

The Cartagena Protocol on Biosafety: interaction between the Convention on Biological Diversity and the World Organisation for Animal Health

C. Sendashonga ⁽¹⁾, R. Hill ⁽¹⁾ & A. Petrini ⁽²⁾

(1) Secretariat of the Convention on Biological Diversity 413 St-Jacques Street, Suite 800 Montreal, H2Y 1N9 Quebec, Canada

(2) OIE (World Organisation for Animal Health) 12, rue de Prony 75017 Paris, France

Summary

The Cartagena Protocol on Biosafety is an international agreement (adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity) that addresses the potential adverse effects of living modified organisms. It focuses primarily on transboundary movements and is therefore relevant to international trade. It includes provisions on import decision-making, risk assessment and management, information-sharing, documentation, capacity-building, compliance, liability and redress, public awareness and participation, and socio-economic considerations. Given the scope of the Protocol, there may be cases where trade in living modified organisms also falls under the mandate of existing international bodies such as the OIE (World Organisation for Animal Health) and other standard-setting bodies. There could therefore be benefits from collaboration between the Secretariat of the Convention on Biological Diversity and the World Organisation for Animal Health on issues such as risk assessment and management, information-sharing, documentation requirements, and procedures related to unintentional transboundary movements. This paper reviews the key provisions of the Protocol and attempts to highlight areas of the agreement which are also of interest to various international bodies, particularly the OIE.

Keywords

Biodiversity – Cartagena Protocol on Biosafety – Convention on Biological Diversity – Genetically modified organism – Living modified organism – Risk analysis – Transboundary movement – World Trade Organization.

Introduction

The Cartagena Protocol on Biosafety (9) (hereafter referred to as 'the Protocol'), is an international agreement that was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity (CBD). It addresses the potential adverse effects on biodiversity, taking also into account risks to human health, of living modified organisms (LMOs), which are defined in the Protocol as any living organism that possesses a novel combination of genetic material obtained

through the use of modern biotechnology. The term LMO is usually considered to be synonymous with GMO (genetically modified organism) or other similar terms, although precise definitions may vary. The Protocol focuses in particular on transboundary movements and is therefore relevant to international trade in LMOs. While the Protocol deals exclusively with LMOs, its remit overlaps with that of other international bodies and agreements that deal to some extent with transgenic organisms. Of particular relevance are bodies and agreements that are relevant to international trade, such as the OIE (World Organisation for Animal Health), the International Plant Protection

Convention (IPPC) and the Codex Alimentarius Commission (Codex). If the Protocol is to be implemented effectively, it will be important for all countries that have ratified it (hereafter referred to as 'the Parties') to take into account the work done by these organisations on the particular issues for which they have specific responsibility. To that end, this paper reviews the key provisions of the Protocol and attempts to highlight areas of the agreement which are also of interest to various international bodies, particularly the OIE. Opportunities for collaboration between the OIE and the Protocol are identified.

Background

The origin of the Cartagena Protocol dates back to the 1992 United Nations Conference on Environment and Development, held in Rio de Janeiro. At that meeting, more than 178 governments adopted Agenda 21, which was a comprehensive action plan for dealing with ways in which human activities affect the environment; it included a chapter on 'environmentally sound management of biotechnology'. At the same meeting, the CBD was opened for signing. The three principal objectives of this Convention are as follows:

- the conservation of biodiversity
- the sustainable use of its components
- the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

One of the issues addressed by the CBD is biosafety, i.e. the need to protect human health and the environment from the potential adverse effects of the products of modern biotechnology. At the same time, biotechnology is recognised as having great potential for the promotion of human well-being and for the sound management of the environment. The CBD clearly recognises these twin aspects of biotechnology and includes provisions for both the promotion of biotechnology and the development of procedures to ensure its safety, for example:

- Article 16, paragraph 1, and article 19, paragraphs 1 and 2, call for access to and transfer of technologies, including biotechnology, that are relevant to the conservation and sustainable use of biological diversity
- Articles 8 (g) and 19, paragraph 3, seek to ensure the development of appropriate procedures to enhance the safety of biotechnology in the context of the overall goal of the Convention, i.e. to reduce all potential threats to the conservation and sustainable use of biological diversity, including risks to human health.

