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Ruth Mackenzie, Françoise Burhenne-Guilmin,
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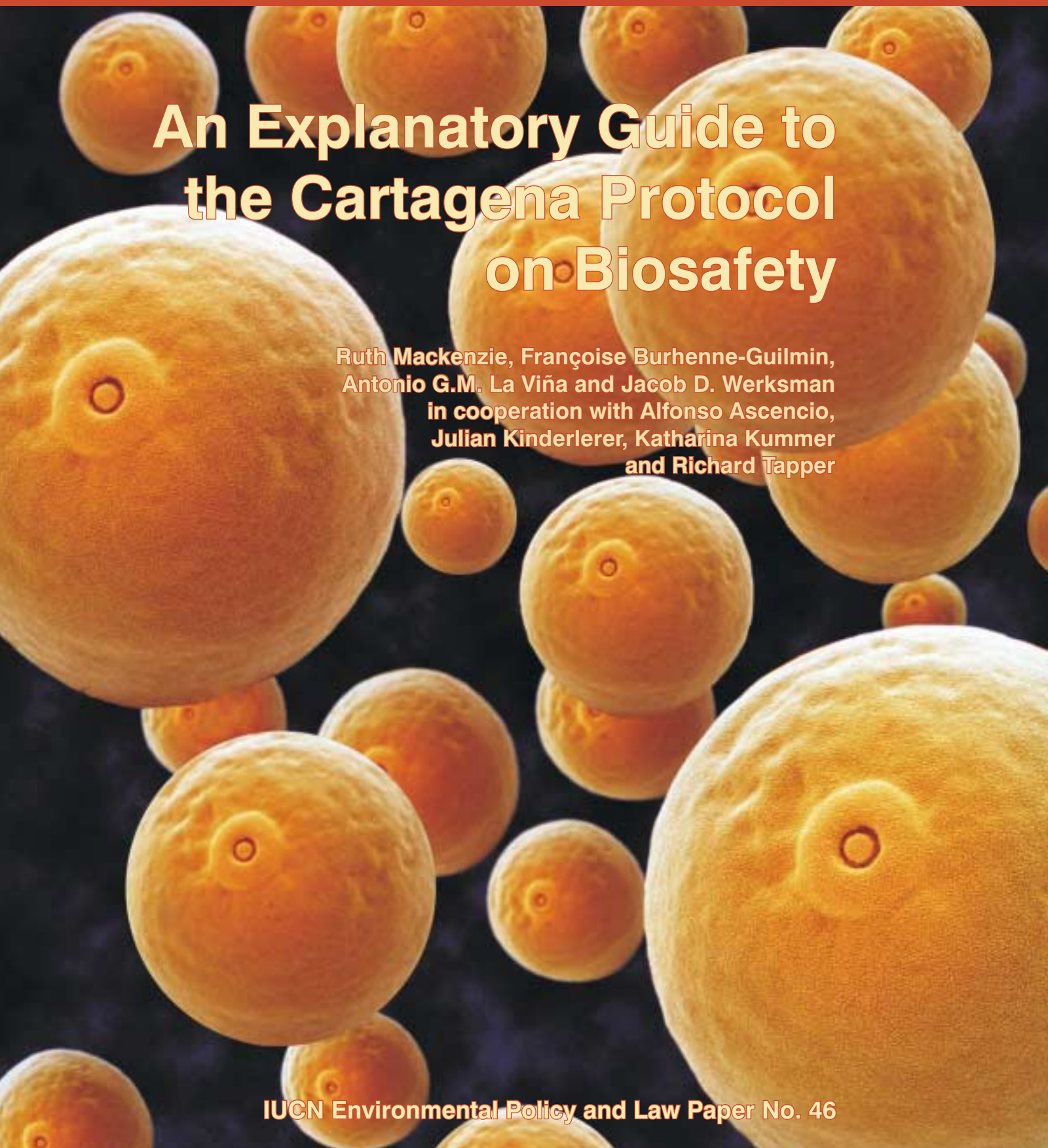

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FIELD

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The World Conservation Union

An Explanatory Guide to the Cartagena Protocol on Biosafety

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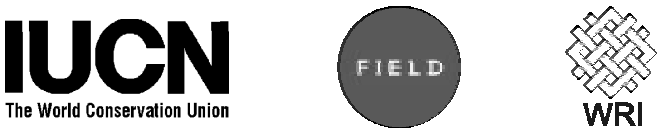

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Foreword

The Cartagena Protocol on Biosafety is one of the most important international treaties recently adopted. It marks the commitment of the international community to ensure the safe transfer, handling and use of living modified organisms. It is an historic commitment as it is the first binding international agreement dealing with biosafety, thereby addressing novel and controversial issues.

To conclude the negotiation of a treaty marks an end, but also a beginning: the beginning of an implementation process which will determine whether the results of the negotiation will, in reality, achieve the objective which originally set the negotiation process in motion. One prerequisite for the successful implementation of a treaty is an understanding of the text itself, and of its implications. In this regard, the Cartagena Protocol is a text that may well not be readily accessible to all those who will need to become involved, in one way or the other, with its implementation. We hope that this Explanatory Guide will both make the Protocol more readily accessible and prove useful as a reference work for those who are involved in its implementation.

IUCN and FIELD are pleased to present the results of a two year process of cooperation and consultation, during which they were joined by WRI. The partnership forged during the preparation of the Guide has been fruitful, constructive, and harmonious. We therefore look forward to continuing our joint efforts in this and related fields, and express our gratitude to those who made this collaboration possible.

John Scanlon, Director, IUCN-ELC
Tony Gross, Director, FIELD
Jonathan Lash, President, WRI

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Acknowledgements

The Guide is the product of a process which started early in 2001. It is the result of the collaboration of IUCN Environmental Law Centre and the Foundation for International Environmental Law and Development (FIELD), later joined by the World Resources Institute. It is also the result of a consultation process over nearly two years.

The initial draft of the Guide, prepared by a small group of authors, was the starting point for an extensive consultation process, producing at each step a refined version. The cornerstones of this consultation process were three workshops, held in September 2001, October 2001, and February 2002.

The participants in the first workshop were all familiar with the Protocol text, and had all participated in its negotiation, either as governmental delegate, or as representative of the non-governmental sector. The purpose of this first workshop was to elicit comments on the content of the Guide, in particular its accuracy, and to identify gaps and deficiencies, as well as to obtain information on some of the negotiating history.

The second workshop was aimed at obtaining comments on the content of the Guide from the perspective of its future users, and feedback on whether the text, in substance and format, facilitated the understanding of the Protocol for those who will work with it in the future. Participants were all from the Central and Eastern European region, and included individuals working in government, non-governmental organizations, and the private sector.

The final workshop considered a completed, revised and edited draft of the Guide. Emphasis was on participation from all parts of the world, in particular developing countries, and from NGOs. In order to maintain continuity, a number of participants who had participated in the first or second workshops were also invited. The workshop reviewed the draft first in plenary, then went through clusters of issues and the corresponding commentaries in working groups, with results reviewed again in plenary to complete the process.

Participants to all workshops attended in a personal capacity, and many of them continued to follow the progress of the Guide throughout the process, commenting on interim stages of the Guide by e-mail.

The "pre-final" draft of the Guide, which resulted from the comments received at the third workshop, was made available to participants at the third meeting of the Intergovernmental Committee for the Cartagena Protocol in the Hague in April 2002. It was also posted on the web sites of IUCN-ELC and FIELD in order to generate further review and comments before the text was finalized.

As a result of this process, many people have assisted in the preparation of the Guide, not only by participating in the workshops described above, but also by providing thoughtful verbal or written comments. All of the comments received were carefully considered by the authors in the preparation of the final text.

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At FIELD, Carolina Lasén Diaz, Fernando Latorre and Alice Palmer, lawyers on FIELD's Biodiversity and Marine Resources, and Trade, Investment and Sustainable Development programmes, provided significant substantive contributions throughout the preparation of the Guide and undertook a technical review during the editorial process.

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Finally, we would like to express our deep gratitude to Veit Koester, both for his advice and support throughout the preparation of this Guide and also for first raising the idea of the need for an explanatory guide to the Protocol which led us to undertake this work.

Our thanks go to all those mentioned above, and others, for their contribution to the Guide. We, however, remain responsible for any weaknesses that remain.

Ruth Mackenzie, FIELD, London
Françoise Burhenne-Guilmin, IUCN ELC, Bonn
Antonio La Viña, World Resources Institute, Washington DC
October 2002

List of abbreviations

AIA	Advanced Informed Agreement
BCH	Biosafety Clearing-House
BSWG	Ad Hoc Working Group on Biosafety
CBD	Convention on Biological Diversity
CHM	Clearing-House Mechanism – established under Article 18(3) CBD
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
COP	Conference of the Parties to the Convention on Biological Diversity
COP/MOP	Conference of the Parties serving as the meeting of the Parties to the Protocol
DNA	Deoxyribonucleic acid
EU	European Union
ExCOP	First extraordinary meeting of the Conference of the Parties
FAO	Food and Agriculture Organization of the United Nations
GATT	General Agreement on Tariffs and Trade
GEF	Global Environment Facility
GMO	Genetically Modified Organism
ICCP	Intergovernmental Committee for the Cartagena Protocol
ILC	International Law Commission
LMO	Living Modified Organism
LMO-FFPs	Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing
MEA	Multilateral Environmental Agreement
REIO	Regional Economic Integration Organization
RNA	Ribonucleic acid
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice (of the CBD)
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
TBM	Transboundary Movement
TBT Agreement	Agreement on Technical Barriers to Trade
UNCLOS	United Nations Convention on the Law of the Sea
UNCTAD	United Nations Conference on Trade and Development
UNEP	United Nations Environment Programme
WHO	World Health Organization
WTO	World Trade Organization

List of short titles of international instruments

Aarhus Convention	Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, 25 June 1998, ECE/CEP/43
Agenda 21	UN Conference on Environment and Development, UN Doc. A/CONF.151/26/Rev.1 (1992)
Basel Convention	Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, 22 March 1989, UNTS vol. 1673 p. 57
Biodiversity Convention	Convention on Biological Diversity, 5 June 1992,UNTS vol. 1760 p.79
Climate Change Convention	United Nations Framework Convention on Climate Change, 9 May 1992, UNTS vol. 1771 p. 107
Kyoto Protocol	Protocol to the United Nations Framework Convention on Climate Change, 11 December 1997, Decision 1/CP.3 of the Conference of the Parties to the Convention
Montreal Protocol	Protocol on Substances that Deplete the Ozone Layer, 16 September 1987, UNTS 1522
Rio Declaration	UN Declaration on Environment and Development, June 14, 1992, UN Doc. A/CONF.151/5/Rev.1 (1992), reprinted in 31 ILM. 876 (1992)
Rotterdam Convention	Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, 10 September 1998, UNEP/FAO/PIC/CONF/5
Stockholm Convention	Convention on Persistent Organic Pollutants, 22 May 2001, Depositary Notification C.N.531.2001, Treaties-96 of 19 June 2001
Stockholm Declaration	Declaration of the UN Conference on the Human Environment, June 16, 1972, UN Doc. A/CONF.48/14/Rev.1 (1973), reprinted in 11 ILM 1416 (1972)
Vienna Convention	Convention on the Law of Treaties, 23 May 1969, UNTS vol. 1155 p. 331

Structure and purpose of this Guide

The main goal of the Guide is to facilitate the understanding of the legal obligations of the Parties under the Cartagena Protocol on Biosafety. It is an explanatory guide, which attempts to provide an information base on the content and origin of the provisions of the Protocol. While it is hoped that the Guide will contribute to the implementation of the Protocol, it is not intended as a detailed guide on how to implement the Protocol at the national level. Rather it attempts to provide an accessible explanation of the Protocol's provisions and to identify issues which Parties may want to consider as they decide how to implement the Protocol.

