversity to indigenous and local communities is highlighted, and Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts, especially on indigenous and local communities.

5.3 Public awareness, education and participation
Public consultation in decision making is mandatory under the Protocol, in accordance with national laws and regulations. The results of such decisions must also be made available to the public. Parties are also under an obligation to promote and facilitate public awareness, education and participation on the impact of LMO activities on biological diversity and human health, and to endeavour to ensure that public awareness and education include access to information on imported LMOs.

5.4 Review of decisions
Parties may at any time review and change their decisions regarding imports of LMOs, in the light of new scientific information on potential adverse effects on biological diversity and human health. The Party must inform the notifier and the BCH, and provide reasons for the decision.

An exporting Party or a notifier may also request an importing Party to review an AIA decision where it considers that either there has been a change in circumstances that may influence the outcome of the risk assessment on which the decision was based, or additional relevant scientific or technical information has become available. The Party of import must then respond within 90 days providing reasons for its decision.

Under the Protocol, the AIA procedure only applies to the first intentional transboundary movement of LMOs for intentional introduction into the environment. However, the Party of import may also exercise its discretion to require a risk assessment for subsequent imports.

5.5 Unintentional transboundary movements and emergency measures
When a Party knows of an occurrence in its territory that has led or may lead to an unintentional transboundary movement that is likely to have significant adverse effects on biological diversity or human health, it must take appropriate measures to notify the BCH and other countries that have been affected or which may potentially be affected. It may also be required to notify relevant international organizations. The Party is under an obligation to immediately consult the countries that have been or may be affected in order to enable them to determine the appropriate response and initiate necessary action, which includes emergency measures.

Notification of such unintentional transboundary movement should include information on the quantities and characteristics and/or traits of the LMO; on the circumstances, estimated date of the release and the use of the LMO in the originating Party; about the possible adverse effects on biological diversity and human health; and on possible risk management measures. A contact point for further information should also be provided. Under customary international law, non-Party states are also under obligation to notify and consult other affected or potentially affected countries. However, they will not be bound by the specific procedures established under the Protocol for unintentional transboundary movements.

5.6 Illegal transboundary movement of GMOs
Parties must adopt appropriate measures to prevent and penalize (if appropriate) import and export of any LMOs that are in contravention of domestic measures implementing the Protocol, which are illegal transboundary movements. In such cases, the affected Party may request the Party of origin to either repatriate or destroy the LMO in question at its own expense. Parties must make available information about cases of illegal transboundary movements pertaining to it, to the BCH.

5.7 Handling, transport, packaging, and identification of transboundary shipments
Parties are to take necessary measures to require that all LMOs that are subject to transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

5.7.1 Identification of LMO-FFPs
The issue of identification of LMO-FFPs was very contentious during the Protocol negotiations and nearly caused the negotiations to collapse for the second time in Montreal in 2000. The compromise was to mandate the COP-MOP to make a decision on the detailed requirements, no later than two years after the Protocol enters into force. This meant that the decision had to be taken by COP-MOP 2, which was held in 2005. However, negotiations collapsed then, and no decision was taken until COP-MOP 3 in 2006.

The issue that was difficult to reach agreement on was about how shipments of LMO-FFPs should be identified. The majority of countries wanted such shipments to be clearly identified as containing LMOs that are not intended for intentional introduction into the environment, while the Miami Group countries would only agree to identify such shipments as ‘may contain’ LMOs not intended for intentional introduction into the environment. This was the compromise settled on and the last issue decided upon during the early hours of the morning when the Protocol was finally adopted.

On the contain/may contain issue, the COP-MOP 3 decision specifies that in situations where the identity of the LMO is known through ‘means such as identity preservation systems’, the shipment must be identified as one that ‘contains’ LMOs that are for direct use as food or feed, or for processing. A two-stage approach is set out for cases where the identity of the LMO shipment is not known.

In cases where the identity of the LMO is not known through ‘means such as identity preservation systems’, the shipment can be identified as one that ‘may contain’ one or more LMOs that are intended for direct use as food or feed, or for processing. This requirement is subject to review and assessment at COP-MOP 5 (2010), ‘with a view to considering a decision’ at COP-MOP 6 (2012) to ensure that the shipment is identified as one that ‘contains’ LMO-FFPs. This means that the ‘may contain’ language should no longer be an option after the interim period.