Article 8 (g) stipulates measures that Parties should take at national level, while Article 19, paragraph 3, provides for the development of a legally binding international

instrument to address the issue of biosafety in the context of the objectives of the CBD, as follows:

'Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity.' (The full text of the Protocol can be found at <http://www.biodiv.org/biosafety/protocol.asp>.)

The highest decision-making body of the CBD, the Conference of the Parties (COP), subsequently decided to develop a biosafety protocol, and established the Open-ended Ad Hoc Working Group on Biosafety for this purpose, which met six times between 1996 and 1999. The key issues and dynamics of the negotiations are reviewed in detail elsewhere (1, 3, 10). The protocol was adopted by an Extraordinary meeting of the COP which began in Cartagena, Colombia, in February 1999 and concluded in Montreal in January 2000. The objective of this protocol, which became known as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, is stated in Article 1 as follows:

'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 health, and specifically focusing on transboundary movements.'

The scope of the Protocol is described in Article 4, and highlights this focus on transboundary movements:

'This Protocol shall apply 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.'

The Protocol came into force in September 2003, and already has more than 100 Parties (11).

Key provisions of the Protocol

The Protocol contains a number of operational provisions, but this section reviews the key provisions, and, where appropriate, the relevant work of the governing body of the Protocol, which is known as the Conference of the Parties serving as the meeting of the Parties to the Protocol

(COP-MOP). The COP-MOP held its first meeting (COP-MOP-1) in February 2004 in Malaysia to establish the procedural and administrative basis of the Protocol, and to put in place the necessary operational tools to support and monitor its implementation. The second meeting of the COP-MOP (COP-MOP-2) is scheduled to take place in June 2005. This section concentrates on those provisions of the Protocol, and the decisions adopted by COP-MOP-1, which are of greatest potential relevance to the work of bodies such as the OIE.

Decision-making procedures for the import of living modified organisms (Articles 7 to 14)

The Protocol describes decision-making procedures for the import of LMOs. The central feature in this regard is the Advance Informed Agreement (AIA) procedure, which applies to LMOs that are destined for release into the environment (e.g. crops for planting). The Protocol contains the following procedures that apply prior to the first intentional transboundary movement of an LMO for intentional introduction into the environment:

- the Party of export, or the exporter, must notify the Party of import
- the Party of import must acknowledge receipt of that notification
- the Party of import may then decide whether or not the import will be approved.

Parties may choose, or the COP-MOP may decide, to exempt certain LMOs or categories of LMOs from the AIA procedure (see Articles 13.1 and 7.4 respectively).

The AIA procedure of the Protocol does not apply to certain categories of LMOs, although Parties have the right to regulate the importation on the basis of domestic legislation. These categories include:

- LMOs in transit (Article 6)
- LMOs destined for contained use (Article 6)
- LMOs intended for direct use as food or feed or for processing (Article 7.3).

For LMOs intended for direct use as food or feed or for processing (LMO-FFPs), a simplified procedure is described in Article 11, which does not require AIA. Under this procedure, a Party must inform other Parties through the Biosafety Clearing-House (the BCH, which is described in a later section), within 15 days, of its decision regarding the domestic use of LMO-FFPs that may be subject to transboundary movement.

Decisions by any potential Party of import on whether or not to accept the import of LMO-FFPs are taken under its

domestic regulatory framework, as long as it is consistent with the objective of the Protocol. A developing country Party or a Party with an economy in transition may, in the absence of a domestic regulatory framework, declare through the BCH that its decisions on the first import of an LMO-FFP will be taken in accordance with risk assessment as set out in the Protocol and within a specified timeframe. The key aspect of the procedure for LMO-FFPs is that as there is no requirement for AIA, Parties must proactively take decisions to regulate import.

In the case of both LMOs for intentional introduction into the environment and LMO-FFPs, there is language in the Protocol that reflects the concept of precaution in decision-making. Specifically, Articles 10.6 and 11.8 state that lack of scientific certainty regarding the extent of the potential adverse effects of an LMO shall not prevent a Party from taking a decision in order to avoid or minimise such effects.

Risk assessment (Article 15)

A Party of import makes its decisions on the import of LMOs for intentional introduction into the environment in accordance with scientifically sound risk assessments (Article 15). The Protocol includes an Annex (Annex III) which sets out principles and methodologies on how to conduct a risk assessment. The key principles are as follows:

- risk assessment should be carried out in a scientifically sound and transparent manner
- 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
- risks should be considered in the context of risks posed by the non-modified recipients or parental organisms
- risks should be assessed on a case-by-base basis.