The Guide begins with a brief Introduction which addresses the subject matter of the Protocol. This section provides general information on the issue the Protocol was intended to address, and the negotiation process. It also provides an overview of the Protocol's provisions, including certain cross-cutting issues. Finally, it identifies certain other international agreements and guidelines of relevance to biosafety. It may be noted here that the "Implementation Tool kit" reproduced in the Supplementary Materials at the end of the Guide also provides a useful overview or checklist of the provisions of the Protocol from an implementation perspective. This "Tool kit" was adopted as part of a recommendation on capacity-building by the Intergovernmental Committee for the Cartagena Protocol (ICCP), the body which was established to undertake preparatory work for the first meeting of the Parties to the Protocol after it enters into effect.

The main section of the Guide provides a "commentary" to each of the Protocol's provisions. This section addresses each Article and Annex of the Protocol in turn and analyzes and explains its provisions. The emphasis here is on outlining the main provisions of the Protocol, as well as highlighting ambiguities or issues which are left unresolved in the text, providing information on possible interpretations, and identifying issues that Parties may want to consider as they develop national implementation measures. Where there are ambiguities in the text, we have tried to provide some guidance as to possible interpretation based upon the provisions of the Protocol, in particular its objective as set out in Article 1. In addition, in a number of instances we have made reference to the negotiating history of the Protocol, and in this regard we were able to draw on advice and inputs from many of those who were closely involved in the negotiations. Of course, a Guide of this type does not purport to provide an authoritative interpretation of the text of the Protocol, and other interpretations are possible. In addition, specific interpretations may be agreed and adopted by the Parties to the Protocol in the future as they consider its provisions further.

When the Protocol was negotiated, States agreed that work on some issues should be left to further negotiation and agreement after the Protocol comes into effect. These include, for example, Article 18(2)(a), Article 27 and Article 34. In these cases, we have given an indication of the work undertaken on these issues by the ICCP. Of course, there are other provisions of the Protocol which the meeting of the Parties may address and provide further guidance on in due course.

The Appendix to the Guide addresses the relationship between the Cartagena Protocol and relevant World Trade Organization Agreements. It was decided to analyze this relationship in detail in an Appendix given the range and complexity of questions that it raises. The potential relationship between the Protocol and relevant WTO Agreements was a contentious issue in the negotiations. The analysis in the Appendix is intended to give a more detailed overview of the types of issues that may arise in assessing this inter-relationship. It does not attempt to, and can not, prejudge the outcome of any particular question or dispute that may arise as to trade measures that a State may impose in relation to LMOs.

The bibliography provides a list of selected writings on the Protocol, largely from academic books and journals.

Finally, we have provided certain supplementary materials for ease of reference at the end of the Guide. These include:

- 2000 Cartagena Protocol on Biosafety – The provisions of the Protocol are reproduced throughout the Guide, but the full text is provided here for ease of reference.
- 1992 Convention on Biological Diversity – As explained in the Introduction, , the 1992 Convention is the parent Convention of the Protocol and contains a number of provisions which remain directly applicable or relevant to its implementation.

- Decision II/5 of the Conference of the Parties to the Convention on Biological Diversity – This decision provided the mandate for the negotiation of the Protocol.
- Decision EM-I/3 of the Conference of the Parties to the Convention on Biological Diversity – In this decision the Conference of the Parties to the Convention on Biological Diversity adopted the Cartagena Protocol on Biosafety. The decision also makes provision for interim arrangements, including preparatory work by the ICCP and the establishment of a roster of experts to aid capacity-building.
- ICCP recommendation 3/5, Annex III Implementation tool kit – As noted above, this tool kit, adopted as part of an ICCP recommendation, provides a useful checklist of obligations of Parties to the Protocol.

Introduction

1. The aim of this Introduction is:
   - to provide succinct information on the history of the Protocol and on its status;
   - to introduce briefly the subject addressed by the Protocol;
   - to address cross-cutting issues that could not appropriately be summed up in the analysis of single articles (e.g. human health); and
   - to give an overview of the Protocol's provisions, its implications and the international context in which it will operate.

2. The Introduction is structured as follows:

   I Origin and history

   II Status and interim measures

   III The issue: biosafety

   IV Cross-cutting issues

   V Overview of the Protocol

   VI Implications of the Protocol

   VII Other relevant international instruments

I. Origin and history

3. The Convention on Biological Diversity (CBD) was adopted in May 1992 in Nairobi, and was opened for signature in Rio de Janeiro on 5 June 1992 at the UN Conference on Environment and Development. It entered into force on 29 December 1992, and as of 20 August 2002 has 185 Parties. Its objectives are:
   - the conservation of biological diversity,
   - the sustainable use of its components, and
   - the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

4. The treaty is a landmark in the field of environment and development. It takes a comprehensive, rather than sectoral, approach to the conservation of the biological diversity of the planet and the sustainable use of bioogical resources. And it also encompasses related socio-economic issues, such as the sharing of benefits from the use of genetic resources and access to technology, including biotechnology.

5. The CBD contains three provisions directly related to living modified organisms (LMOs). One (Article 19(3)) has generated the negotiations of the Cartagena Protocol (see below paragraphs 10-11). The two others (Article 8(g) and 19(4) contain obligations applicable to all Parties to the CBD independently of their becoming Parties to the Protocol.

6. Article 8(g) deals with domestic measures generally. It requires Parties to regulate, manage or control risks associated with LMOs resulting from biotechnology which are likely to have impacts on the conservation and sustainable use of biological diversity, taking also into account the risks to human health. Article 19(4) considers transfers of LMOs from one Party to another. It requires each Party to provide information on domestic regulations concerning use and safety to any other Party to which a LMO is provided, as well as any available information on the adverse effects which the introduction may have for this Party.

7. The term "living modified organism" used in the Protocol stems from its use in the CBD, in particular Article 19(3), which is at the origin of the Protocol. The content of the term was, however, narrowed by CBD COP Decision II/5 (which set the mandate for the Protocol negotiations) to those LMOs resulting from modern biotechnology (see Box 15).

8. While the CBD is comprehensive, it also provides the possibility for the Conference of the Parties (COP) to the CBD to negotiate additional annexes and protocols, to better implement its objectives.

9. Article 28 of the CBD mandates Parties to cooperate in the formulation and adoption of protocols and sets out basic rules as to their consideration and adoption. It does not specify which subject matter covered by the CBD might be addressed by future protocols. Article 28 therefore leaves it to the Parties to the CBD to decide (through the CBD COP), in the course of the implementation of the CBD, whether and on which subject a protocol would be a useful additional tool in the achievement of the objectives of the CBD.

Box 1. What is a protocol?

A Protocol is a binding international instrument, separate from, but related to, another treaty.

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

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

In addition, the parent treaty usually defines basic institutional and procedural links between the two instruments, for example it may indicate that provisions in the treaty itself (e.g. related to dispute settlement) will also apply to any protocol adopted under it.

The protocol itself may, however, add further links to the parent treaty, for example by designating mechanisms existing under the treaty (e.g. the Conference of the Parties) also to serve the protocol. This is the case for the Cartagena Protocol (see commentary to Articles 29–31).

10. However, in Article 19(3), the negotiators of the CBD singled out living modified organisms for special treatment. Article 19(3) provides:

> The 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 LMO resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity.

11. The content of Article 19(3) of the CBD was contentious, as views differed on the need for internationally agreed rules on biosafety. During the negotiation of the CBD, the debate centred on two alternatives: (i) language making the development of a protocol on biosafety mandatory; or (ii) language not explicitly calling for a protocol, but instead requiring the Parties to consider the need for one. The latter view prevailed.

12. In 1994, at the first meeting of the Conference of the Parties to the CBD in Nassau, Bahamas, two meetings were authorized to consider the need for and modalities of a protocol on biosafety. Accordingly, a panel of experts met in Cairo in May 1995, and was followed by an open-ended (i.e. open to all Parties to the CBD and to observers) Ad Hoc Group of Experts on Biosafety which met in Madrid in July 1995. The large majority of delegations present at the Madrid meeting favoured the development of a protocol on biosafety. But while there was general agreement that certain issues, such as an advance informed agreement procedure, should be included in a protocol, other possible elements, such as liability and compensation and socio- economic considerations, were the subject of considerable disagreement.

13. At its second meeting in 1995 in Jakarta, Indonesia, the COP considered the results of the experts' work. After lengthy debate, the COP decided to establish an open-ended Ad Hoc Working Group on Biosafety (BSWG) to elaborate a protocol on biosafety for consideration by the COP, and provided it with the following terms of reference (Decision II/5):

Box 2. The road to the Cartagena protocol on biosafety (and beyond)

- Phase 1: 1970s and 1980s (problem identification)
- Phase 2: late 1980s and beginning of 1990s (framework development)
- Phase 3: 1989–1992 (Biodiversity Convention negotiating process)
- Phase 4: 1992–1995 (issue definition)
- Phase 5: 1996–2000 (negotiation)
- Phase 6: 2000–entry into force (interim period)

i. The Open-ended Ad Hoc Working Group should be composed of representatives, including experts, nominated by Governments and regional economic integration organizations.

ii. The Open-ended Ad Hoc Working Group shall, in accordance with operative paragraph 1 of the present decision:

(a) Elaborate, as a priority, the modalities and elements of a protocol based on appropriate elements from Sections I, II and III, paragraph 18 (a),[1] of Annex I of the report of the Open-ended Ad Hoc Group of Experts on Biosafety;

(b) Consider the inclusion of the elements from Section III, paragraph 18 (b),[2] and other elements, as appropriate;

iii. The development of the draft protocol shall, as a priority:

(a) Elaborate the key concepts and terms that are to be addressed in the process;

(b) Include consideration of the form and scope of advance informed agreement procedures;

(c) Identify relevant categories of LMOs resulting from modern biotechnology.

iv. The protocol will have to reflect that its effective functioning requires that Parties establish or maintain national measures, but the absence of such national measures should not prejudice the development, implementation and scope of the protocol.

v. The protocol will take into account the principles enshrined in the Rio Declaration on Environment and Development and, in particular, the precautionary approach contained in Principle 15 and will:

(a) Not exceed the scope of the CBD;

(b) Not override or duplicate any other international legal instrument in this area;

(c) Provide for a review mechanism;

(d) Be efficient and effective and seek to minimize unnecessary negative impacts on biotechnology research and development and not to hinder unduly access to and transfer of technology.

vi. The provisions of the CBD will apply to the protocol.

vii. The process will take into full account the gaps in the existing legal framework identified through analysis of existing national and international legislation.

viii. The process shall be guided by the need for all Parties to cooperate in good faith and to participate fully, with a view to the largest possible number of Parties to the CBD ratifying the protocol.

ix. The process will be carried out on the basis of the best available scientific knowledge and experience, as well as other relevant information.

x. The process of developing a protocol should be conducted as a matter of urgency by an open-ended ad hoc group, which will report on progress to each subsequent meeting of the Conference of the Parties. The Open-ended Ad Hoc Working Group should endeavour to complete its work in 1998.[3]

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1 18(a) Consensus was reached on the following items:
- (i) All activities related to LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, including research and development, handling, transfer, use and disposal.
- (ii) Transboundary movement of LMOs resulting from modern biotechnology and other transboundary issues, including unintended movement of LMOs resulting from modern biotechnology across national boundaries and their potential adverse effects.
- (iii) The release of LMOs resulting from modern biotechnology in centres of origin and genetic diversity.
- (iv) Mechanisms for risk assessment and risk management.
- (v) Procedure for advance informed agreement.
- (vi) Facilitation of exchange of information from all publicly available sources, including to local communities.
- (vii) Capacity-building in all the aspects required for biosafety.
- (viii) Implementation mechanisms.