In both cases, where the shipment is identified as one that ‘contains’ LMOs as well as where the shipment is one that ‘may contain’ LMOs, the documentation accompanying

them must include the following details:

- that the LMOs are not intended for intentional introduction into the environment
- the common, scientific and, where available, commercial names of the LMOs
- the transformation event code of the LMOs or, where available, as a key to accessing information in the BCH, its unique identifier code
- the internet address of the BCH for further information

5.7.2 Identification of LMOs destined for contained use

For LMOs destined for contained use, they must be clearly identified as LMOs, and requirements for their safe handling, storage, transport, and use must be specified. The contact point for further information as well as the name and address of the individual and institution to whom the LMOs are being delivered are information that must also be included. COP-MOP 1 adopted a decision which specifies more details on these requirements.

5.7.3 Identification of LMOs for deliberate release and other LMOs within the scope of the Protocol

For LMOs that are intended for intentional introduction into the environment as well as other LMOs within the scope of the Protocol (e.g. LMOs in transit), documentation information must clearly identify them as LMOs, specify their identity and relevant traits and/or characteristics, and any requirements for safe handling, storage, transport, and use. The contact point for further information must be included as well as the name and address or the importer and exporter. In addition, a declaration that the transboundary movement is in conformity with the requirements of the Protocol must be included. COP-MOP 1 adopted a decision which specifies more details on these requirements.
COP-MOP 1 also adopted a decision providing examples of templates that could accompany shipments of LMOs destined for contained use and for intentional introduction into the environment as well as for other LMOs within the scope of the Protocol. In addition, the COP-MOP 1 decision addresses unique identification systems, particularly the system that has been developed by the Organisation for Economic Co-operation and Development (OECD) for GM plants.

5.8 Information sharing and the Biosafety Clearing-House

The Protocol establishes a Biosafety Clearing House (BCH) to function as a mechanism for the procedure that applies for LMO-FFPs and as a means through which information relevant to the implementation of the Protocol is made available by the Parties. It also serves to facilitate the exchange of scientific, technical, environmental, and legal information and experience with LMOs and to assist Parties to implement the Protocol. Parties must make available to the BCH any information required to be made available to the BCH under the Protocol as well as any existing laws, regulations and guidelines for implementation of the Protocol; information required for the AIA procedure; any bilateral, regional and multilateral agreements and arrangements; summaries of risk assessment or environmental reviews of LMOs generated by its regulatory process, including where appropriate, relevant information regarding ‘products thereof’; final decisions on import or release of LMOs; and reports to the COP-MOP on measures taken to implement the Protocol, including on implementation of the AIA procedure.

5.9 Confidential information

References to information sharing in the Protocol are usually qualified by a reference to respect confidential information as specified by Article 21. It must be noted that confidentiality is only vis-à-vis the public or a third party, and that no information can be withheld from the competent national authority. The notifier may identify information that it has submitted to the Party of import that it would like to be treated as confidential, providing justification upon request. The Party of import then decides on whether or not the information identified by the notifier qualifies as confidential information.

If the Party of import decides that the information identified does not qualify as confidential information, it must consult the notifier and must inform the notifier of its decision before releasing the identified information to the public. The Party of import should provide reasons upon request, as well as have an opportunity for consultation and for an internal review of the decision before it discloses the information to the public. Parties shall protect information received under the Protocol and deemed as confidential and must ensure that it has procedures in place to protect such information. It must do so in a manner no less favourable than its treatment of confidential information on LMOs that are domestically produced. The Party of import shall not use such information for commercial purposes unless it has the written consent of the notifier.

If a notifier withdraws a notification, the Party of import shall respect the confidentiality of commercial and industrial information including research and development information, as well as information on which there is no agreement as to its confidentiality. The Protocol specifies that the following information should never be considered as confidential: the name and address of the notifier; the general description of the LMO; the summary of the risk assessment of the effects on biological diversity and human health; and any methods and plans for emergency response.

5.10 Capacity building

The Protocol recognizes the special needs and vulnerabilities of developing countries, in particular the least developed and small island developing States, and Parties with economies in transition. To this end, Parties are required to cooperate in developing and strengthening human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, including through existing global, regional, subregional, and national institutions and organizations and through facilitating private sector involvement, as appropriate.

