

# THE BIOSAFETY PROTOCOL

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The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol) was adopted in early 2000. The Protocol derives much of its significance from the fact that it provides the first lineaments of a legal regime addressing some environmental and human impacts of genetic engineering. It does so on the basis of the precautionary principle, a principle of international environmental law which provides that conservationist measures can be undertaken even in the absence of complete scientific information regarding potential adverse effects on the environment.

The Cartagena Protocol must be understood in the context in which it arises. Two main points must be made at the outset in this regard. Firstly, as a Protocol to the Biodiversity Convention, the fundamental principles and objectives of the Convention also apply here. This implies, for instance, that the Protocol also follows the objectives of the Convention which include not only biodiversity conservation but also its sustainable use and the fair sharing of the benefits arising out of the utilisation of biological resources. Secondly, while the Protocol is an environmental law treaty by virtue of being linked to the Biodiversity Convention, it is in fact fundamentally a treaty seeking to regulate trade in living modified organisms (LMOs) among member states. As such, it is concerned equally with the environmental impacts of genetic engineering and the economic interests of exporting states.

## DEVELOPMENT OF THE PROTOCOL

The rapid development of genetic engineering over the past few decades has been closely linked to development of relevant legal frameworks. On the one hand, the growth of genetic engineering has been made possible by the trend towards accepting the patenting on life forms, first in the United States and later on at the international level. On the other hand, the potential side effects of genetically modified organisms (or in this context LMOs) on the environment and human health have been of concern as reflected in recent debates. These have led to calls for the development of 'biosafety' legal frameworks or frameworks to regulate the production, use, dissemination and trade in LMOs.

The drafters of the Biodiversity Convention already attempted in 1992 to provide answers to some of the issues related to the development of genetic engineering. At the time, negotiators only managed to acknowledge the existence of biosafety concerns and called upon member states to endeavour to adopt a protocol setting out procedures concerning the use, transfer and handling of potentially harmful LMOs.<sup>1</sup> A formal mandate for the negotiation of a Protocol was adopted in 1995 by the Conference of the Parties.<sup>2</sup>

The negotiations were at first marked by a strong North-South division. In the first stages, developing countries were driving the biosafety agenda. They sought the development of a legal instrument covering most aspects of the development and use of LMOs, fearing that the

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<sup>1</sup> Article 19.3 of the Convention on Biological Diversity, Rio de Janeiro, 5 June 1992, 31 *International Legal Materials* 818 (1992).

<sup>2</sup> Decision II/5, Consideration of the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms, *Report of the Second Meeting of Conference of the Parties to the Convention on Biological Diversity*, Jakarta, 6-17 Nov. 1995, UN Doc. UNEP/CBD/COP/2/19.

lack of proper international regulatory framework would put their environments at risk.<sup>3</sup> Developed countries were generally not keen on the development of a comprehensive instrument which could restrict the development of their biotechnology industry in the longer term.

This initial fault line evolved over the four years of negotiations. Over time, different interest groups emerged in the negotiating process. Most developing countries still sought the development of a comprehensive instrument. In direct opposition to this first group, there emerged the so-called Miami Group consisting of an alliance of developed and developing states with important stakes in the international trade in agricultural commodities. The Miami Group which comprised diverse states like Argentina, Chile, Canada and the United States wanted to avoid the imposition of excessive restrictions on international trade in LMOs. A third group, the 'compromise' group comprised diverse states like Japan, Mexico, Norway, South Korea and Switzerland which held positions generally in-between the other two groups and sought to resolve issues blocking an agreement. On the whole, the negotiations were difficult, in particular because they concerned not only environmental issues but also trade issues. It proved impossible to find an agreement in Cartagena during the special session called to adopt the Protocol in February 1999 in particular concerning the coverage of LMOs and the relationship of the Protocol with the World Trade Organization (WTO). In early 2000, following the breakdown of trade talks at the Seattle ministerial conference of the WTO, the Protocol's negotiators reconvened in Montreal in a more conciliatory mood and managed to bring the negotiations to a close.