2 18(b) The following issues, though not enjoying consensus, were supported by many delegations:
- Socio-economic considerations
- Liability and compensation
- Financial issues.

3 Decision II/5, UNEP/CBD/COP/2/19.

14. Decision II/5 is important as it set the mandate of the BSWG and provided guidance to the negotiators on specific points. In particular, it modified the content of the term 'LMO' provided in Article 19(3) of the CBD by limiting it to those resulting from 'modern biotechnology' rather than from 'biotechnology'. (For further discussion of this issue, see Box 15)

15. The BSWG was chaired by Veit Koester of Denmark. Six meetings of the BSWG were held, between July 1996 and February 1999. After four meetings, by February 1998, it became clear that the goal set by the COP for the BSWG to complete its work in 1998 was not feasible. Two further meetings were authorized. After the fifth meeting, in August 1998, a set of 43 draft articles of the Protocol had been prepared, but 15 of these remained entirely in 'square brackets', indicating a lack of agreement on their inclusion in the Protocol, and another 650 square brackets remained throughout the text, enclosing particular words or phrases on which agreement was still elusive.

16. It is against this background that the sixth and final meeting of the BSWG was held in Cartagena, Colombia, in February 1999, which was to be immediately followed by the first Extraordinary Meeting of the Conference of the Parties (ExCOP) to the CBD. Progress was made on some issues. Towards the end of BSWG 6, the Chair put forward a draft consolidated text of the Protocol and proposed to BSWG that this be adopted and forwarded to ExCOP.[4] This was a 'clean text' – i.e. it contained no provisions in square brackets. Instead, the Chair had attempted to find compromise solutions to outstanding areas of disagreement. The text was forwarded to the ExCOP. However, in spite of much discussion and negotiation, by the end of the ExCOP meeting the Parties to the CBD had failed to reach agreement on the text of the Protocol, and the ExCOP was formally suspended.[5]

17. During the course of the meetings in Cartagena, five distinct negotiating groups of countries had emerged with different views on the outstanding core issues. They were:

    The Miami Group: Argentina, Australia, Canada, Chile, Uruguay, USA

    The Like-minded Group: the G77 countries (less the three members in the Miami Group)

    The European Union

    The Central and Eastern Europe Group

    The Compromise Group: Japan, Korea, Mexico, Norway and Switzerland, later joined by Singapore and New Zealand.

    These groups played a significant role in the negotiations during and after the ExCOP.

18. Following the suspension of the ExCOP, informal consultations by the Chair of the ExCOP, Minister Juan Mayr of Colombia, took place in order to ascertain whether there was a political will to resume negotiations. This being the case, two informal meetings took place in Vienna (September 1999) and Montreal (January 2000). These negotiations focused on the remaining core issues which were crucial to the overall agreement of the Protocol. At this stage, these core issues were: the scope of the Protocol; LMOs intended for direct use as food or feed, or for processing (LMO-FFPs); the precautionary principle; identification and documentation requirements; and the relationship between the Protocol and other international agreements, notably the World Trade Organization (WTO) Agreements. Other aspects of the Protocol remained untouched after BSWG 6.

19. The final negotiation of these core issues took place at the resumed session of the ExCOP which immediately followed the January 2000 informal meeting in Montreal. Of a highly political nature, with the participation of more than thirty Ministers, the final compromise on core issues was struck during the night of 28/29 January 2000. The Protocol was adopted at 5 a.m. on 29 January 2000.[6]

20. The Protocol contains important new rights and obligations for its Parties, relating to the transboundary movement, handling and use of LMOs. Its central operational provisions create an Advance Informed Agreement

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4 UNEP/CBD/ExCOP/1/2, Appendix 1.

5 Decision EM-I/1, UNEP/CBD/ExCOP/1/3, Annex 1.

6 For further information on the negotiations, see for example Earth Negotiations Bulletin (http://www.iisd.ca/linkages); Bail, C. Falkner, R. and Marquard, H. (eds.), *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?* (Earthscan, 2002); Newell, P. and Mackenzie, R. "The Cartagena Protocol on Biosafety: Legal and Political Dimensions", *Global Environmental Change,* Vol.10 (3) (2000); Gupta, A. "Governing Trade in Genetically Modified Organisms: the Cartagena Protocol on Biosafety", *Environment* 42:4 (2000), 23–33; and Falkner, R. "Regulating biotech trade: The Cartagena Protocol on Biosafety" *International Affairs* 76:2 (2000), 299–313.

Box 3. 1996–2000. The negotiation phase

1. Elements definition phase
   - 1996 (July, 5 days) First meeting of the BSWG
   - 1997 (May, 5 days) Second meeting of the BSWG
2. Drafting and negotiation phase
   - 1997 (October, 5 days) Third meeting of the BSWG
   - 1998 (February, 7 days) Fourth meeting of the BSWG
   - 1998 (August, 14 days) Fifth meeting of the BSWG
   - 1999 (14-24 February, 9 days) Sixth meeting of the BSWG and ExCOP (Extraordinary Conference of the Parties)
3. Final negotiation phase
   - 1999 (July) Informal consultations - to consider whether to resume negotiations
   - 1999 (September) Informal consultation meeting - paving the way for resolving differences
   - 2000 (January) Informal consultations followed by the resumed ExCOP (24-29 Jan) to resolve remaining core issues and adopt the Protocol.

(AIA) procedure, whereby an exporter wishing to export certain categories of LMOs to a country for the first time must notify the Party of import in advance and provide certain information relating to the LMO. The Party of import then has an opportunity to examine this information and may decide to accept or reject the import, or attach conditions to it, based on a risk assessment. The Protocol also contains provisions on information exchange, capacity-building and financial resources. These provisions are described in more detail below (see Section V).

II. Status and interim measures

21. The Protocol was opened for signature at the fifth meeting of the CBD COP in Nairobi, Kenya in May 2000 and 68 Parties to the CBD signed. Thereafter, the Protocol was open for signature at UN Headquarters in New York until June 2001. Altogether, 103 Parties have signed the Protocol. Parties to the CBD which have not yet signed the Protocol may accede to it. Expectations appear to be high at present that the Protocol may enter into force in 2003. Entry into force requires 50 ratifications (see Article 37).

22. In the interim, the Extraordinary Meeting of the COP in January 2000 established an Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), to undertake preparatory work for decisions to be taken at the first meeting of the Parties,[7] which will take place shortly after the Protocol enters into force (see Article 29). The President of the ICCP is Ambassador Philémon Yang of Cameroon. CBD COP 5 adopted a decision regarding the work plan and budget of the Intergovernmental Committee.[8] The CBD COP requested countries to designate a national focal point for the ICCP and to inform the Executive Secretary of the CBD accordingly.

23. ICCP held its first meeting in Montpellier, France in December 2000, its second meeting in Nairobi in October 2001 and a third meeting in The Hague in April 2002. At the end of these meetings, considerable progress had been made in preparing for the tasks and decisions of the first meeting of the Parties to the Protocol.

III. The issue: biosafety

A. Selective breeding and genetic modifications

24. Throughout human history farmers have used selective breeding to improve crops and stock by breeding from the plants or animals that had qualities they wanted to strengthen. The deliberate retention of the best of the agricultural production for future use as seed for sowing, or animals for breeding, has meant that quality has been continuously enhanced over the ages. In this way, farmers have for centuries developed animals and crops for

7 Decision EM-I/3, UNEP/CBD/ExCOP/1/3, Annex.

8 Decision V/1, UNEP/CBD/COP5/23, Annex III.

desired characteristics, such as resistance to disease, or ability to cope better with specific climatic and environmental conditions, and for increased production.

25. In addition, biological fermentation processes have been used for centuries to process food in order to improve taste, palatability and safety, and to increase the period for which foods may be stored. Examples include the production of yoghurts and cheeses from milk, fermentation of grains to produce beer, wine production, and the use of yeast in bread making.

26. The selective breeding techniques used by farmers, and more recently by specialist crop and animal breeders, rely on the genetic variation already present in the population, which includes mutations that occur spontaneously in nature. These techniques have been responsible for the development of all the major crops and animals used in farming today, and continue to be of central importance in agriculture. Commercial chickens, for example, have been selected over about 50 generations for growth rate and they now grow more than four times faster than the original breeds.[9]

27. Breeding processes may, in some cases, overcome natural barriers in that new varieties can be made through human intervention in ways that may not easily happen naturally. Plants that are sexually compatible, but which would not normally come into contact for physical reasons, can successfully be cross-pollinated. In addition, vegetative propagation of many varieties enables production of disease free plants which can then be used in agriculture.

28. Genetic modification, which is also referred to as 'genetic engineering', uses a variety of methods to isolate single genes from one or more micro-organisms, plants or animals and insert them into the genetic material of the cells of another. These methods are collectively termed '*in vitro* nucleic acid techniques', and have been developed since the 1970s. Through genetic modification, genes are transferred and modified in ways that are not possible in nature, i.e. between different species and between animals and plants and micro-organisms. Once inserted, these genes may be transferred to offspring of the modified individual through normal reproductive processes. Box 4 describes the historical background to the development of these techniques, and Box 18 outlines the stages in making a new LMO using insertion of genetically modified ('recombinant') DNA.[10]

Box 4. History[11]

The knowledge on which the techniques of genetic modification are based dates from the 1950s, when James Watson, Francis Crick, Maurice Wilson and Rosalind Franklin discovered the structure of DNA, the now-familiar double helix of nucleotides that bears the genetic information for the biosynthesis of proteins like enzymes, certain hormones (e.g. insulin) and whole parts of the body (e.g. nails, hair). This new understanding opened up the possibility that the genetic coding of organisms could be altered to give them new characteristics that natural evolution or selective breeding could not produce.

