Editorial

Biosafety in the International Context – The Cartagena Protocol

Helmut Gaugitsch

Correspondence address: Dr. Helmut Gaugitsch, Umweltbundesamt GmbH – Federal Environment Agency Austria Ltd., Spittelauerlände 5, A-1090 Wien, Austria (gaugitsch@ ubavie.gv.at)

The Cartagena Protocol on Biosafety was adopted on 29 January 2000 in Montreal/Canada. It has its name from the city of Cartagena in Colombia where, due to the original schedule, the Protocol should have been adopted in February 1999. However, at that time – although a compromise could nearly be reached – the negotiations did not lead to a consenus between the various negotiating groups, a reason for which they had to be suspended and resumed once again.

The Cartagena Protocol is the global legal instrument for the regulation of transboundary movement, handling and use of so called 'Living Modified Organisms' (LMOs). The term LMOs which is used here has the same meaning as the term 'Genetically Modified Organism' (GMO) which is commonly used in the European Union. Other terms, such as 'transgenic organisms', 'genetically engineered organisms', 'organisms with novel traits', which are commonly used in various parts of the world and in various regulatory systems, basically have the same meaning as well.

The Cartagena Protocol has its origins in the Convention on Biological Diversity (CBD), which had been adopted at the United Nations Conference for Environment and Development (UNCED) in Rio de Janeiro in 1992. This Convention, which basically aims at the conservation and sustainable use of biological diversity, addresses LMOs in Article 19, which calls for a consideration of the 'need for and modalities of a protocol'. The term LMO was introduced in the Convention mainly for political reasons as the negotiating partners could not agree on one of the terms used in the various systems. Also, the definition of 'genetic modification' and its regulatory implications was highly controversial at that time.

Article 19 in the CBD led to discussions and negotiations on the 'need for and modalities of a Protocol'. It was in 1995, at a meeting in Madrid and subsequently at the Second Meeting of the Conference of the Parties to the CBD (COP-2) in Jakarta/Indonesia, that a Mandate for the negotiations of a Protocol was agreed upon. According to that, the Protocol should specifically focus on the transboundary movement of LMOs. From the first meeting in 1996 held in Aarhus/Denmark to the sixth meeting in 1999 held in Cartagena, and the failure mentioned of having reached a compromise there, a couple of meetings of the so-called Biosafety Working Group were held in order to elaborate a compromised text for the Protocol. As some of the core parts of the draft Protocol had been quite controversial between the negotiating groups, the final compromise made in Montreal in January 2000 was quite difficult to reach and concessions had to be made from all sides. However, the Cartagena Protocol has been regarded from many countries, institutions and persons involved, as well as from observers, as a major step towards global biosafety and an international harmonization of the regulations on the transboundary movement, handling and use of LMOs (GMOs). The following are the core elements of the Protocol which contribute to its reputation as an instrument which carefully balances the various interests in the area of modern biotechnology and biosafety, by focussing on its major goal – the conservation and sustainable use of biological diversity:

- In case of a transboundary movement of LMOs, which are intended for an intentional introduction into the environment in the importing country, a so called 'Advance Informed Agreement' (AIA)-Procedure has to be followed, which allows the importing country to undertake a full risk assessment and make a decision on the basis of a notification which has to include the relevant data.
- LMOs which are intended for direct use such as food, feed or for processing in the importing country (LMO-FFPs), or which are basically agricultural commodities including LMOs, may be subject to a somewhat lighter procedure: If a country approves these LMO-FFPs and they are going to be exported, it has to notify this to the so-called Biosafety Clearing House (BCH). This is a global information exchange mechanism for biosafety which is currently in its pilot phase. It is designed as a powerful internet-based system with a central component at the Secretariat of the CBD (which is the Secretariat to the Cartagena Protocol as well) and decentralised components (in the Parties). If a potentially importing party so wishes, it can then ask the exporting party for more information on this LMO-FFP within a limited period of time and can request a decision-making procedure comparable to the AIA procedure described above.
- For the first time in an MEA (multinational environmental agreement) the precautionary principle has been formulated. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO shall not prevent a party from making a decision in order to avoid or minimise such potential adverse effects. This has to be regarded as a major step in the context of protection of human health and the environment. However,

the practical implementation of the precautionary principle has yet to be clarified.