#### GENERAL FEATURES OF THE PROTOCOL

The Cartagena Protocol must firstly be placed in its broader context. It is directly related to the Biodiversity Convention from which it derives. As such the Convention provides a general legal framework for the conservation and use of biodiversity. Given the broad scope of the Convention, a great number of specific issues could be taken up by subsequent protocols. It is therefore of significance that the first protocol to be adopted after the coming into force of the Convention does not deal with any of the more traditional aspects linked to the conservation of biodiversity but with the risks associated with the development of a new technology. By virtue of being directly linked to the Convention, the basic principles of the latter also apply to the Protocol. However, it is striking that the Protocol goes beyond the Convention in one important aspect. It applies to LMOs that 'may have adverse effects on the conservation and sustainable use of biological diversity', adopting in this regard the language of the Convention, but goes further by also integrating the possible risks to human health of LMOs.<sup>4</sup>

The Cartagena Protocol is an environmental treaty by virtue of the fact that it addresses the potential environmental impacts of LMOs. However, if the Protocol is an environmental treaty, it is also an international trade agreement insofar as it mainly seeks to regulate trade in LMOs.<sup>5</sup> This is made clear by the fact that the Protocol applies mainly to the first transboundary movement of LMOs that may have adverse effects on the conservation and

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<sup>3</sup> Robert Falkner, 'Negotiating the Biosafety Protocol: The International Process', in Christoph Bail, Robert Falkner and Helen Marquard (eds.), *The Cartagena Protocol on Biosafety – Reconciling trade in Biotechnology with Environment and Development?* 3 (London: Earthscan, 2002).

<sup>4</sup> Article 1 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 20 Jan. 2000, 39 *International Legal Materials* 1027 (2000) [hereafter Cartagena Protocol].

<sup>5</sup> Thomas Cottier, 'Implications for Trade Law and Policy: Towards Convergence and Integration', in Christoph Bail, Robert Falkner and Helen Marquard (eds.), *The Cartagena Protocol on Biosafety – Reconciling trade in Biotechnology with Environment and Development?* 467 (London: Earthscan, 2002).

sustainable use of biological diversity. In other words, the Protocol can be seen as a trade regulation treaty which authorises import restrictions on certain products on the basis of their potentially harmful impact on the environment.

In principle the Protocol applies to all LMOs. This is, however, qualified by several exceptions concerning the types of LMOs and the types of activities. Firstly, the scope is limited to LMOs that may have adverse effects on the conservation and sustainable use of biological diversity. Secondly, the Protocol does not apply to pharmaceuticals for humans that are regulated by other treaties.<sup>6</sup> Thirdly, the procedure concerning the first intentional transboundary movement of LMOs does not apply either in case of transit or in cases where LMOs are destined for contained use.<sup>7</sup> Fourthly, the procedures outlined in the Protocol only apply to the first transboundary movement for intentional introduction into the environment. Fifthly, the procedure outlined with respect to the first transboundary movement of LMOs does not apply in the case of LMOs intended for direct use as food or feed, or for processing (LMO-FFP). In this case, lesser obligations only provide that states must endeavour to exchange relevant information with regard to LMO-FFP.

#### ADVANCED INFORMED AGREEMENT

The Cartagena Protocol seeks to regulate transboundary movements of LMOs by specifying the conditions under which trade can be undertaken. This comes in the form of a procedure for ‘advanced informed agreement’ (AIA). In essence, the AIA procedure gives the importing state the right to refuse entry to LMOs covered by the procedure on the basis of a risk assessment carried out according to the provisions of the Protocol.<sup>8</sup> In other words, importing states have the right to restrict imports in order to minimise possible adverse effects on the conservation and sustainable use of biodiversity of LMOs. As noted, the AIA procedure only applies to LMOs that have not been excluded from its scope. In practice, this implies that the AIA procedure will apply mainly to seeds and micro-organisms which constitute only a small percentage of all LMOs that are traded.