When, in the 1970s, it became possible to isolate individual genes, refashion them and copy them in cells, huge commercial possibilities opened up. Ways of applying this new technology to medicine were developed quite rapidly. The technology could also be used in industry to produce new fine chemicals and pharmaceuticals using living organisms as "factories". Applying these methods successfully to plants took longer; the first genetically altered whole food, Flav'r Sav'r tomatoes came on the market in 1994 in the USA. Since then the growth in the number and range of genetically modified products has steadily increased. As the general public has become more aware of the impact of these discoveries, concerns over the use and safety of genetic modification have also been raised.

9 The Royal Society "The Use of Genetically Modified Animals" May 2001, Science Advice Section. See http://www.royalsoc.ac.uk/files/statfiles/document-139.pdf.

10 DNA is deoxyribonucleic acid, which is present in almost all living cells and contains information coding for cellular structure, organisation and function.

11 Based on: "Genetic modification: an overview for non-scientists", Report of the New Zealand Royal Commission on Genetic Modification, Wellington, 2001, p.363.

29. Genetic modification and selective breeding differ in important ways:

- Selective breeding selects for combinations of genes from within the natural pool of genetic variation in the crops or animals concerned, and therefore enables selection and breeding for traits that may be influenced by several or many separate genes, as well as traits under the control of single genes. Breeding normally takes place between individuals of the same species, or in some cases, between closely related species, and if necessary, may apply techniques to overcome some barriers to breeding between the individuals concerned. No modifications are made to the genetic material of the individuals concerned.
- In genetic modification, scientists isolate single genes that control particular characteristics, copy them with modifications and splice them with other control elements from genes to form a 'gene construct' (see Box 16) so that they work well within the target organism, then insert them, usually in a random position, within that organism. The techniques used for gene modification involve steps that take place *in vitro*, that is they take place outside of any organism. The use of genetic modification techniques allows very large evolutionary barriers to be crossed, and for one or a few genes to be moved between organisms, including organisms which have not been known to have genetic contact.[12]

30. The commercial use of genetically modified organisms (GMOs) in agriculture is currently limited almost exclusively to different varieties from four crop species: soybeans, maize (corn), oilseed rape (canola), and cotton. In 2001, 99% of all GMO crop area world-wide was grown in four countries:[13] 68% of the crop area planted with GMOs was in the USA, 22% in Argentina, 6% in Canada, and 3% in China. World-wide, 46% of the total area that was sown with soybeans was sown with genetically modified (GM) soybean varieties, and for maize 7% of the total crop area was sown with GM maize varieties.[14]

31. Since 1994 the number of GMOs that may be marketed as human food has increased. For example, up to 52 approved crop varieties (from 13 different species) in the USA;[15] 43 (six different species) in Japan;[16] 12 (five different species) in Australia and New Zealand;[17] five (two different species) in the EU;[18] and four (three different species) in South Africa.[19] While only a few approved GMOs may be used directly as food, products from approved GMOs, especially flour from GM maize, and oils extracted from GM soya and GM oilseed rape, are used in the production of processed foods, generally mixed with products derived from non-GMOs.

B. Genetic modification: the debate

32. Genetic modification is only one of the techniques of modern biotechnology (used in its general sense, rather than in the specific way modern biotechnology is defined in the Protocol: see Article 3(i)). Others – for example, the use of tissue culture techniques – differ from genetic modification in that they do not involve the modification of individual genes, and are not regarded as controversial. It is thus important to note that while genetic modification is a contested issue, the debate does not relate to these other techniques of modern biotechnology.

33. Agenda 21, adopted at the 1992 Conference on Environment and Development, states that modern biotechnology "promises to make a

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12 Wright, S. *Molecular Politics – Developing American and British Regulatory Policy for Genetic Engineering 1972–1982*, (University of Chicago Press, 1994), p.76.

13 James, C. *Global Review of Commercialized Transgenic Crops: 2001*, ISAAA Briefs No. 24, p.6.

14 James, C. *Global Review of Commercialized Transgenic Crops: 2001*, ISAAA Briefs No. 24, p.15.

15 U.S. Food and Drug Administration/Center for Food Safety & Applied Nuturition/Office of Food Additive Safety, March 2002: List of completed Consultations on Bioengineered Foods, available at: http://vm.cfsan.fda.gov/~lrd/ biocon.html

16 Japanese Ministry of Health, Labour and Welfare/Department of Food Safety, Oct 2002: List of the products whose safety assessments were completed by MHLW, available at: http://www.mhlw.go.jp/english/topics/food/ sec01.html

17 Food Standards Australia New Zealand/Te Mana Kounga Kai – Ahitereiria me Aotearoa, as of September 2002: Genetically modified or GM Foods – Current Applications and Approvals, available at: http://www.foodstandards. gov.au/whatsinfood/gmfoods/gmcurrentapplication1030.cfm

18 Belgian Biosafety Server, April 2001: Novel Food Notifications persuant to Article 5 of Regulation (EC) N° 258/97 of the European Parliament and of the Council, available at: http://biosafety.ihe.be/NF/Gmfoods/ Notifications_art5_258_97.html

19 South African National Department of Agriculture, 2002: Genetically modified organisms that have been cleared for commercial release and/or for food and animal feed only http://www.nda.agric.za/geneticresources/AnnexureB.htm

significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improve supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes". As illustrated in Box 5, genetic modification has already numerous scientific and some commercial applications and is likely to be further developed due to high expectations of its potential in healthcare, agriculture, industrial production, and environmental protection.

34. There are, however, also serious concerns about genetic modification. They range from ethical considerations to potential risks to human health and the environment, and encompass also a number of socio-economic issues. These concerns are heightened given the relatively small amount of experience with the application of the technology to date, and the fact that any adverse effects may only be manifested over the long term. A vigorous, and often polarized, debate is taking place, centred on potential risks and benefits of genetic modification.

35. Advocates argue that application of genetic modification can help to provide:

- food needs of the future;
- better foods of higher quality;
- foods from which allergenic or toxic substances have been removed;
- renewable energy crops e.g. biomass grown for conversion to energy (e.g. willow) and biofuel (biodiesel and bioethanol) which can replace fossil fuels and mineral oils;
- bulk chemicals, mainly oils, derived from linseed, oilseed rape and sunflowers;
- speciality chemicals such as pharmaceuticals, cosmetics and dyes;
- speciality biocomposites such as biologically derived fibres (mainly derived from hemp and flax); lignocellulosic glues, dispersants, fertilizers, and additives; bioplastics, paper and board such as those derived from starches;[20]
- better health care possibilities;
- new pharmaceuticals better targeted towards particular diseases in particular patients;
- chemicals produced with few environmental pollutants in a more controlled fashion;
- beneficial changes to agricultural and industrial practice, including diminution of environmental pollution; and
- significant environmental benefits, including new possibilities for monitoring and controlling environmental effects.

36. On the other hand, critics argue that:

- modern biotechnology transcends that which humans should be doing;
- there is currently little evidence to support the claim of increased agricultural yield;
- many widely promoted examples of GM applications have failed due to the limitations inherent in the technology and the complexity of the problems tackled, e.g. production of allergen-free rice; fast-growing pigs with additional hormone genes; and micro-organisms designed to digest soil contaminants;
- from a health point of view, there is currently insufficient information regarding toxicity and allergenicity of food products derived from GMOs;
- the environmental consequences of the release of GMOs into the environment are likely to be significant, in particular the effects on biological diversity;
- deleterious changes to agricultural and industrial practices, including an increase in environmental pollution, may be so severe that they should not be permitted;
- the socio-economic consequences are potentially severe, e.g. through displacement of cash crops or traditional crops and disruption of small scale farming systems that are prevalent in developing countries;
- the small number of companies involved in agricultural biotechnology, and the grouping of seed-stock and chemical control agents in these companies is unacceptable; and
- patents on living organisms, genes and/or genetic resources are unacceptable, in particular:

[20] The Royal Society, Non-Food Crops: Response to the House of Lords Select Committee Inquiry on Non-Food Crops, June 1999. See http://www.royalsoc.ac.uk/files/statfiles/document-31.pdf

Box 5. Examples of genetic modification

GM bacteria

Possibly the most important area of genetic modification, albeit in containment, is that of single-cell organisms modified to act as chemical factories for the production of food additives (including flavour enhancers) and fine chemicals. In 1997, the U.S. Environmental Protection Agency approved the first genetically engineered bacteria for agricultural use. The bacterium, a strain of *Rhizobium meliloti*, contained genes from five different species and was genetically altered to enhance its ability to provide nitrogen to alfalfa plants on farmland.[21]

GM agricultural crops

One of the most prominent developments of genetic modification technology has been the creation of transgenic agricultural crop varieties. Many millions of hectares of commercial transgenic crops are grown annually, although it is impossible to obtain exact figures as official data are not always available. In 2001 alone there were 35.7 million hectares of GM crops grown in the United States, 3.2 million hectares in Canada, 11.8 million hectares in Argentina and at least 1.5 million hectares in China.[22] From the two traits currently used, herbicide-tolerant crops are grown on 77% of the area, crops producing the Bt-toxin on 15%, "stacked" varieties producing Bt-toxin and showing herbicide-tolerance on 8%. Most of the harvest is used as animal feed.

Many other traits have been inserted into agricultural crops but are grown on a small scale or have not yet been commercialized. Papaya has been modified to provide resistance to papaya ringspot virus.[23] Rice yellow mottle virus attacks rice in Africa – modern biotechnology has produced a rice resistant to the virus.[24] Vaccines against diseases of the gastro-intestinal tract have been produced in bananas and potatoes.[25]

GM Trees

Biotechnology companies have linked up with key players in the industrial forest sector to support research that will increase tree growth rates, modify wood structure, alter trees' reproductive cycles, improve tolerance to certain herbicides and even store more of the gases that are responsible for global warming. While forest-related biotech research is still in its infancy compared with agriculture, field trials of GM trees have proliferated around the world. Recent research shows that, since 1988, there have been 184 GM tree field trials globally. More trials have been conducted with poplar than any other species due to its popularity as a pulp and paper species. The U.S. has released the largest number of GM trees via field trials, with 74% of the world-wide total.[26]

GM Animals

The first GM animal was a mouse,[27] which was developed in early 1988, when the Harvard Oncomouse was patented in the USA. The technology has been applied during the 1990s to some mammals, including cattle, pigs, sheep,[28] and mice.[29] It has also been applied to poultry. The creation and use of GM animals continues to increase. In Great Britain in 2000 there were 581,740 procedures in which GM animals were used or bred, 14% more than in 1999. Around 99% of these involved mice.[30]

GM Fish

Commercial aquaculture has made use of GM technology and there is also specialist interest for aquarium species. The Atlantic and Pacific salmon has received most media attention, particularly those that contain an

Cont.

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21 Van Aken, J. *Genetically engineered bacteria: U.S. lets bad gene out of the bottle,* Greenpeace report (January 2000).

22 James, C. *Global Review of Commercialized Transgenic Crops: 2001*, ISAAA Briefs No. 24, p.17.

23 Gonsalves, D. "Annual Review of Phytopathology" (1998) 36: 415-437.

24 Pinto, Y. M. *et al*. "Nature Biotechnology" (1999) 17: 702-707.

25 Thanavala, Y. *et al*. "Proceedings of the National Academy of Sciences of the USA" (1995) 92(8): 3358-3361.

26 Asante-Owusu, R. *GM technology in the forest sector.* WWF International, Gland (1999).

27 Gordon J.W., Ruddle F.H. " Integration and stable germ line transmission of genes injected into mouse pronuclei", *Science* (1981) 214:1244–1246.

