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# The Cartagena (Biosafety) Protocol

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**Abstract** The development and content of the Cartagena Protocol and the progress being made in its implementing are described. When progress has been made in developing the administrative measures needed to underpin its operation, the Protocol will significantly regulate the international distribution of genetically modified organisms.

**Keywords:** biosafety, Cartagena Protocol, GMO, LMO, Precautionary Principle

## Background

The Convention on Biological Diversity (CBD, the RIO Convention<sup>1</sup>) was agreed in December 1993, with the objective of protecting the world's biodiversity. Among its many provisions was a requirement to develop a biosafety protocol. The intention was to ensure that living modified organisms (LMOs) (the term used in the CBD for genetically modified organisms, GMOs) – which 'may have an adverse effect on the conservation and sustainable use of biological diversity' are not moved across national boundaries unless there are established controls to ensure safe handling and use. LMOs are defined as 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'.

The decision that a biosafety protocol should be developed reflected the concern of many governments about the consequences to the environment of releasing LMOs. This is today clearly paralleled in public attitudes in many countries, even when their governments are satisfied by current controls. There was also a deep mistrust by a number of developing nations of the intentions of some of the multinational

companies that dominated the early developments in genetic engineering. This was fuelled by some early mistakes made when GMOs were tested without proper control. However, other countries were unenthusiastic about the development of an effective Protocol because it might introduce restraints on trade between nations.

After extensive and arduous negotiations extending over several years, a Biosafety Protocol was agreed in Montreal in 2000 and is now known as the Cartagena Protocol.<sup>2</sup> As with all international agreements, it requires signature and then ratification by individual governments; it comes into force 90 days after ratification by 50 countries. The number of signatories (August 2001) is 105 and the Protocol has so far been ratified by five countries. There seems little doubt that sufficient countries will ratify the protocol for it to become accepted. The USA is not a signatory to the CBD and will be formally unaffected by the Protocol. Nevertheless, its significance in biotechnology and role as a major producer and exporter of LMOs has led to its detailed involvement in discussions on the development and implementation of the Protocol.

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## Development of the Protocol

The Protocol represents a consensus view reached by countries with very different agendas. Some countries saw a Protocol as inhibitory to trade in agricultural commodities and Argentina, Australia, Canada, Chile, Uruguay and the USA presented this view as a group (the Miami Group). Other countries were deeply suspicious of the potential of LMOs to cause environmental harm. Further, the protocol was recognised as introducing a new factor in world trade, which had previously been regulated primarily by the World Trade Organisation (WTO), which many countries felt paid too little attention to environmental issues. Trade issues were major items of contention in the discussions leading to the Protocol, with the control of international movements involving LMO commodities (eg cereals and oilseeds) being a particular issue. A further difficulty was that many countries wished to incorporate the Precautionary Principle into the Protocol. This may allow negative decisions about the acceptance of LMOs to be taken even in the absence of hard evidence of environmental harm. The Precautionary Principle is held by many to conflict with the reliance on good science in decision-taking, which dominates legislation in this area in most developed nations.

The discussions about the scope and wording of the Protocol took place between countries organised into loose and divergent groups with differing objectives. Many of the conflicts were resolved during the course of discussions. Eventually, the remaining contentious points were settled by compromises between groups representing:

- countries that are exceptionally dependent on agricultural commodity trading and expect LMOs to be major commodities (the Miami Group) and that were deeply antagonistic to the concept of a Protocol that would affect trade. The Miami Group's objections led to the breakdown of earlier Protocol negotiations in 1999 at Cartagena;
- a large group of countries that believed

that LMOs could create harm to the environment (many of which were non-aligned developing countries); and

- intermediate groups seeking compromise and played a conciliatory role. These included Norway, Switzerland and the European Union.

Work to develop the Protocol took place in two different contexts. The political negotiations, which presented the major problems, took place during special Conferences of the Parties to the CBD, while the detailed technical discussions of the measures required to define a Protocol took place in the format of an open-ended *ad hoc* Working Group on Biosafety. Additionally there were three sets of informal consultations in 1999 and 2000, attempting to overcome the contentious issues that had led to the breakdown of negotiations in Cartagena in February 1999. It is interesting that during the prolonged course of the negotiations a number of countries moved from the group that was intent on producing major restrictions on LMO transfer and use to a less restrictive attitude. This reflected the development of biotechnology activities in these countries and recognition that their national interest required a more conciliatory attitude.

A full account of the negotiations that led to the Protocol, and subsequent developments, can be found on the web site of the International Institute for Sustainable Development.<sup>3</sup> The Protocol is essentially a statement of principles to be followed and is a document that lacks detail. Also, the language used in places is somewhat ambiguous and allows an element of interpretation by the importing country. Nevertheless it will place obligations on all those who wish to transfer LMOs from one country to another and the biotechnology industry is clearly in this group.