The generic methodology of risk assessment described in Annex III of the Protocol begins with the identification of a potential hazard (e.g. a particular LMO trait). Risks are assessed by a combined evaluation of the likelihood of adverse effects and the consequences should those effects be realised. The principles and methodology for risk assessment that are contained in the Protocol are similar to those of conventional risk assessment frameworks (2).

Risk management (Article 16)

Risk management is also an integral part of the Protocol. Parties are required to do the following:

- adopt measures and strategies for preventing adverse effects and for managing and controlling the risks identified by risk assessments (Articles 16.1 and 16.2)

- take measures to prevent unintentional transboundary movements (Article 16.3)
- ensure that LMOs undergo appropriate periods of observation prior to use (Article 16.4)
- cooperate in identifying LMOs or traits that may pose risks to biodiversity and take appropriate management measures (Article 16.5).

Parties are also required to take the necessary steps in the event of the accidental release of LMOs (Article 17).

In addition to Articles 16.1 and 16.2 described above, the risk assessment methodology described in Annex III also refers to the identification of management strategies for addressing risks. In this way, risk assessment and risk management are interrelated, because the results of the risk assessment depend in part on the risk management options that are considered.

Information-sharing and the Biosafety Clearing-House (Article 20)

The Protocol established the BCH in order to facilitate the exchange of scientific, technical, environmental and legal information on living modified organisms and to assist Parties to implement the Protocol. Parties are required to use the BCH to communicate to other Parties their contact information, regulatory frameworks, results of import decisions, results of risk assessments, occurrences of unintentional transboundary movements of LMOs, and several other types of information. In addition, there are many types of information in the BCH that are provided on a voluntary basis and that are useful to a wide range of users, not only Parties and other governments.

At its first meeting, the COP-MOP adopted the modalities of operation of the BCH. These modalities outline the role of the BCH, its characteristics, its administration, the role of the BCH national focal points (i.e. government representatives responsible for managing communication between the CBD Secretariat and their respective governments) modalities for technical oversight and advice, the obligations of partner organisations, reporting arrangements, and procedures for periodic review by the COP-MOP.

Handling, transport, packaging and identification (Article 18)

The Protocol requires Parties to take measures to ensure the safety of the handling, packaging and transportation of LMOs that are subject to transboundary movement. The Protocol's text specifies what information must be provided in documentation that should accompany transboundary

shipments of LMOs. The details of these requirements vary according to the intended use of the LMOs. The Protocol also allows for possible future development of standards for handling, packaging, transport and identification of LMOs.

Capacity-building (Article 22)

The Protocol requires Parties to cooperate in the development and strengthening of human resources and institutional capacities in biosafety in order to promote the effective implementation of its provisions. In this regard, at their first meeting, the Parties adopted an action plan for capacity-building which defined appropriate roles for different entities. Importantly, databases outlining capacity-building needs and opportunities have been built and are contained in the BCH. In addition, the BCH contains a roster of experts on biosafety who can support the implementation of the Protocol by providing advice and other assistance as appropriate.

Compliance (Article 34)

As mandated by Article 34, COP-MOP-1 considered and approved procedures and mechanisms to help Parties comply with their obligations and to address cases of non-compliance. A compliance committee consisting of 15 members was established.

Liability and redress (Article 27)

The first meeting of the COP-MOP established a working group of legal and technical experts on liability and redress in the context of the Protocol. The task of this working group is to elaborate international rules and procedures regarding liability and redress for damage resulting from transboundary movements of LMOs. The group is expected to complete its work in 2007.

Public awareness and participation (Article 23)

Article 23 states that Parties should promote public awareness of the Protocol, both on their own and in cooperation with other States and international bodies, and that Parties should promote public participation in matters relating to the Protocol and ensure that the public has access to information on any LMOs that may be imported. In accordance with national laws and regulations, the public is to be consulted in the decision-making process regarding LMOs, made aware of the results of such decisions and informed about the means of public access to the Biosafety Clearing-House. The issue of public awareness and participation will be considered at COP-MOP-2 in June 2005.

Socio-economic considerations (Article 26)

The Protocol states that Parties may take into account socio-economic considerations, consistent with their international obligations, in reaching a decision on imports of LMOs. In addition, Parties are encouraged to cooperate on research and to exchange information on the socio-economic impacts of LMOs. This aspect of cooperation will also be addressed by COP-MOP-2 in June 2005.