28 Hammer R.E., Pursel V.G., Rexroad Jr., C.E. *et al.* "Production of transgenic rabbits, sheep and pigs by microinjection", *Nature.(* 1985) 315:680–683.

29 Simons J.P., McClenaghan M., Clark A.J. "Alteration of the quality of milk by expression of sheep betalactoglobulin in transgenic mice", *Nature* (1987) 328:530–532.

30 The House of Lords Select Committee on Animals in Scientific Procedures, Report July 2002. Available at: http://www.publications.parliament.uk/pa/ld200102/ldselect/ldanimal/150/1500

Box 5. Examples of genetic modification (cont.)

additional gene for growth hormone production and an anti-freeze gene. These fish have shown three-fold growth rate increases and potential to exploit colder waters. Reports indicate that transgenic salmon have also displayed severe deformities.[31]

GM Insects

The fruitfly *Drosophila melanogaste*r was one of the first organisms to be genetically engineered over 20 years ago, and has been regularly used in medical and scientific research.[32] The genetic modification of other insects has begun only recently. For instance, researchers are trying to create mosquitoes engineered not to host the malaria virus.[33]

- it is important that farmers are able to keep seed from one season to the next;
- intellectual property claims on gene or nucleic acid sequences without a true invention being made should not be permitted.

C. Genetic modification and biological diversity

37. Against this background, specific concerns about genetic modification have emerged in relation to biological diversity conservation.

38. Advocates of the application of genetic modification argue that it could result in benefits for biodiversity and the broader environment, suggesting, for example, that the effects of genetic modification could include:

- better agricultural efficiency, which could reduce the need for agricultural lands, and through this, could reduce the pressure for conversion to agriculture of forests and other ecosystem types important for biological diversity;
- use of plants engineered to produce pesticides internally could lead to reduced application of chemical pesticides;
- use of micro-organisms in industrial processes, for example in fuel and plastic production, could lead to a reduction in the use of chemicals.

39. However, a number of concerns regarding the effects of GMOs on biodiversity have also been raised. At a general level, it has been suggested that GMOs released into the environment may pose similar types of risks to those presented by invasive alien species. In relation to deliberate release (for example, for the field-testing or commercial growing of GM crops, or the release of GM fish in aquaculture or mariculture projects), concerns about the effects of GMOs on biological diversity include, for example:

- the potential dispersal of the organism in the environment – for example through invasiveness or enhanced competitiveness;
- the potential transfer of the inserted genetic material (and related characteristics) to other organisms – for example through cross-pollination;
- potential impacts on non-target species – for example some studies have suggested that crops modified to be resistant to insect pests may also have adverse effects on beneficial insects and birds;
- potential impacts on soil bacteria and the nitrogen cycle; and
- indirect effects on the environment – for example where the impacts arise from changed agricultural practices associated with the management of a GM crop rather than from the GM crop itself.

40. In addition, socio-economic considerations related to biological diversity conservation are a subject of concern. The lifestyles, livelihoods and cultures of traditional and indigenous communities, rural communities, and others may be directly or indirectly affected.

41. Reports and events have documented these risks and exemplified them in specific cases

[31] Royal Society of Canada. *Elements of precaution: Recommendation for the regulation of food biotechnology in Canada* (Ottawa, 2001).

[32] Rubin, G. and Spradling, A. (1982) "Genetic transformation of *Drosophila* with transposable element vectors", *Science*; 218:3448–3453.

[33] Zitner, A. "Splicing the sting out of bugs", *LA Times,* (April 9, 2000) 10–22.

over the past few years. For instance, a recent report of the European Environment Agency[34] indicates that GM and non-GM crops will intermingle their genetic materials "at higher frequencies and at greater distances than previously thought" and considers the significance of pollen-mediated gene flow from six major crop types that have been genetically modified.

D. The challenge: regulating for biosafety

42. As a result of the debate outlined above, there have been increasing policy discussions on how to regulate the application of genetic modification techniques at the national level and a number of national regulatory frameworks have been established. As activities involving the technology expanded, and in particular as actual and potential commercial use increased, the scope of national regulations tended to expand. Designing frameworks for GMO regulations has not been easy, as the main challenge was perceived to be establishing an appropriate balance between potentially important technological benefits and appropriate environmental and human health safeguards. But as the debate evolved, the role of law as a "provider" of biosafety, i.e. as the provider of mechanisms to ensure the safe handling, transfer and use of genetically modified organisms, increasingly came to the fore.

43. The challenges of biosafety, in particular in the context of the transboundary movement of GMOs, made an international regime a prerequisite for an efficient regulatory system: biosafety cannot be achieved without a coordinated approach between countries. This is why the Protocol has been negotiated.

IV. Cross-cutting issues

44. In the negotiation of the Protocol, a number of issues were controversial and difficult to resolve. Among them, several are relevant to a number of provisions of the Protocol – these include provision of information important for the implementation of the Protocol, in particular through the Biosafety Clearing-House (BCH, see Article 20), and socio-economic considerations. Others are cross-cutting though the Protocol as a whole.

Issues which permeate the Protocol as a whole include:

- human health,
- precaution, and
- trade (see also Appendix)

A. The Protocol and human health issues

45. The appropriate treatment of human health issues in the Protocol was contentious from the outset of the negotiations. Article 19(3) of the CBD makes no reference to human health. In the discussion of the mandate to negotiate a Protocol, the subject of human health was nevertheless considered – and proved controversial. To some, an instrument on biosafety which failed to cover human health issues was not a viable proposition; for others, however, human health should not be covered at all in the context of a Protocol to the CBD.

46. Ultimately, the negotiators compromised, and the final version of the Protocol recognizes throughout that risks to human health are to be "taken also into account". Thus, the Protocol specifically mentions human health in various provisions, including in Article 4 on Scope:

> This Protocol shall apply to… [LMOs] that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

47. The wording "taking also into account risks to human health" has its origin in Article 8(g) of the CBD. Independently of any other instrument in this field, including the Protocol, Article 8(g) requires Parties to the CBD to "regulate, manage or control the risks associated with use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts, that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health".

48. In the absence of any additional explanatory provision in either the CBD or the Protocol, however, the meaning of the phrase "taking also into account the risks to human health" remains somewhat unclear. This is all the more so as not much of the debate on this

[34] *Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer* (EEA, 2002, Environmental issue report no. 28).

subject during the negotiations has been recorded. The wording was introduced by the European Union at an early stage. Several delegations considered that direct impacts of LMOs on human health should not be covered by the Protocol – as they were dealt with in other contexts. However, many others – including particularly those from developing countries – wished to give the same weight to impacts of LMOs on human health and on biological diversity.

49. The first approach leads to the conclusion that risks posed by a LMO to human health are taken into account under the Protocol *only* if they result from the potential adverse effects of the same LMO on biological diversity.

50. The other approach leads to the conclusion that risks posed by a LMO to human health are to be taken into account under the Protocol also in the absence of, or separately from, potential adverse effects of the LMO considered on biological diversity. This would be the case, for instance, for any change in allergenic properties of pollen as a result of genetic modification, or the consumption of GM food.

51. Both interpretations can be supported by the phrase "taking also into account risks to human health". The practical effect of the absence of unambiguous guidance in the Protocol itself on this issue, along with the lack of consensus on one or the other above mentioned interpretations, appears to be that, under the Protocol at least, Parties will have a certain latitude and flexibility in deciding which human health aspects to cover in their implementation of the Protocol – unless and until they decide upon an authoritative interpretation collectively in the meeting of the Parties to the Protocol.

B. The Protocol and precaution

52. It has long been recognized that prevention of environmental harm must be "the Golden Rule for the environment",[35] for both ecological and economic reasons. At best, it is difficult to remedy environmental injury, and in many cases the damage is simply irreversible. Even where damage is reparable, the cost of restoration or rehabilitation is often prohibitive.

53. The "principle of prevention" has thus become a cornerstone of environmental law, both domestic and international. It involves the use of special techniques such as risk assessment and analysis, or environmental impact assessment, of the potential effects of the planned activity, followed by a decision to allow it (with or without management measures), or to prohibit it.

54. Applying preventive measures requires and presupposes sufficient scientific knowledge, and clear scientific evidence presented in the various assessment processes regarding the consequences of the contemplated action. The question is then, from a policy point of view, whether the risk is considered acceptable (ecologically, economically, socially) and should be taken, or whether it should be prevented.

55. A special, but not infrequent situation arises, however, when lack of scientific certainty or consensus prevails. It is for such circumstances that the legal concept of precaution has been developed in the 1970s. It has subsequently increasingly been reflected in international treaties, as well as national law, and has become known as the precautionary principle. Its most commonly referred to formulation is that contained in Principle 15 of the Rio Declaration, adopted by States at the UN Conference on Environment and Development in 1992 – the single most important non-binding international instrument adopted by States after the Stockholm Declaration of 1972.

56. In short, the precautionary principle holds that uncertainty regarding serious potential environmental harm is not a valid ground for refraining from preventive measures. In this sense, the principle's chief characteristic is to operate as enabling action, and authorizing preventive measures, in circumstances of scientific uncertainty.

57. Whether and to what extent there is scientific uncertainty is therefore critical in the context of precautionary action. There is no internationally agreed definition of " scientific uncertainty", nor are there internationally agreed general rules or guidelines to determine its occurrence. Those matters are thus dealt with – sometimes differently – in each international instrument incorporating precautionary measures.

[35] Kiss, A. *Introduction to International Environmental Law*, Programme of Training for the Application of Environmental Law, Course 1, UNITAR (1997).

Box 6. Principle 15 of the Rio Declaration

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

58. While there is no controversy about the usefulness of the concept of precaution *per se*, there has been much debate recently about its nature, in particular whether it is a legal principle in addition to being a sound policy approach. Some argue that the concept of precaution has not attained the status of a principle of law, and hence does not as such constitute a legal obligation. The controversy arose at international level in particular because, while the precautionary principle has been reflected in a number of international agreements, they utilize different formulations and differences remain as to the proper scope of application of the principle and its practical implications. This generated concerns that states may apply the precautionary principle in such a way as to cause potential conflicts with international trade rules.

59. The issue of precaution is thus likely to continue to arise within the WTO, now perhaps more directly in the context of the WTO negotiations on trade and the environment, mandated at the November 2001 WTO Ministerial Conference in Doha, Qatar.

60. While the debate continues, the use of precautionary provisions in international treaty law as well as in national legislation continues to grow. Moreover the formulation of these provisions appears to be becoming increasingly concrete and specific.

Precautionary provisions in the Protocol

61. Decision II/5 of the Conference of the Parties, which provided the detailed negotiating mandate for the Protocol, provided that "the Protocol will take into account the principles enshrined in the Rio Declaration on Environment and Development and, in particular, the precautionary approach contained in Principle 15" (see Box 6).

62. Precaution is relevant to the regulation of LMOs as there remains a lack of scientific certainty and consensus as to their potential impacts on the environment and human health, particularly over the long-term.