Financial resource needs and access to and transfer of technology and know-how should be fully taken into account in accordance with the CBD. Cooperation in capacity building should include scientific and technical training in the proper and safe management of biotechnology, in the use of risk assessment and risk management, and the enhancement of technological and institutional capacities in biosafety. This should be subject to the different situations, capabilities and requirements of the Parties.

COP-MOP 1 adopted the ‘Action Plan for Building Capacities for Effective Implementation of the Protocol’ as well as the Coordination Mechanism for the

implementation of the Action Plan. The Action Plan identifies key elements that require concrete action; the processes/steps that should be undertaken; implementation at the national, subregional, regional, and international levels; monitoring and coordination of different actors undertaking capacity-building initiatives; and identifies a possible sequence of actions and activities identified in the Action Plan. An updated Action Plan was adopted at COP-MOP 3.

The Coordination Mechanism consists of the Liaison Group on capacity building for biosafety, biosafety capacity building databases in the BCH, an information sharing and networking mechanism consisting of the biosafety information resource centre and the biosafety capacity building network, coordination meetings and workshops, and a reporting mechanism.

COP-MOP 1 also adopted a number of guidance documents, on the 'Role of Different Entities in Supporting Capacity Building', an 'Implementation Tool Kit', as well as a 'Set of Indicators for Monitoring Implementation of the Action Plan for Building Capacities for the Effective Implementation of the Protocol'.

A related mechanism for capacity building under the Protocol is the Roster of Experts, which was established by a decision of the Extraordinary COP to the CBD the adopted the Protocol, to provide advice and other support, to conduct risk assessment, make informed decisions, develop national human resources, and promote institutional strengthening associated with the transboundary movements of LMOs to developing country Parties and Parties with economies in transition in fields relevant to risk assessment and risk management related to the Protocol.

5.11 Liability and redress

The issue of liability and redress was one of the most contentious during the Protocol negotiations. The majority of developing countries wanted operational provisions included in the Protocol, while the Miami Group did not want any provisions on liability and redress included in the Protocol. The compromise was to include text in the Protocol that mandates further work to develop a liability and redress regime.

Accordingly, COP-MOP 1 adopted a process to elaborate international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of LMOs. Five Working Group meetings are to be held, and the regime should be adopted in May 2008 at COP-MOP 4, in line with the mandate to endeavour to complete the process within four years. As of March 2007, three Working Group meetings have already been held, and the subsequent negotiations are scheduled to be held in October 2007 and March 2008.

(See Chapter 31 'Liability and redress for damage arising from genetically modified organisms: Law and policy options for developing countries'.)

5.12 Non-Parties and bilateral, regional, multilateral agreements and arrangements

The Protocol also specifies that any transboundary movement of LMOs between Parties and non-Parties should be consistent with the objective of the Protocol. As an

international law, the Protocol cannot bind countries which are not Parties, but can only place obligations on countries which are Parties. Therefore, Parties are under the obligation to ensure that transboundary movement of LMOs between them and non-Parties is consistent with the objective of the Protocol.

Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements. Parties are also required to encourage non-Parties to adhere to the Protocol and to contribute appropriate information to the BCH on LMO transactions in their territory. COP-MOP 1 adopted a guidance document on the transboundary movement of LMOs between Parties and non-Parties. Parties may also enter into bilateral, regional and multilateral agreements and arrangements with each other on intentional transboundary movements of LMOs. These agreements and arrangements must be consistent with the objective of the Protocol, and must not result in a lower level of protection than that provided for in the Protocol. Parties must inform each other through the BCH of any such agreements or arrangements that they have entered into before or after the date of entry into force of the Protocol. However, if an agreement or arrangement was entered into before the date of entry into force of the Protocol, but it is not consistent with its objective and results in a lower level of protection than the Protocol, the Protocol will take precedence over that agreement or arrangement.

The provisions of the Protocol will not affect intentional transboundary movements between the Parties that take place pursuant to such agreements and arrangements, provided that they are consistent with the objective of the Protocol and do not result in a lower level of protection. Only intentional transboundary movements shall not be affected, and other provisions of the Protocol which do not relate to transboundary movements will apply.

5.13 Compliance with the Protocol

The compliance mechanism under the Protocol is separate from and without prejudice to the dispute settlement procedures and mechanisms under the CBD. It is meant to promote compliance of the Parties with their obligations under the Protocol.