Relevance of other international bodies to transboundary movements of living modified organisms

The Protocol focuses on transboundary movements; therefore any bodies and agreements that address international trade in LMOs are highly relevant to its implementation. Here, the authors focus on three which have been widely noted as particularly relevant:

- Codex
- the IPPC
- the OIE.

These three bodies are identified as competent standard-setting bodies under the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement). The SPS Agreement addresses the application of domestic measures for the protection of human health (via food safety), plant health, and animal health. Members of the WTO must provide justification for the application of domestic measures that affect trade, and are encouraged to base such measures on international standards. The role of standard-setting lies with appropriate standard-setting bodies and the OIE, the IPPC and Codex are specifically identified in the SPS Agreement as having responsibility for standard setting in animal health, plant health and food safety, respectively (4, 14). The SPS Agreement specifies in Article 5 that WTO members shall take measures based on the assessment of risks, taking into account risk assessment techniques developed by the relevant international organisations. For this reason, it is in the realm of risk assessment, which underlies domestic decision-making regarding the import and use of plants, animals, and foods, that there is a particular joint interest between the Protocol and these three bodies.

Codex Alimentarius Commission

The Codex Alimentarius Commission develops standards, guidelines and other texts with the aim of promoting

consumer health and ensuring fair trade practices in the food trade. The work of Codex is relevant to the Protocol in the case of foods that meet the definition of an LMO. As previously mentioned, Article 3 of the Protocol defines an LMO as ‘any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology’. (A living organism is defined as ‘any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids’ and ‘modern biotechnology’ is defined as the application of *in vitro* nucleic acid techniques or the fusion of cells beyond the taxonomic family ‘that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection’ [9].) Consequently, any foods which are produced from LMOs, but which are processed to an extent that they do not meet the definition of a living organism, would not be covered by the Protocol.

Several aspects of the work of Codex are relevant to the implementation of the Protocol. For example, the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Modern Biotechnology developed ‘Principles for the risk analysis of foods derived from modern biotechnology’, a document which was adopted by the Commission at its 26th session in July 2003. Other groups under Codex that do work relevant to the Protocol include the Committee on General Principles and the Committee on Methods of Analysis and Sampling.

International Plant Protection Convention

The IPPC aims to prevent and control the introduction and spread of any plants, animals or pathogenic agents which are injurious to plants. The IPPC is particularly relevant to the Protocol, given the potential direct or indirect effects of transgenic crops on non-transgenic varieties or other plants in natural or agricultural systems. The Interim Commission on Phytosanitary Measures (ICPM), the interim governing body of the IPPC, has recently adopted a standard entitled ‘Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms’ (13). Given the areas of mutual interest, the CBD Secretariat and the Food and Agriculture Organization of the United Nations have signed a Memorandum of Cooperation regarding cooperation between the IPPC and the Protocol.

World Organisation for Animal Health

The World Organisation for Animal Health (OIE) is an intergovernmental organisation created by the International Agreement of 25 January 1924, which was signed by 28 countries. In May 2004, the OIE comprised 167 Member Countries.

The missions of the OIE are as follows:

a) Transparency in the animal disease situation worldwide: each Member Country is committed to reporting to the OIE on its health status regarding significant animal diseases and diseases transmissible to humans. The OIE then disseminates the information to all Member Countries to enable them to take appropriate action to protect themselves.

b) Collection, analysis and dissemination of veterinary information: using its network of internationally recognised scientists, the OIE collects, analyses and publishes the latest scientific information on significant animal diseases, including those transmissible to humans, especially regarding their prevention and control.

c) Strengthening of international coordination and cooperation in the control of animal diseases: the OIE provides technical expertise to Member Countries requesting assistance with animal disease control and eradication operations, particularly developing countries. It does this in coordination with other international organisations responsible for supporting and funding the eradication of animal diseases.

d) Promotion of the safety of world trade in animals and animal products: the OIE develops standards for use by Member Countries to protect themselves against disease incursions during trade in animals and animal products, while avoiding unjustified trade barriers. The WTO recognises OIE standards as international references in the fields of animal diseases and zoonoses.

e) Improving the legal framework and resources of national Veterinary Services: the Veterinary Services and laboratories of developing and transition countries are in urgent need of support to build the necessary infrastructure, resources and capacities that will enable them to benefit more fully from the WTO SPS Agreement and to provide a higher level of animal health and public health protection.

f) To improve the safety of food of animal origin and to promote animal welfare through a science-based approach: OIE Member Countries have decided to improve the safety of food of animal origin by improving coordination between the activities of the OIE and those of Codex. The standard-setting activities of the OIE in this field focus on eliminating hazards existing prior to the slaughter of animals or the primary processing of their products (meat, milk, eggs, etc.) that could be a source of risk for consumers.