## Detail of the Protocol

### Exclusions

As a result of negotiations, several exclusions are incorporated into the

Protocol that are of particular importance to the biotechnology industry. The exclusions are as follows:

- Products made using LMOs but not containing them.
- Pharmaceuticals, provided that they have already been subject to adequate examination by other international agreements or organisations. Pharmaceuticals containing LMOs, such as gene therapy products, can thus be transferred across national boundaries unaffected by the Protocol. However, the importing country retains the right to require a risk assessment. A caveat to this exclusion is that, in future, efforts may be made to interpret the term 'international agreements' narrowly, so that approval by some regional regulatory systems may be excluded.
- Commodities consisting of LMOs that are destined for use in food, feed or for processing, which are excluded from the Advanced Informed Agreement (AIA) procedure. This was a key point that allowed the crop-exporting countries such as USA, Canada and Argentina to agree to the Protocol.
- LMOs intended for contained use. This allows the transfer of genetic material for research in contained use to continue and assists in the development of capacity in developing countries. However, some concerns have been expressed that containment may not be implemented properly in the country of import.
- LMOs in transit through an intermediate country (though this can still regulate the transit).
- LMOs that have been agreed at a conference of the Parties to the CBD as 'being unlikely to have adverse effects on conservation and sustainable use of biodiversity, taking also into account risks to human health'.

### Requirements

LMOs can only be imported into a country for deliberate release into the environment if there is an AIA from the importing country.

This parallels the position established for trade in hazardous chemicals (which works well in practice). An AIA will apply only to the first intentional movement of LMOs across a national boundary, though the Protocol allows importing countries to require a risk assessment for subsequent imports. Risk assessments are to be carried out in conformity with Annex III of the Protocol.<sup>2</sup>

To allow the AIA mechanism to function, notification, acknowledgement of notification and decision procedures are required. The Protocol requires that each country sets up a competent authority to perform the necessary administrative functions.

AIA decisions made on the first notification of intention to import may be changed if new scientific information becomes available. This applies to both importers and exporters.

A simplified procedure enables an importing country to specify LMOs that are exempt from AIA, and to allow trans-boundary movement to proceed simultaneously with notification. Information as to which LMOs are included in these groups must be supplied to the Biosafety Clearing House, discussed below.

The importing country may invoke the precautionary approach when taking a decision ('lack of scientific certainty due to insufficient information of the potential adverse effects on biodiversity shall not prevent a Party from taking a decision'). It also allows socio-economic factors to be taken into account in coming to decisions; these decisions will be incorporated into the revised European Directive regulating the deliberate release to the environment of GMOs, which has now been published as 2001/18/EC.

Procedures can be established for countries to form groups and establish, for example, regional agreements for trans-boundary movements.

Many developing country members involved in the discussions wished to establish a liability procedure, but this is not included, except in so far as one Article of the Protocol requires this to be considered at

later meetings of the Parties. The topic was discussed at meetings during 2001.

Many of the countries affected by the Protocol do not currently possess adequate scientific and administrative infrastructures to allow them to make informed decisions in the area of AIA. As a measure to ameliorate this, a Biosafety Clearing House (BCH) is to be established to facilitate the exchange of scientific, technical, environmental and legal information. This will contain information about laws and regulations established to implement the Protocol, summaries of risk assessments and environmental reviews of LMOs generated as a result of the implementation of the Protocol and decisions made in the context of the Protocol. There are requirements to maintain confidentiality about sensitive commercial information.

### **Developments since the Protocol was accepted in Cartagena**

The mechanism adopted to implement the Protocol is the Intergovernmental Committee for the Cartagena Protocol (ICCP). This body held its first meeting (ICCP1) in Montpellier, France, in December 2000 and decided<sup>4</sup> that its immediate priorities were to develop the concept of the Biosafety Clearing House by setting up a pilot scheme and to address the subject of handling, packaging and identification of LMOs.

After discussions held in Montreal in March 2001,<sup>5</sup> the BCH mechanism is now well defined. It will be scaleable and flexible, to allow future development, and will have a central database. Collaboration with partners is seen as desirable. BCH seems likely to provide a worthwhile, Internet-based system for providing information about LMOs that seek AIA for transfer across national borders. Arrangement for non-electronic access will be established. A regional meeting to further the BCH concept was held in Africa in February 2001,<sup>6</sup> and another will be held in Latin America.<sup>7</sup> The BCH will facilitate the transfer of information about trade in LMOs and will be of particular value to countries

that do not have the capacity to evaluate LMOs themselves.