63. During the Protocol negotiations, the need for some reference to precaution was widely accepted (as indicated by Decision II/5 of the COP.) Controversy surrounded the questions of how precaution should be reflected, and in particular: (i) whether references to precaution should be characterized as the "precautionary principle" or the "precautionary approach"; and (ii) whether there should be any reference to precautionary measures in the operative part of the Protocol or merely in the Preamble and Objective.

64. Those who opposed operative provisions on precaution argued that the Protocol was itself a precautionary instrument, since no specific damage associated with LMOs had been proved. They also feared that the precautionary approach would be used as a justification for protectionist trade measures – i.e. restrictions on the import and use of LMOs not backed up by scientific evidence.

65. Proponents of precautionary provisions stressed the relative novelty of LMOs and the lack of experience with them – particularly in some receiving environments and in developing countries. They argued that even with proper risk assessment, some uncertainty may still remain and that in such circumstances countries should have the right to adopt precautionary measures to protect biodiversity and human health.

66. The Protocol refers to or reflects the concept of precaution in a number of its provisions:

- The Preamble and Article 1 of the Protocol both refer to the precautionary approach contained in Principle 15 of the Rio Declaration.
- Annex III(4) on risk assessment provides that "[l]ack 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".
- Article 10(6) and Article 11(8), addressing import decisions for LMOs and LMO-FFPs (see para. 91) respectively, provide that lack of scientific certainty due to insufficient relevant scientific information

and knowledge regarding the extent of the potential adverse effects of a LMO on biodiversity, taking into account risks to human health, shall not prevent a Party of import from taking a decision, as appropriate, with regard to the import of the LMO in question.

- These two provisions address the situation where, having carried out a risk assessment based on information provided in accordance with Annex I, and on the basis of Article 15 and Annex III, the Party of import concludes that there remains a lack of certainty about the extent of potential adverse effects of the LMO on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The basic question addressed during the negotiation was: in such circumstances, should a Party be able to prohibit or restrict the proposed import on the basis of the precautionary principle/ approach?
- As adopted, Article 10(6) and Article 11(8) represent one of the most explicit examples of operationalization of the precautionary principle/approach in any multilateral environmental agreement. Where the conditions in Article 10(6) or Article 11(8) are met, a Party of import has the right under the Protocol to take precautionary measures. Lack of scientific certainty may arise, for example, as a result of a lack of sufficient scientific information and knowledge about the LMO itself, about the receiving environment, or about the potential interaction between the two.

C. Biosafety and the World Trade Organization (WTO)

67. Another area of contention during the negotiations was the relationship between the Protocol and relevant provisions in the WTO Agreements.

68. Under the Agreements of the WTO, Members are bound by certain obligations that limit their right to restrict imports. Any country that joins the WTO automatically becomes a Party to a "package" of multilateral trade agreements, including the General Agreement on Tariffs and Trade 1994 (GATT), the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), and the Agreement on Technical Barriers to Trade (TBT Agreement).

69. Inevitably, the question of compatibility has arisen regarding the relationship between the Protocol provisions and WTO commitments: a number of countries in the Protocol negotiations were concerned that rights and obligations of Parties under the Protocol should not conflict with, or take precedence over, the rights and obligations of Members under the WTO Agreements. They sought to insert a "savings" clause into the Protocol stating that the provisions of the Protocol would not affect the rights and obligations of any Party deriving from any existing international agreement (including the WTO Agreements). This was unacceptable to many other countries which were concerned that such a provision would limit their right to rely on the Protocol in restricting or prohibiting the import of any LMO which they considered potentially damaging to the environment or to human health. Their concern was exacerbated by the fact that, unlike the Protocol, the WTO has a mandatory and binding dispute settlement procedure, to which disputes between WTO Members involving trade in LMOs might be submitted.

70. In the end, it was agreed that the relationship of the Protocol with other international agreements would be dealt with in three paragraphs of the Protocol's Preamble. A commentary on these three preambular clauses appears in the section of this Guide on the Preamble below. A more detailed discussion of the possible interactions between the provisions of the Protocol and those of relevant WTO Agreements is contained in the Appendix to this Guide.

V. Overview of the Protocol[36]

71. This section provides a general overview of the provisions of the Protocol. More detailed analysis is contained in the article-by-article commentary.

72. The objective of the Protocol is, in accordance with the precautionary approach, "to

[36] This section is based on an information package on the CBD for Pacific Island Countries (2000) produced by the South Pacific Regional Environment Programme (SPREP), the Foundation for International Environmental Law and Development (FIELD) and the World Wide Fund for Nature-South Pacific Program (WWF-SPP) as part of a UK Department of Environment, Food and Rural Affairs (DEFRA) Darwin Initiative project.

contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs, taking also into account risks to human health, and specifically focusing on transboundary movement" (Article 1).

73. The term "living modified organism" is defined in the Protocol (Article 3) as those living organisms that "possess a novel combination of genetic material" and are "obtained through the use of biotechnology".

A. Scope of the Protocol and AIA procedure (Articles 4–7)

74. The Protocol's general coverage includes the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account also risks to human health (Article 4). However, some categories of LMOs or transboundary movements are excluded. In some cases the exclusions are limited to specific provisions relating to the AIA procedure, in others they operate as general exclusions from all of the Protocol's provisions. An overview of the scope of the Protocol is set out in Box 7 and explained further below. Even where certain LMOs are excluded from some or all of the Protocol's provisions, they may, of course, still be subject to national regulation.

75. There were extensive discussions during the negotiations of the Protocol regarding the inclusion of products of LMOs, i.e. processed materials of LMO origin. These were referred to throughout the negotiations as "products thereof". In the end, products of LMOs were not generally included. However, they are addressed in Article 23(3)(c), Annex I(i) and Annex III(5) in relation to risk assessment, in as far as such products contain detectable novel combinations of replicable genetic materials obtained through the use of biotechnology.

B. Advanced Informed Agreement (AIA) procedure (Article 7)

76. The AIA procedure applies on the *first* occasion that a LMO covered by Article 7 is intentionally moved from a Party into another Party. The elements of the AIA procedure are described below.

Competent authority

77. All Parties must designate one or more national competent authorities, which will be responsible for performing the administrative functions required by the Protocol, and authorized to act on the Party's behalf with regard to those functions (Article 19).

Notification and information

78. The first step in the AIA procedure is the notification of the proposed transboundary movement to the Party in which the LMO is to be imported. This notification must contain certain information relating to, *inter alia*, the exporter, the LMO and its intended use. Annex I to the Protocol specifies the particular information that must be supplied in conjunction with the notification.

Box 7. Scope of the Protocol and of the AIA procedure: Articles 4–7

LMOs subject to the provisions of the Protocol

- *All* LMOs which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 4).

LMOs subject to AIA provisions

- LMOs intended for intentional introduction into the environment (Article 7(1)).

LMOs excluded from the Protocol's AIA provisions

- LMOs in transit (Article 6(1)).
- LMOs destined for contained use in the Party of import (Article 6(2)).
- LMOs intended for direct use as food or feed, or for processing (LMO-FFPs) (Article 7(2)).
- LMOs identified by the meeting of the Parties to the Protocol as being not likely to have adverse impacts (Article 7(4)).

LMOs excluded from the Protocol's provisions on transboundary movements

- LMOs that are pharmaceuticals for humans that are addressed by other international organizations or agreements (Article 5).

Decision of Party of import

79. Within 90 days of receiving the notification, the Party of import must acknowledge receipt. Within 270 days of receiving the notification, the Party of import must communicate its decision to the notifier and to the Biosafety Clearing-House established under the Protocol (see below). In its decision, the Party of import may either:

- Approve the import of the LMO, with or without conditions;
- Prohibit the import of the LMO;
- Request additional information; or
- Inform the notifier that the import decision will be taken within a further defined period of time.

80. Failure by a Party of import to communicate its decision within 270 days does *not* imply its consent to the import of the LMO.

Risk assessment

81. A Party of import must base its decision on a risk assessment carried out in a scientifically sound manner. Risk assessment requirements are addressed in Article 15 and Annex III of the Protocol. The risk assessment must be based at a minimum on information provided in the initial notification and other available scientific evidence to identify and evaluate possible adverse effects of the LMO on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

82. While it is the obligation of the Party of import to ensure that its decision is based on a risk assessment, it may require the exporter to carry out and/or bear the costs of the risk assessment.

83. In reaching a decision on whether to approve the import of a particular LMO, a Party of import may also take into account the precautionary principle, and certain socio- economic considerations. As discussed above, the Protocol provides that lack of relevant scientific information and knowledge does not prevent the Party of import from taking a decision to avoid or minimize such potential adverse effects (Article 10(8)). The Protocol also allows the Party of import, in reaching a decision, to take into account socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities (Article 26). In considering socio- economic impacts, Parties must act consistently with their other international obligations, including, for Members of the WTO, relevant WTO rules.

84. Carrying out and/or evaluating a risk assessment on a LMO will require a broad range of technical and scientific expertise. Decision-making may require the development or significant adaptation of domestic institutions in addition to the competent national authority designated under the Protocol.

Confidential information

85. Under Article 21, the Party of import must permit the notifier to identify which information provided under the notification and information procedure is to be treated as confidential. Where requested, the notifier must give justification for this designation. If there is disagreement as to which information should qualify as confidential, the Party of import should consult with the notifier, prior to any disclosure. Parties must not disclose confidential information received under the Protocol, or use it for a commercial purpose, except with the written consent of the notifier. The Protocol specifies certain information which cannot be considered confidential, including a general description of the LMO, a summary of the risk assessment of its effects on biodiversity and human health, and methods and plans for emergency response.

National discretion

86. Although the Protocol sets out a specific AIA procedure for imports of certain LMOs, it allows Parties a fair degree of flexibility in the way this is applied. This flexibility, however, is subject to an overriding obligation to act in accordance with the objective of the Protocol.

- First, a Party of import may decide to apply its own domestic regulatory framework in reaching an import decision, so long as this is consistent with the Protocol (Article 9(3) and Article 14(4)).
- Second, a Party of import may decide to adopt simplified procedures for the import of certain LMOs, provided that adequate measures are applied to ensure the safe transboundary movement of LMOs in accordance with the Protocol's objective (Article 13).

- Third, Parties may enter into bilateral, regional or multilateral agreements or arrangements regarding the intentional transboundary movement of LMOs. These must be consistent with the objective of the Protocol and must not result in a lower level of protection than that provided in the Protocol. Parties must inform the Biosafety Clearing-House of any such arrangements. The specific AIA provisions of the Protocol will not apply to intentional transboundary movements of LMOs between Parties to those agreements or arrangements (Article 14).
- Fourth, Parties are allowed, in relation to AIA and the other provisions of the Protocol, to take action for the conservation and sustainable use of biodiversity that is *more* protective than that provided in the Protocol. However, such action must be consistent with the objective and provisions of the Protocol, and be in accordance with a Party's other obligations under international law (Article 2(4)).

C. LMOs not subject to AIA provisions

87. As indicated in Box 7, the Protocol's specific AIA procedure does not apply to the transboundary movements of certain LMOs. However, the other provisions of the Protocol remain applicable to such LMOs. This exclusion also does not affect the right of Parties to subject all LMOs to risk assessment prior to decisions on import.