In recognition of the close relationship between animal health and animal welfare, the OIE is developing, at the request of its Member Countries, standards on animal welfare.

Potential for collaboration between the Cartagena Protocol on Biosafety and the World Organisation for Animal Health

This section identifies potential areas in which the Protocol and the OIE could collaborate. The principal areas of mutual interest are discussed, including:

- risk assessment and risk management
- information-sharing
- documentation and handling requirements
- unintentional transboundary movements and emergency measures.

Risk assessment and risk management

Building on the risk assessment and risk management provisions of the Protocol, COP-MOP-2 will consider risk issues, focusing particularly on the following areas:

- clarification of the issues involved
- development of guidance and a framework for a common approach in risk assessment and risk management
- cooperation in identifying LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biodiversity, also taking into account risks to human health, and taking appropriate measures regarding the treatment of such LMOs or specific traits (Article 16, paragraph 5).

The OIE, IPPC and Codex use the term risk analysis to encompass risk assessment, risk management, and, in some cases, risk communication. Meanwhile, the Protocol refers to risk assessment and risk management, but does not refer to risk communication and does not use the overarching term of risk analysis. Regardless of terminology, it is important to note that these are areas of mutual interest.

The OIE emphasises the importance of using risk analysis in assessing risks and developing effective risk management strategies that do not create unnecessary trade barriers. The importation of animals and animal products always involves a degree of disease risk to the importing country, due to one or several diseases or infections (7, 8). Within the mandates of the OIE, the principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the

importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material.

The chapter on risk analysis in the *Terrestrial Animal Health Code* (5) alludes to the role of the OIE with respect to the WTO SPS Agreement. It provides definitions and describes the OIE in-house procedure for the settlement of disputes. It also provides guidelines and principles for conducting transparent, objective and defensible risk analyses for international trade. The components of risk analysis described in the chapter are hazard identification, risk assessment, risk management and risk communication (Fig. 1).

The process of import risk analysis should include an assessment of the exporting country which considers the following factors:

- the results of an evaluation of their Veterinary Services
- the various subpopulations of animals of differing health status that have been defined within that country
- the surveillance systems in place for monitoring animal health.

The OIE is recognised under the WTO SPS Agreement as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live animals and animal products. The SPS Agreement requires that WTO Members base their sanitary measures on international standards, guidelines and recommendations, where they exist, unless an alternative approach can be justified. Members may choose to adopt a higher level of protection than that provided by international texts if there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate. In such circumstances, Members are subject to obligations relating to risk assessment and to a consistent approach to risk management.

The SPS Agreement encourages Governments to make wider use of risk analysis and to undertake assessments as appropriate to the circumstances of the actual risk involved.

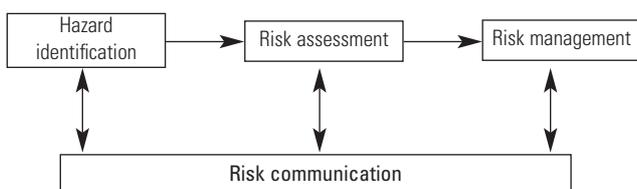


Fig. 1
The four components of risk analysis

Issues of risk management/risk assessment in which the Protocol and the OIE have a mutual interest include:

- the harmonisation of methodologies or approaches, as appropriate
- the consideration of risks in comparison to non-LMO counterparts.

For the immediate future, there are several opportunities for cross-collaboration in relation to risk assessment and risk management. The considerable expertise of the OIE in the assessment and management of animal health risks means that they could provide valuable input to the deliberations of the COP-MOP on the risk assessment and risk management of LMOs. The OIE and other relevant experts could make contributions to meetings of the COP-MOP and to pre-sessional documentation for those meetings where views have been invited from relevant organisations, beginning with the second meeting of the COP-MOP, which is scheduled for 30 May to 3 June 2005. The first meeting of the COP-MOP invited international organisations to submit to the CBD Secretariat any existing guidance materials related to risk assessment and risk management, in advance of consideration of the issue by COP-MOP-2.