The handling, packaging, transport and identification issues were discussed in Paris in May 2001, where a range of options was identified.<sup>8</sup> On the one hand it was recognised that there were well-established procedures that dealt with these issues for goods in transit from one country to another, and that these could usefully be used for LMOs. These included the normal invoicing and consignment documentation, existing intergovernmental mechanisms regulating the transport of, for example, plant pests for quarantine purposes (a meeting to consider the application of the phytosanitary regulations concerning plant pests was held in Rome in September 2001<sup>9</sup>), the OECD seed scheme, UN recommendations for transport of non-infectious GMOs or, where there was a possibility of harm, transport of dangerous goods. However, when these were viewed from the point of view of the Protocol, it was recognised that there were some small gaps in existing procedures and this led to suggestions that a new system based on the requirements of the Protocol should be established. There was further discussion of this subject at the second ICCP meeting (ICCP2) in Kenya in October 2001.<sup>10</sup>

With regard to issues of compliance, central to the operation of the Protocol, the ICCP discussed this topic in September 2001,<sup>11</sup> and reported to ICCP2. This meeting discussed the views submitted to it by governments.

Additionally, the agenda for the ICCP2 meeting<sup>10</sup> included discussions on liability and redress (Article 27), monitoring and reporting (Article 33) and a range of other issues necessary for effective implementation of the Protocol. Among the latter are the financial mechanisms that must underpin the Protocol, decision-making procedures and the sharing of information.

### **Conclusions**

In general, it appears that the Cartagena Protocol will affect the biotechnology

industry to a smaller degree than initially seemed likely, as a consequence of the exclusion of commodities and of pharmaceuticals from its scope. However, it is important that the Biosafety Protocol has created a body that can act with real authority in regulating aspects of trade in genetically modified organisms. The WTO believes itself to be dominant in trade-related affairs and at its abortive meeting in Seattle had contemplated setting up a forum in which biotechnology issues could be discussed. The chaos induced by protesters in Seattle prevented consideration of this issue but it may return to the WTO agenda. However, the language of the Protocol, once it has been ratified, appears to establish that it will be of major significance alongside other international agreements.

Much remains to be done before the Protocol is implemented on the ground and its administration will present major headaches. Clearly it is possible to bring framework measures similar to those used for trade in hazardous materials into play for the Protocol. However, a major difficulty is the lack in many cases of infrastructure – both administrative and scientific – in developing countries. This issue is widely recognised and has led to an emphasis on the need for capacity building to allow sound implementation of the Protocol. An open-ended meeting of experts on capacity building was held in July 2001.<sup>12</sup>

Those organisations involved in research will welcome the exclusion of LMOs intended for contained use from the requirement for AIA, for the international movement of these organisms is of massive proportions and significance. For example the transfer of genetically modified microorganisms from a laboratory to another in a different country is essential for biotechnological research and to place restrictions on this would have inhibited

much desirable R&D. It would also have made capacity building much more difficult in those states where it is required. There will be general relief that a compromise was reached which excludes commodities from the major requirements of the Protocol; indeed it seems clear that no agreement could have been reached if AIA had been required for all imports of commodity LMOs such as maize and soya.

As with all international agreements, the real impact will be determined by the details of implementation agreed in the years after the initial agreement. It is clear that relatively rapid progress is being made and that the protocol will require serious consideration by many sectors of the biotechnology community.

## References

1. UNEP 1993 Convention on Biological Diversity. URL: <http://www.biodiv.org/doc/legal/cbd-en.pdf>
2. UNEP 2000 Biosafety Protocol. URL: <http://www.biodiv.org/biosafety/protocol>
3. International Institute for Sustainable Development. URL: <http://iisd.ca/linkages/>
4. UNEP 2000. UNEP/CBD/ICCP/1/9. URL: <http://www.biodiv.org/doc/meetings/iccp/iccp-01/official/iccp-01-09-en.pdf>
5. UNEP 2001. UNEP/CBD/TEBCH/1/5. URL: <http://www.biodiv.org/doc/meetings/tebch/tebch-01/official/tebch-01-05-en.pdf>
6. 2001 UNEP UNEP/CBD/BCH/Afr.Reg/1/2. URL: <http://www.biodiv.org/bch/bch-rm-afr-01.asp>
7. UNEP 2001. UNEP/CBD/BCH/LAC.Reg/1/2. URL: <http://www.biodiv.org/bch/mtg-lac-01.asp>
8. UNEP 2001. UNEP/CBD/BS/TE-http/1/3. URL: <http://www.biodiv.org/biosafety/mtg-te-http.asp>
9. UNEP 2001. URL: <http://www.biodiv.org/doc/notifications/ntf-2001-08-14-plt-conserv-en.asp>
10. UNEP 2001. UNEP/CBD/ICCP/2/15. URL: <http://www.biodiv.org/doc/meetings/iccp/iccp-02/official/iccp-02-15-en.pdf>
11. UNEP 2001. CBD/STTM/DC. URL: <http://www.biodiv.org/biosafety/mtg-te-cmpl.asp>
12. UNEP 2001. UNEP/CBD/BS/EM-CB/1/3. URL: [http://www.biodiv.org/biosafety/mtg-te\\_cpcty.asp](http://www.biodiv.org/biosafety/mtg-te_cpcty.asp)