COP-MOP 1 established procedures and mechanisms on compliance, which spelt out the objective, nature and underlying principles, and also established a Compliance Committee, and specified its functions and procedures. The decision also addresses information and consultation, measures to promote compliance and address cases of non-compliance, and review of the procedures and mechanisms.

COP-MOP 2 adopted the rules of procedure for Compliance Committee meetings. However, on the issue of voting, there was no agreement on taking a decision by a two-thirds majority, and this issue is still unresolved.

5.14 Relationship with other international agreements

(For a full discussion, see Chapter 27, ‘The WTO Agreements: An Introduction to the Obligations and Opportunities for Biosafety’.)

5.15 Review
The Protocol will be reviewed five years after its entry into force, i.e. at COP-MOP 4 in 2008, and at least every five years thereafter to evaluate its effectiveness, including an assessment of its procedures and annexes.

6. National implementation of the Protocol

The Protocol sets minimum standards for the regulation of LMOs – Parties may take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the Protocol. However, the action must be consistent with the objectives and provisions of the Protocol and be in accordance with the Parties' other obligations under international law.

Parties are also under an obligation to take the necessary and appropriate legal, administrative and other measures to implement their obligations under the Protocol. This means that national measures such as a national biosafety law should be put in place to implement Protocol obligations.

7. Conclusions

The Protocol contains many important principles, which are now established in international law. However, it is a negotiated text with deficiencies for biosafety. While strengthening the Protocol and rectifying its deficiencies should be the long-term goal, it is critical that national governments, and developing countries in particular, formulate domestic biosafety laws that improve on the scope and standards set by the Protocol, and which also comprehensively regulate the domestic development and use of GMOs.
As an international law that is binding on countries that are Party to it, the Protocol presents obligations on and opportunities for sovereign countries. As a negotiated text, many flexibilities for interpretation and implementation are available for countries to utilize, putting real biosafety at the heart of national regulation.

In conclusion, the Protocol is just the start of the long and difficult road to effective international regulation of genetic engineering. Much more needs to be done, and countries must act to ensure that real biosafety becomes a reality.

References and Background Reading

Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes. Montreal: Secretariat of the Convention on Biological Diversity.

Secretariat of the Convention on Biological Diversity (2004). Global Biosafety: From Concepts to Action. Decisions from the First meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena

Protocol on Biosafety. Kuala Lumpur, Malaysia 23-27 February 2004. Montreal: Secretariat of the Convention on Biological Diversity.

Secretariat of the Convention on Biological Diversity (2005). Facing the Biosafety Challenge: Towards Effective Implementation of the Protocol. Decisions of the Second meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety. 30 May to 3 June 2005 Montreal, Canada. Montreal: Secretariat of the Convention on Biological Diversity.

Secretariat of the Convention on Biological Diversity (2007). Biosafety: Building Further Consensus for Action, i-vi +72 pages, Montreal, Quebec, Canada.

Mackenzie, Ruth, Burhenne-Guilmin, Françoise, La Viña, Antonio G.M. and Werksman, Jacob D. in cooperation with Ascencio, Alfonso, Kinderlerer, Julian, Kummer, Katharina and Tapper, Richard (2003). An Explanatory Guide to the Cartagena Protocol on Biosafety. IUCN, Gland, Switzerland and Cambridge, UK. xvi + 295pp.

The Cartagena Protocol on Biosafety: A Record of the Negotiations (2003). Montreal: Secretariat of the Convention on Biological Diversity.

Biosafety and the Environment: An Introduction to the Cartagena Protocol on Biosafety (2003). Montreal: Secretariat of the Convention on Biological Diversity and Geneva: United Nations Environment Programme.

Cartagena Protocol on Biosafety: From Negotiation to Implementation. Historical and New Perspectives as the World marks the Entry-into-force of the Protocol (2003). Montreal: Secretariat of the Convention on Biological Diversity.

Mayr, J. and Soto, A. (2003). The Cartagena Protocol on Biosafety: A History.

Lim, L. L. and Lim, L. C. (2007). Identification requirements for shipments of genetically engineered commodities: Analysis of the decision adopted under the Cartagena Protocol on Biosafety. Third World Network, Penang, Malaysia.