Information sharing

As described earlier, the BCH plays a key role in the provision and exchange of information in support of the implementation of the Protocol. The information that is housed in the BCH includes the following:

- national legislation, regulations and guidelines applicable to decisions on imports of LMOs
- relevant bilateral, multilateral and regional agreements and arrangements
- contact details for competent national authorities and emergency contacts
- decisions regarding the import or release of LMOs
- decisions regarding the domestic use of LMO-FFPs
- occurrences of unintentional or illegal transboundary movements
- summaries of risk assessments or environmental reviews
- capacity-building projects
- capacity-building opportunities for, and expressed needs of, developing country Parties
- a roster of experts on biosafety.

The first meeting of COP-MOP invited relevant international organisations to offer their cooperation as

active partners in the implementation of the BCH and to enter into collaborative arrangements in this regard. In addition, the modalities of operation of the BCH, adopted at the first meeting of COP-MOP, recommend further development of the BCH in close cooperation with relevant international organisations, in order to maximise the use of existing experience and expertise.

The World Animal Health Information System

One of the main missions of the OIE is to inform its Member Countries about the world animal health situation. To fulfil its mandate in this respect the OIE manages the world animal health information system. This system relies on the commitment of Member Countries to notify the OIE about outbreaks of the animal diseases listed by the OIE (both aquatic and terrestrial), including zoonoses.

The OIE system includes an alert procedure to warn the international community of significant epidemiological events in Member Countries. These events have been recently redefined and include:

- the first occurrence or re-occurrence of an OIE-listed disease or infection in a country or *zone/compartiment* (please see the section at the end of this paper for an explanation of these terms as defined in the *Terrestrial Code*)
- the first occurrence of a new strain of a pathogen of a listed disease in a country or zone/compartiment
- a sudden and unexpected increase in morbidity or mortality caused by an existing listed disease
- an emerging disease with significant morbidity/mortality or zoonotic potential; evidence of change in the epidemiology of a listed disease (e.g. host range, pathogenicity, strain of causative pathogen), particularly if there is a zoonotic impact.

This alert system is aimed at the Veterinary Services of Member Countries, enabling them to take any necessary protective measures as quickly as possible to minimise the international spread of pathogens. This system operates by publishing the information that is provided by Member Countries; it does this on a weekly basis, or, if necessary, within 24 hours of receipt. This information is also sent to OIE Reference Laboratories and Collaborating Centres and to international and regional organisations, as well as to any other institutions or individuals interested in receiving such information.

The monthly and annual data supplied by Member Countries on animal diseases and zoonoses prior to 2005 can be consulted by accessing the OIE database Handistatus II (www.oie.int/hs2/report.asp?lang=en).

Some of the information-sharing activities of the OIE may be relevant to the Protocol as they relate to the notification and control of transboundary diseases and therefore could be useful to Parties, Governments and other users of the BCH.

Documentation and handling requirements

Documentation to accompany transboundary shipments of LMOs is an issue of importance under the Protocol. The text outlines some basic requirements, and further specifications were developed by COP-MOP-1. Further refinements will be made at COP-MOP-2 for the case of LMO-FFPs. The documentation requirements are summarised in Table I. For the OIE, international trade in animals and animal products depends on a combination of factors which should be taken into account to minimise impediments to trade, without incurring unacceptable risks to human and animal health.

The animal health situation in the exporting country and in the importing country should be the basis for determining the requirements for trade which have to be met. To maximise the harmonisation of the health aspects of international trade, Veterinary Services of Member Countries should base their import requirements on the OIE standards, guidelines and recommendations. These take into account factors such as the quality of the Veterinary Services/Competent Authorities in importing countries, the quality of their laboratory system and the structure of their animal industry.

Certification requirements should be exact and concise, and should clearly convey the requirements of the importing country, and the actual situation in the exporting country. The OIE *Terrestrial Code* and the *Aquatic Animal Health Code* (6) list the responsibilities of the importing and the exporting countries in relation to health certification and include model international veterinary certificates. The import requirements included in these certificates should assure that commodities introduced into the importing country comply with the national level of protection that it has chosen for animal and human health. Importing countries should restrict their requirements to those justified for such a level of protection. The international veterinary certificate should not include requirements for disease agents or diseases which are not OIE listed, unless the importing country has identified the disease agent as presenting a significant risk for that country, after conducting a scientifically based import risk analysis.