LMOs in transit

88. The Protocol's specific AIA procedure does not apply to LMOs in transit. This exclusion is without prejudice to any right of a Party of transit to regulate the transport of LMOs through its territory. Parties may make available to the Biosafety Clearing-House its decisions regarding the transit of specific LMOs through its territory.

LMOs destined for contained use

89. Again, the Protocol's AIA procedure does not apply to the transboundary movement of LMOs destined for contained use undertaken in accordance with the standards of the Party of import. Contained use is defined in Article 3(b) of the Protocol to include activities in which LMOs are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.

90. Once again, this exclusion does not affect any right of a Party to subject *all* LMOs to risk assessment prior to decisions on import and to set standards for contained use in its jurisdiction. i.e. although the AIA procedure does not apply under the provisions of the Protocol, a Party (or any other State) can, through its national legislation, require risk assessment and prior authorization before the import of a LMO for contained use.

LMOs intended for direct use for food, feed or for processing (LMO-FFPs)

91. The term "LMOs intended for direct use as food or feed, or for processing" (LMO-FFPs) covers activities such as exports of genetically modified agricultural commodities, such as GM soybeans or maize for food or feed use, or GM tomatoes. The potential application of the Protocol, and in particular the AIA procedure, to LMO-FFPs was among the most controversial issues in the negotiation of the Protocol.

92. As noted above, the specific AIA procedure set out in Articles 8, 9, 10 and 12 of the Protocol does not apply to LMO-FFPs. However, the other provisions of the Protocol do apply to LMO-FFPs and certain specific obligations regarding LMO-FFPs are set out in Articles 11 and 18(2)(a).

93. Article 11 establishes a multilateral information exchange procedure on LMO-FFPs through the Biosafety Clearing-House. Where a Party makes a decision on domestic use of a LMO that may be exported for direct use as food or feed or for processing, it must notify the other Parties through the Biosafety Clearing-House within fifteen days. Information specified in Annex II of the Protocol must be provided.

94. Parties to the Protocol may require prior consent for import of LMO-FFPs under their relevant domestic regulatory framework. Parties with laws or regulations applicable to the import of LMO-FFPs must make these available through the Biosafety Clearing-House. The Protocol recognizes, however, that some countries may not yet have applicable laws and regulations in place. It therefore provides that developing countries (and countries with economies in transition), which do not have an applicable domestic regulatory framework in place, may declare through the Biosafety Clearing-House that

they will take a decision on the first import of a LMO-FFP in accordance with a risk assessment, and within a time frame of not more than 270 days. The Protocol does not specify when this 270 period begins to run, nor does it specify any direct notification procedure between the exporter and the Party of import. Failure by a Party to communicate its decision within 270 days may not be interpreted as either consent to or refusal of the import of the LMO-FFP concerned.

95. As under the AIA procedure, Parties are entitled to take into account the precautionary principle in reaching decisions on imports of LMO-FFPs (Article 11(8)).

96. Under Article 18, LMO-FFPs must be accompanied by documentation specifying that they "may contain" LMOs, and that they are not intended for intentional introduction into the environment. This means that if a Party to the Protocol receives a shipment from another Party of agricultural commodities which *may* contain LMOs, it should be alerted to this fact by the accompanying documentation, even if it has not explicitly subjected imports of LMO-FFPs to a prior consent procedure under Article 11. In the Protocol negotiations, many countries argued that shipments of LMO-FFPs should *clearly* be identified as LMOs. However, certain agricultural exporting countries objected to such a requirement as this would require producers to segregate GM and non-GM grains at all stages of production, whereas current practice is to commingle them. They argued that such a requirement would be too costly. The meeting of the Parties to the Protocol is to take a decision on any detailed requirements in this respect within two years of the Protocol entering into force.

97. Parties are also entitled, in their domestic regulatory framework, to require advance notification and approval of the proposed transboundary movements of LMO-FFPs, provided that these measures are consistent with the objective of the Protocol (Article 11(4)).

LMOs identified by the meeting of the Parties to the Protocol as being not likely to have adverse effects

98. Article 7(4) allows the Meeting of the Parties, at a later date, to decide to exclude specific LMOs or categories of LMOs from the application of the AIA procedure. This provision was included to take account of developments in the future: there may come a time when certain LMOs will have been shown to be sufficiently safe to exempt their transboundary movement from the AIA procedure.

LMOs that are pharmaceutical for humans that are addressed by other relevant international agreements or organizations

99. Under Article 5, these LMOs are excluded from the AIA procedure, and from the other provisions of the Protocol related to transboundary movement.

D. Other provisions

Biosafety Clearing-House

100. The Protocol establishes a Biosafety Clearing-House as part of the Clearing-House Mechanism under Article 18(3) of the CBD. The function of the Biosafety Clearing-House is to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs and to assist Parties to implement the Protocol. Article 20(3) sets out certain categories of information that Parties are to make available to the Biosafety Clearing-House. These include:

- Laws, regulations and guidelines for implementation of the Protocol
- Bilateral, regional and multilateral arrangements under Article 14
- Decisions on import or release of LMOs
- Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes of Parties

101. As noted above, the Biosafety Clearing- House has specific functions regarding LMO-FFPs. In relation to transboundary movement of LMO-FFPs, the Biosafety Clearing-House plays a vital role: it is the central mechanism through which Parties will be made aware of the use of LMO-FFPs and their potential transboundary movement, as well as the national laws which will apply to imports of LMO-FFPs. It is also the mechanism through which Parties with no domestic regulatory framework in place will be able to declare that they require notification and risk assessment prior to a first import of a LMO-FFP.

Capacity-building and financial resources

102. The Protocol requires Parties to co-operate in the development and strengthening of human resources and institutional capacities in

biosafety in developing country Parties, particularly least developed countries and small island developing States. Despite references to cooperation in capacity-building, there are no specific commitments from developed countries with regard to capacity-building.

103. The financial mechanism established under the CBD (operated by the Global Environment Facility (GEF)) is to be the financial mechanism for the Protocol. Guidance to the financial mechanism with regard to financial resources for implementation of the Protocol will go through the CBD COP. No specific guidance is given in the Protocol as to the level of financial resources that may be needed for implementation of the Protocol.

104. The fifth meeting of the CBD COP emphasized the importance of financial support for capacity-building for implementation of the Protocol.[37] A number of capacity-building initiatives in relation to biosafety are already either underway or in the pipeline. COP 6 reinforced this by providing additional guidance to the GEF regarding the provision of financial resources, requesting GEF to support national capacity building in biosafety.[38]

Unintentional transboundary movement of LMOs

105. In addition to its extensive provisions on intentional transboundary movements of LMOs, the Protocol also addresses, in Article 17, unintentional transboundary movements. It sets out notification and consultation requirements with regard to releases of LMOs that lead or may lead to unintentional transboundary movements that are likely to have significant adverse effects. Parties must provide to the Biosafety Clearing-House details of a contact point for receiving any such notifications.

Illegal transboundary movements of LMOs

106. The Protocol requires Parties to adopt domestic measures to prevent and penalize transboundary movements of LMOs that occur in contravention of domestic measures implementing the Protocol. In the case of such illegal movements, the affected Party may request the Party of origin to dispose of the LMOs by repatriation or destruction. The Biosafety Clearing-House must be notified of all cases of illegal transboundary movement.

Liability and redress for damage caused by LMOs

107. The question of liability and redress for any damage caused by LMOs was another contentious issue in the negotiations. It was not possible to resolve this issue during the negotiations, and the Protocol requires the first meeting of the Parties to the Protocol to adopt a process with respect to the appropriate elaboration of international rules and procedures for liability and redress for damage arising out of the transboundary movements of LMOs. This process is meant to be completed within four years.

Institutional arrangements

108. The Protocol establishes institutional arrangements to carry out further work on the elaboration and review of rules for the safe transboundary movement, handling and use of LMOs. It will "share" institutions with the CBD in that the CBD COP will serve as the "meeting of the Parties" to the Protocol. This body is known by the cumbersome title "the Conference of the Parties serving as the meeting of the Parties to the Protocol" (COP/MOP)(see Article 29). However, only countries that become Parties to the Protocol will be able to participate in decision-making by the meeting of the Parties. Non-Parties to the Protocol (including non-Parties to the CBD) will be able to participate in the meeting of the Parties only as observers. The COP/MOP will play an important role in the evolution of the Protocol and may undertake further work on some of the areas on which the Protocol text does not presently provide clear guidance.

109. Subsidiary bodies established under the CBD, such as the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) may also serve the Protocol (Article 30). Similar rules as for the meeting of the Parties will apply with regard to participation.

110. The Secretariat of the CBD will also act as the Secretariat for the Protocol. Countries that become Parties to the Protocol will have to contribute to any additional costs of Secretariat services for the Protocol, and the first meeting of the Parties will decide on budgetary arrangements in this regard.

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[37] Decision V/11, paragraph 11, UNEP/CBD/COP/5/23.

[38] Decision VI/17, UNEP/CBD/COP/6/20.

111. At its first meeting, the meeting of the Parties is due to consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of the Protocol and to address cases of non-compliance (Article 30). This may result in the establishment of additional institutions.

Dispute settlement and compliance

112. The Protocol does not contain specific provisions on the settlement of disputes arising under the Protocol, but it refers back to the relevant provisions of the CBD (Article 32). Article 27 of the CBD provides for optional recourse to judicial settlement or arbitration, or a conciliation procedure that is mandatory at the request of one of the parties to a dispute. Separate from the dispute settlement procedure, as mentioned above the Protocol mandates the development by the meeting of the Parties of procedures and mechanisms to promote compliance with the provisions of the Protocol (Article 34).

Non-Parties

113. Under the Vienna Convention on the Law of Treaties, a protocol cannot create rights and obligations for non-Parties without their consent. However, the Protocol, in Article 24, does regulate the conduct of Parties in relation to transboundary movements of LMOs involving non-Parties. Such transboundary movements must be consistent with the objective of the Protocol and may be the subject of bilateral, regional and multilateral agreements between Parties and non-Parties in accordance with Article 24.

VI. Implications of the Protocol

114. The overview of the provisions of the Protocol above suggests that it is likely to have significant implications for countries that become Party to it. Developing and implementing appropriate national reguations to regulate imports of LMOs is likely to require significant human, financial and technical resources. As noted above, while the Protocol does address capacity-building and financial resources, the scope of these provisions is not yet clear, and will require further development in the form, in particular, of further guidance from the Conference of the Parties to the GEF. However, GEF has already provided financial resources for capacity-building in the form of a significant project on national biosafety frameworks being implemented by UNEP. A number of other intergovernmental and national agencies are undertaking capacity-building initiatives in relation to national biosafety frameworks.

115. The Protocol offers to its Parties significant benefits in that it provides a potentially globally accepted set of rules on LMOs, important in particular to ensure transparency in the transboundary movement of LMOs and application of advance informed agreement regarding imports. At the same time, the Protocol sets in place an institutional mechanism through which implementation can be fostered, and continued dialogue and cooperation can be effected. The overall goal, and resulting benefit, is to provide a degree of legal certainty in the field of biosafety regulation.