More specifically, in the case of a first intentional transboundary movement for intentional introduction into the environment, the exporting state first has to notify in writing the importing state before the movement of LMO takes place.<sup>9</sup> Information requirements for this notification are included in Annex I. The state of import must then acknowledge receipt of the notification and indicate whether the procedure is to follow the importing state’s regulations – which must comply with the Protocol – or the procedure outlined in the Protocol.<sup>10</sup> Importantly, failure to acknowledge receipt of a notification does not signify that the state of import agrees to the LMO movement. The final decision indicating whether the movement will be allowed or denied must be based on a risk assessment carried out in a scientifically sound manner according to the methodology outlined in Annex III. The party of import has nine months to take a decision whether to allow the movement or refuse it.

Two specific features of the procedure must be highlighted. Firstly, if the state of import fails to notify the exporting state its decision within the agreed time frame, this cannot be construed as an acceptance of the shipment. Secondly, the risk assessment whose purpose is to identify and evaluate the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity or human health in the likely potential receiving

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<sup>6</sup> Article 5 of the Cartagena Protocol, *supra* note 4.

<sup>7</sup> Article 6 of the Cartagena Protocol, *supra* note 4.

<sup>8</sup> Articles 10 & 16 of the Cartagena Protocol, *supra* note 4.

<sup>9</sup> Article 8 of the Cartagena Protocol, *supra* note 4.

<sup>10</sup> Article 9 of the Cartagena Protocol, *supra* note 4.

environment must be carried out by the state of import in a scientifically sound manner.<sup>11</sup> The Protocol, however, recognises that there may be cases where scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the importing state may be insufficient to provide certain conclusions. In such cases, in accordance with the precautionary approach the importing state is authorised to take a negative decision with regard to the proposed transboundary movement with a view to avoid or minimise potential adverse effects.<sup>12</sup>

As noted, in the case of LMO-FFPs, the AIA procedure does not apply and they are covered by separate provisions under Article 11. In effect, in the case of LMO-FFPs, state parties to the Protocol only undertake to provide each other with information concerning the regulatory framework that they adopt in this field. With regard to import decisions, importing states must take decisions in pursuance of their legal framework which must be consistent with the overall objectives of the Protocol. The Protocol takes into account the fact that developing countries or countries with an economy in transition may not have regulatory frameworks in place in this field. In this case, Article 11.6 outlines the criteria on which these countries must base their import decision. The Protocol indicates that the risk assessment must again be undertaken in accordance with Annex III. In all cases, import states can rely as in the case of the AIA procedure on the precautionary principle to take a negative decision even in the face of uncertainty with regard to the adverse effects on the environment or human health.

#### ADDITIONAL FEATURES OF THE PROTOCOL

As noted, the Protocol is in essence a trade agreement allowing import restrictions for certain categories of LMOs and allowing import states to bar importation even in cases where scientific information with regard to potential adverse effects on the environment or human health is insufficient at the time of decision. The Protocol goes further and authorises state parties to take into account the socio-economic impacts arising from the import of a given LMO, in particular with regard to the value of biodiversity for local communities.<sup>13</sup>

Beyond the regulation of trade envisaged for the different categories of LMOs covered, one of the important functions of the Protocol is to foster information exchange among state parties. To facilitate this, a Biosafety Clearing-House has been set up. It is directly linked to the clearing house mechanism established under the Biodiversity Convention. It will serve mainly to help parties in fulfilling their obligations by providing all useful information regarding implementation and by facilitating access to information on biosafety for the public in member states.

Further, in order to give some expression to the broader focus that developing countries had promoted, some obligations with regard to handling, transport, packaging and identification have been incorporated into the Protocol. With respect to the identification of LMOs, the Protocol provides specific obligations regarding all LMOs covered under the Protocol. Thus, even in the case of LMO-FFPs, it must be clearly indicated that they ‘may contain’ LMOs. Beyond the general identification obligations, the Conference of the Parties has been given the task to take further action in this area after the Protocol enters into force.

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<sup>11</sup> While risk assessment is carried out by the importing state, Annex III sets out a number of requirements that States must fulfil for their risk assessment to be deemed compliant with the Protocol. *See* Annex III of the Cartagena Protocol, *supra* note 4.

<sup>12</sup> Article 10.6 of the Cartagena Protocol, *supra* note 4.

<sup>13</sup> Article 26 of the Cartagena Protocol, *supra* note 4.