An exporting country should be prepared to supply the following information to importing countries on request:

- information on the animal health situation and on the national animal health information systems used to determine whether that country is free of listed diseases (or

Table I
Documentation requirements for transboundary shipments of living modified organisms (LMOs)

Intended use of the living modified organism	Documentation requirements	
	Information requested in the Protocol	Information requested in the Decisions of COP-MOP-1
Intentional introduction into the environment	<ul style="list-style-type: none"> – identified as an LMO – specification of the identity, traits, and characteristics of the LMO – requirements for safe handling, storage, transport, use – contact point for further information – name and address of importer and exporter – declaration that the requirements of the Protocol have been met 	<ul style="list-style-type: none"> – COP-MOP-1 requested the use of a commercial invoice or other document required or utilised by existing documentation systems (includes suggested formats) – COP-MOP-1 gave more precise details about the exact nature of the information that must be provided when exporting LMOs, e.g. common and scientific name and transgenic traits and characteristics such as events of transformation: see Decision BS-I/6, Paragraph B-3(b) (12) – COP-MOP-3 will consider the possibility of stand-alone documentation*
Direct use as food or feed, or for processing	<ul style="list-style-type: none"> – identified as 'may contain' LMOs and not intended for release into the environment (details to be decided by the COP-MOP) – specification of the identity and any unique identification – contact point for further information 	<ul style="list-style-type: none"> – the decisions of COP-MOP-1 are interim, pending final decision by COP-MOP-2 – COP-MOP-1 requested the use of a commercial invoice or other document required or utilised by existing documentation systems, pending decision at COP-MOP-2 – COP-MOP-1 urged that the documentation include organism names, transformation event codes and unique identifier codes – COP-MOP-1 urged that documentation states that a shipment contains LMOs if that is known to be the case
Contained use	<ul style="list-style-type: none"> – identified as an LMO – requirements for safe handling, storage, transport, use – contact point for further information 	<ul style="list-style-type: none"> – COP-MOP-1 requested the use of a commercial invoice or other document required or utilised by existing documentation systems (includes suggested formats) – COP-MOP-1 gave more precise details about exactly what information should be included in the documentation relating to the export of LMOs for contained use: see Decision BS-I/6, Paragraph B-3(a) (12) – COP-MOP-3 will consider the possibility of stand-alone documentation

COP-MOP: Conference of the Parties serving as the meeting of the Parties to the Protocol

* Stand-alone documentation refers to documents that are solely for the purposes of the Protocol, as opposed to existing documentation such as commercial invoices

has free zones), including the regulations and procedures in force for maintaining its free status

- information on the occurrence of transmissible diseases
- details of the country's ability to apply measures to control and prevent the relevant listed diseases
- information on the structure of the Veterinary Services/Competent Authorities and the degree of authority which they exercise
- technical information, particularly on the biological tests and vaccines that are applied.

Given the documentation requirements of the Protocol and the OIE, there may be opportunities for collaboration in those cases where both agreements are applicable. It should be noted that both the Protocol and the OIE have the mandate to set standards with respect to documentation requirements.

Unintentional transboundary movements and emergency measures

Article 17 of the Protocol requires Parties to notify the BCH, and potentially affected States, in the event of a release which leads to, or may lead to, an unintentional transboundary movement of an LMO that is likely to have adverse effects on biodiversity. Each Party is required to specify a contact point for the purpose of receiving such notifications. In addition, Parties under whose jurisdiction such releases occur are required to consult potentially affected States to determine appropriate responses, including emergency measures.

OIE Member Countries are obliged to make available to other countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases and to assist in achieving better worldwide control of these diseases.

OIE Member Countries are also obliged to provide information on the measures taken to prevent the spread of diseases. These include quarantine measures and restrictions on the movement of animals, animal products and biological products, and other miscellaneous objects which could by their nature be responsible for the transmission of disease.