- In the Preamble of the Protocol, the relationship to other international agreements (such as the WTO) has been put into concrete terms. There should be no hierarchy, e.g. between the WTO as a trade instrument and the Cartagena Protocol as an MEA, but they should be mutually supportive. Again the meaning of this provision has to be clarified in practical terms. However, it has to be regarded as a major step forward also with the view of the trade implications of the global transboundary movement of LMOs and any possible restrictions due to decisions under the Cartagena Protocol.
- The Cartagena Protocol includes provisions for identification of LMOs, which is comparable to or a prerequisite for labelling. Certain categories of LMOs have to be clearly labelled as LMOs, while shipments potentially containing LMO-FFPs have to be identified as 'may contain LMOs', with the requirement that this provision is to be reviewed and clarified within 2 years after the entry into force of the Protocol. This topic was the most controversial one in the final hours of the negotiations and only the least common denominator could be adopted as a compromise in Montreal in order to avoid another failure. As this provision has clear implications for international trade, it is also the one which gets high attention in the current discussion after the adoption of the Protocol.
- Within 4 years after entry into force of the Protocol, a liability regime for any negative effects of LMOs has to be elaborated. Again, this has been one of the most controversial topics in the negotiations and – in addition to the discussions on compliance – gets high attention in the current discussions as well.

The Cartagena Protocol has been signed by more than 100 countries and 13 have currently ratified it (among them the EU member states Spain and the Netherlands). It will enter into force after at least 50 ratifications. The EU and its member states, as well as other countries, are currently working on implementation and ratification of the Protocol. The Protocol is currently being discussed intensively for the following reasons:

- A couple of countries, such as USA, Canada, Argentina are planting certain LMO plants on a rather large scale (e.g. more than 90% of the soya production in Argentina involves genetically modified soya). These plants are mainly produced for exports. Also some other so-called 'developing countries' are quite interested in producing and/or importing LMOs. As a result, global trade with LMOs is a reality and this requires a strong and enforceable Biosafety Protocol.
- The question of labelling, segregation and traceability, which is high on the political agenda not only in the EU, but also in other countries, e.g. in Asia, and any solutions are related to the outcome of the discussion on identification within the Cartagena Protocol and further clarification or interpretation of the 'may contain' provision for LMO-FFPs. Expert meetings are convened for this purpose in March 2002 in Montreal.
- The next meeting of the so-called 'Intergovernmental Committee of the Cartagena Protocol' (ICCP), the ICCP-3, is going to take place at the end of April 2002 in The Hague/ Netherlands, just after COP-6 of the CBD. Besides the question of identification, important topics such as the further development of the Biosafety Clearing House (BCH), compliance and liability are on the agenda for this meeting. There are high expectations with respect to a good preparation for a first meeting of the Parties, which will hopefully follow in the near future.

For the Protocol to enter into force soon and to reach its goal, the protection of biodiversity from any potential adverse effects from LMOs and the contribution to its sustainable use, especially in countries with a lack of capacity and potentially vulnerable ecosystems, it will be necessary that a broad range of as many countries as possible ratify and apply the Cartagena Protocol. This should also include the major exporters of LMOs.

Dr. Helmut Gaugitsch is Scientific Officer (Deputy Head) of the Department of General Ecology and Nature Protection at the Federal Environment Agency (Umweltbundesamt) in Vienna, Austria. His work concerns environmental aspects of biotechnology, specifically in the risk assessment of GMO releases and product applications. He is member of the Austrian Biotechnology Advisory Committee. Since 2002, Helmut Gaugitsch belongs to the Editorial Board of ESPR – Environ. Sci. & Pollut. Res. (see also [Gaugitsch H, Soja G, Janssen I, Torgersen H (1998): Risk Assessment of Conventional Crop Plants in Analogy to Transgenic Plants. ESPR – Environ. Sci. & Pollut. Res. **5** (2) 89–93]).