A consensus could not be reached regarding a liability regime and redress for damage resulting from transboundary movements of LMOs. The Protocol provides that the Conference of the Parties will have the task of elaborating rules and procedures in this regard within four years of the Protocol's entry into force.<sup>14</sup>

#### THE PROTOCOL IN ITS BROADER CONTEXT

The Protocol's place in international law has been one of the difficult issues that negotiators tried to address but failed to clearly solve in the end. The preamble includes two separate clauses on the relationship of the Protocol with other international law instruments. It first highlights that the Protocol does not imply any change in the rights and obligations of states under existing international treaties. This clause was inserted at the behest of countries that were worried the Protocol might be interpreted as altering the obligations contained in WTO treaties. The second clause emphasises that the Protocol is not subordinated to other international agreements. This is meant to highlight that while WTO obligations are not affected by the Protocol, the former should not detract anything from the substance of the new obligations adopted under the Protocol. While the two clauses just mentioned are phrased generically, they appear just after a paragraph recalling that trade and environment should be mutually supportive with a view to achieving sustainable development. The relationship envisaged here thus concerns mainly the interaction between the Protocol as an environmental agreement and the WTO agreements as trade agreements.

The two clauses inserted in the Protocol make the situation inconclusive with regard to the interpretation of environment and trade agreements in the case of a conflict between states' obligations under the Protocol and under WTO agreements. However, these provisions are not without significance: WTO treaties which have an impact on environmental management do not provide any guidance concerning the interpretation of potentially conflicting obligations in international environmental treaties. In such a context and in the absence of hierarchy between environment and trade agreements, states must implement all their obligations in a consistent manner. The Protocol at least explicitly provides the lineaments of rules of interpretation. Further, in the absence of a binding dispute settlement mechanism in the context of the Biodiversity Convention, they provide a reminder to any other adjudicative body, such as a WTO dispute settlement panel, that obligations under the Protocol cannot be sidelined as irrelevant to the solution of a dispute arising in a WTO context. Barring the exceptional case of a dispute arising in the WTO, the main burden of adjustment for states that are parties to the Biosafety Protocol and the WTO will be at the domestic level. While international rules provide only partial guidance with regard to the integration of obligations in the trade and environment fields, states must implement all their international obligations in a coherent and consistent manner.

There exists a potential for conflict insofar as the possibility to impose import restrictions or the necessity to identify LMO-FFPs may give rise to challenges in the WTO context. Further, while the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) authorises member states to adopt biosafety measures that restrict trade even in the absence of scientific certainty with regard to the adverse effects on the environment, these can only be temporary in nature.<sup>15</sup> The way in which the precautionary principle is applied is also quite different since WTO member states must always strive to minimise negative trade effects when taking biosafety measures.

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<sup>14</sup> Article 27 of the Cartagena Protocol, *supra* note 4.

<sup>15</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, Marrakesh, 15 Apr. 1994, in World Trade Organization, *The Legal Texts – The Results of the Uruguay Round of Multilateral Trade Negotiations* (Cambridge: Cambridge University Press, 1999).

## CONCLUSION

The Protocol constitutes an important treaty because it is the first binding international legal instrument addressing some environmental and health impacts of modern biotechnology. However, the present treaty remains limited in scope, both with regard to the coverage of LMOs and the kind of activities it seeks to regulate. In effect, the Protocol restricts itself to providing a framework for trade in LMOs from an environmental perspective. It generally seeks to facilitate trade in LMOs by laying down certain obligations for exporters and importers and therefore creating clear rules for transboundary movements of LMOs. This implies, for instance, that importers must undertake risk assessment in what is recognised as a scientifically sound manner. The Protocol, however, goes much further than its WTO equivalent, the SPS Agreement, and establishes a procedure which not only gives the importing state the final say in a decision on a transboundary movement but is also based on the precautionary principle which permits importing states to put restrictions on imports even in the absence of scientific certainty with regard to the potential adverse effects of LMOs on the environment. In other words, insofar as the Biosafety Protocol tackles a trade issue from an environmental perspective, it is a successful treaty whose conclusion was helped in large part by the failure of the trade talks at the 1999 ministerial conference of the WTO.

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