Conclusions

In view of the ongoing development and commercialisation of the products of modern biotechnology, there is potential for certain LMOs to fall within the scope of the Cartagena Protocol on Biosafety and the mandate of the OIE. It would be appropriate for the secretariats and governing bodies of these organisations to keep up to date on each other's work. This would enable collaboration to take place as appropriate on particular issues as they arise. This paper has highlighted the most likely ways in which that collaboration could take place. ■

Explanation of terms as defined in the *Terrestrial Animal Health Code*

Compartment – one or more establishments under a common biosecurity management system containing an animal subpopulation with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biodiversity measures have been applied for the purpose of international trade.

Zone – a clearly defined part of a country containing an animal subpopulation with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.

Le Protocole de Carthagène sur la biosécurité : interactions entre la Convention sur la diversité biologique et l'Organisation mondiale de la santé animale

C. Sendashonga, R. Hill & A. Petrini

Résumé

Le Protocole de Carthagène sur la biosécurité est un accord international, adopté le 29 janvier 2000 pour compléter la Convention sur la diversité biologique. Il porte sur les effets préjudiciables potentiels des organismes vivants modifiés, traitant principalement des mouvements transfrontaliers et concernant par conséquent les échanges internationaux. Il comporte des clauses sur la prise de décision en matière d'importation, l'évaluation et la gestion des risques, le partage des informations, la documentation, le développement des compétences, le respect des dispositions légales, les responsabilités et les sanctions, la sensibilisation et la participation du grand public, ainsi que les considérations socio-économiques. Compte tenu du champ d'application du Protocole, il peut exister des cas où le commerce des organismes vivants modifiés relève également de la mission d'organismes internationaux existants tels que l'Organisation mondiale de la santé animale (OIE) ou d'autres instances qui fixent des normes. Une collaboration pourrait par conséquent être fructueuse entre le Secrétariat de la Convention sur la diversité biologique et l'Organisation mondiale de la santé animale sur des questions

telles que l'évaluation et la gestion des risques, le partage de l'information, les exigences documentaires et les procédures liées aux mouvements transfrontaliers involontaires. Cet article examine les propositions clés du Protocole et met en évidence les points qui intéressent également différentes instances internationales telles que l'OIE.

Mots-clés

Analyse de risque – Biodiversité – Convention sur la diversité biologique – Mouvements transfrontaliers – Organisation mondiale du commerce – Organismes génétiquement modifiés – Organismes vivants modifiés – Protocole de Carthagène sur la biosécurité.



Protocolo de Cartagena sobre bioseguridad: interacciones entre el Convenio sobre la Diversidad Biológica y la Organización Mundial de Sanidad Animal

C. Sendashonga, R. Hill & A. Petrini

Resumen

El Protocolo de Cartagena sobre bioseguridad es un acuerdo internacional – aprobado el 29 de enero de 2000 en calidad de acuerdo adicional del Convenio sobre la Diversidad Biológica –, relativo a los potenciales efectos adversos de los organismos vivos modificados. Se centra, fundamentalmente, en los movimientos transfronterizos y, por lo tanto, es aplicable al comercio internacional. Su texto incluye disposiciones relativas a la adopción de decisiones en el ámbito de las importaciones, la evaluación y gestión de riesgos, el intercambio de información, la documentación, la creación de capacidades, la conformidad, la responsabilidad y la compensación, la sensibilización de la opinión pública y su participación, y consideraciones socioeconómicas. Vista su esfera de aplicación, pueden presentarse casos en que el comercio de organismos vivos modificados también recaiga en el ámbito del mandato de organizaciones internacionales existentes, como la Organización Mundial de Sanidad Animal (OIE) y otros organismos normativos. En consecuencia, la colaboración entre la Secretaría del Convenio sobre la Diversidad Biológica y la Organización Mundial de Sanidad Animal podría resultar de utilidad para abordar asuntos tales como la evaluación y gestión de riesgos, el intercambio de información, los requisitos relativos a la documentación y los procedimientos que deben aplicarse en el caso de movimientos transfronterizos involuntarios. En este artículo se examinan las disposiciones fundamentales del Protocolo y se subrayan los aspectos del Acuerdo de interés para la actividad de diferentes organizaciones internacionales, en particular para la OIE.

Palabras clave

Análisis de riesgos – Convenio sobre la Diversidad Biológica – Diversidad biológica – Movimiento transfronterizo – Organismo modificado genéticamente – Organismo vivo modificado – Organización Mundial del Comercio – Protocolo de Cartagena sobre bioseguridad.



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