116. These benefits will be realized only to the extent that the Protocol is widely ratified and effectively implemented. The latter is to a large extent dependent on effective individual national regulatory systems addressing not only imports and exports, but also the use and release of LMOs at domestic level. Developing such legislation will require extensive consultation with a range of relevant departments and agencies, as well as the public, local industry and agriculture, and research institutions.

VII. Other international instruments relevant to the Protocol

117. The development of new technologies of genetic modification since the early 1970s has prompted discussions on safety in biotechnology in many international organizations. A number of intergovernmental agencies are active in this field. Some instruments have been adopted which explicitly address biosafety, generally in the form of guidelines, and some are in preparation. It is beyond the scope of this introduction to go into these in any detail. Global instruments which were, or are, most relevant to the Protocol are briefly addressed below.

Two international instruments played an important role prior to the adoption of the Protocol:

UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment (1992)

118. Two of the aims of the UNIDO Code of Conduct were to outline the general principles governing standards of practice for all

Box 8. Possible elements of national biosafety regulations

In the elaboration of a national biosafety legal framework, some elements which States have considered include the following:

- Define the objectives of the framework
- Define the scope of the framework – what activities and organisms are covered
- Place responsibility for implementation of the framework on a Minister or Ministers and on particular government department(s) or agency
- Establish or designate advisory body(ies) to advise on technical aspects of regulatory decisions
- Establish a general prohibition on activities involving LMOs unless an authorisation/licence or other approval has been obtained in accordance with regulations
- Establish a system of permits or authorizations for activities involving LMOs
- Allow for exemptions or "fast-track" or simplified procedures for certain LMOs with which there is extensive experience under the regulations, or which have been deemed to be "low-risk"
- Provide for public information and consultation on permit applications and policy issues
- Set out information required in an application for a permit (information required may vary according to the type of LMO and/or the intended activity)
- Address the protection of commercial confidential information
- Establish a risk assessment procedure, whereby risks associated with the release or other activity are identified, in accordance with risk assessment criteria
- Allow for risk management conditions to be attached to permits, including any applicable labeling or marking requirements
- Set out procedures for monitoring and review of activities subject to permit, including compliance with conditions
- Set out penalties and sanctions for non-compliance
- Make provisions for liability for any damage arising out of activities involving LMOs
- Address unintentional releases and emergency measures
- Make certain transitional arrangements in respect of pre-existing activities or applications

A useful reference material is the Implementation tool kit prepared by the ICCP (Recommendation 3/5, Annex III) which provides a compilation, as a checklist, of obligations found in the Protocol. It divides these obligations into administrative tasks, legal requirements and/or undertakings, and procedural requirements. The Implementation tool kit is reproduced in the Supplementary Materials.

parties involved in the introduction of organisms or their products into the environment, and to encourage and assist the establishment of appropriate national regulatory frameworks, particularly where no adequate infrastructure yet existed.

UNEP International Technical Guidelines for Safety in Biotechnology (UNEP Guidelines) (1995)

119. These Guidelines were adopted by the Global Consultation of Government-designated Experts in 1995, under the auspices of UNEP. The CBD COP recognized the UNEP Guidelines as a useful interim mechanism to facilitate the management of risks, pending finalization of the Protocol. The UNEP Guidelines provide technical guidance on evaluating biosafety, identifying measures to manage foreseeable risks and to facilitate processes such as monitoring, research and information exchange.

120. The Guidelines were developed on the basis of common elements and principles found in existing national, regional and international instruments, regulations and guidelines, and draw on experience gained through their implementation.

121. Other international instruments, albeit adopted well before the Protocol, address issues which are of relevance to specific aspects of its implementation.

International Plant Protection Convention (IPPC) (adopted 1951, amended 1979, revised 1997)

122. The IPPC is an international treaty for co-operation in plant protection, which aims to "to secure common and effective action to

prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control". The IPPC allows Parties to take phytosanitary measures to prevent the introduction and/or spread of pests, based on a pest risk analysis, which covers both economic and environmental factors including possible detrimental effects on natural vegetation. LMOs that could be considered a plant pest could fall within the scope of the IPPC and be subject to its provisions.

123. The IPPC, which was originally adopted in 1951, amended in 1979 and revised in 1997, incorporates a process for the development of International Standards for Phytosanitary Measures. Pending entry into force of the 1997 IPPC, an Interim Commission on Phytosanitary Measures (ICPM) has been established. At the second meeting of ICPM, an exploratory open-ended working group was set up to address issues of GMOs, biosafety and invasive species in relation to IPPC and report back to ICPM. The working group recommended the development of a supplementary standard to specifically address the plant pest risks of LMOs/products of modern biotechnology, as a matter of urgency. This is to include a review of plant pest risks associated with LMOs/products of modern biotechnology carried out in cooperation with the CBD.

124. Under the WTO SPS Agreement, sanitary and phytosanitary measures which conform to certain international standards, guidelines or recommendations are deemed to be necessary to protect human, animal or plant life or health, and thus presumed to be consistent with the SPS Agreement and GATT 1994 (see Appendix). These include standards and guidelines adopted under the IPPC, as well as the Office International des Epizooties and *Codex Alimentarius* (see below).

The Office International des Epizooties (OIE) (1924)

125. The OIE plays a similar role to the ICPM, in relation to animal health and disease. The OIE produces and assesses scientific evidence and operates by consensus to develop harmonizing standards, guidelines and recommendations, especially for trade in animals and products of animal origin. In relation to GMOs, OIE has carried out work on scientific evaluation of GMOs which are pharmaceuticals for animals (which are subject to the Protocol's AIA procedure). The OIE Standards Commission has had an Ad Hoc Working Group on Biotechnology since 1996, but has not yet adopted any international standards in this field.

The *Codex Alimentarius*

126. This is a non-binding Code developed by the *Codex Alimentarius* Commission, a body of FAO/World Health Organization which elaborates standards, general principles, guidelines, and recommended codes of practice in relation to food safety and related issues.[39] The *Codex* is significant in relation to LMOs because standards may be adopted in future on safety of foods derived from biotechnology (for example, addressing issues of potential allergenicity; possible gene transfer from LMOs; pathogenicity deriving from the organism used; nutritional considerations; risk assessment and authorization procedures; and appropriate labelling).

127. The *Codex* has underway at least three processes of relevance to LMOs. The Task Force on Foods Derived from Biotechnology is working, *inter alia*, on Principles for Risk Analysis of Foods Derived from Modern Biotechnology. The Committee on General Principles is elaborating Draft Working Principles for Risk Analysis. The Committee on Food Labelling is preparing recommendations for the Labelling of Food Obtained through Biotechnology (See also Box 12).

FAO's regional fisheries bodies

128. Members of this group of interrelated institutions have adopted codes of practice on the use of introduced aquatic and marine species and GMOs. Work is ongoing within FAO, with ICLARM (International Center for Living Aquatic Resources Management) and OIE, to develop appropriate biosafety policies for aquatic genetic resources. In so far as genetically modified aquatic species are intended for deliberate release into the environment, their transboundary movement will be subject to the AIA procedure of the Protocol.

[39] In relation to the IPPC and *Codex Alimentarius,* see *FAO and the Biosafety Protocol to the Convention on Biological Diversity*, 28 July 1998, website of the FAO, http://www.fao.org

The Convention on Access to Information, Public Participation and Access to Justice in Environmental Matters (Aarhus, adopted 1998, entered into force 2001)

129. Measures of both a binding and non-binding character are contemplated within the UN/ECE Aarhus Convention framework for further developing access to information, public participation and access to justice with respect to GMOs.[40] Guidelines on this subject[41] have been prepared for adoption at the first meeting of the Parties to the Convention in October 2002, and for use by all Parties as a non-binding, voluntary instrument. In addition, possible legally-binding options for further developing the application of the Convention in the field of GMOs are being considered, and this work will be continued by the Working Group on Genetically Modified Organisms to be established at the first meeting of the Parties to the Aarhus Convention with a view to preparing decisions for adoption by the Parties at their second meeting.

Cooperation regarding implementation of the Protocol

130. All the above activities are of relevance to the Protocol, and cooperation between the organizations mentioned, and many others, and the Secretariat of the Protocol will be important in the future. The subject has already been raised before the ICCP and, for some activities, co-operation is already ongoing or contemplated.

[40] MP.PP/2002/5, 12 August 2002 (ECE).

[41] MP.PP/2002/6, 15 August 2002 (ECE).

Preamble

131. *The preamble of an international agreement sets out the context in which the agreement was negotiated and concluded. Under general rules of treaty interpretation the preamble is not considered to be part of the legally binding or "operative" text of the agreement. Instead the preamble forms part of the "context" in which the agreement's obligations must be interpreted. It often recalls and refers to any related international agreements that may have provided the mandate for the negotiations or that the negotiators felt were in other ways relevant to the agreement. In practice, negotiators will also often include in the preamble references to principles or concepts that are relevant to the international agreement, but that proved too controversial to be included as binding obligations in the operative text.*

The Parties to this Protocol,

Being **Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",**

132. The opening preambular paragraph indicates that this international agreement is a Protocol to the CBD, and that it has been negotiated and adopted by the Parties to the CBD, in accordance with Article 28 of the CBD. The background to these negotiations is described in the Introduction.

Recalling **Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,**

133. Article 19(3) of the CBD established the mandate for the negotiation of a Protocol on Biosafety. It requires the Parties to the CBD to:

> 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 LMO resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.

134. Article 19(4) creates a general obligation for Parties to the CBD to provide information on any LMO transferred to another Party. This obligation exists in the CBD independently of the Protocol – it is thus binding on States that are Parties to the CBD even if they do not become Parties to the Protocol.

135. Article 8 (g) of the CBD requires Parties to:

> [e]stablish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

136. Article 8(g) obliges Parties to the CBD to regulate risks associated with LMOs at the national level, including both domestically produced and imported LMOs. The reference to "risks to human health" in Article 8(g) is also incorporated into the scope of the Protocol (see Introduction).

137. Article 17 of the CBD deals with exchange of information. The reference here underlines the importance of information-sharing for biosafety regulation, particularly for developing countries.

Recalling **also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,**

138. This paragraph recalls the legal basis for the launch of the Protocol negotiations, i.e. decision II/5 adopted at the second meeting of the CBD COP in Jakarta in 1995. This is described more fully in the Introduction.

Reaffirming **the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,**

139. This reference to Principle 15 of the Rio Declaration places the Protocol and its precautionary approach to regulating LMOs in the context of a historical and broader international recognition of the importance of precaution in protecting the environment. The precautionary approach is also referred to or reflected in certain operative provisions of the Protocol. The precautionary approach is discussed in the Introduction, as well as in the commentary on the relevant operative provisions (see commentary on Articles 1, 10(6) and 11(8)).

Aware of **the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,**

Recognizing **that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,**

140. These two paragraphs reflect key perspectives in the biosafety debate, namely, on the one hand, recognition of the potential benefits of modern biotechnology, and, on the other, concerns over potential effects of LMOs on the environment and on human health. These are considered in more detail in the Introduction to this guide.

Recognizing also **the crucial importance to humankind of centres of origin and centres of genetic diversity,**

141. By pointing out here that centres of origin and centres of genetic diversity (see Box 9) are of crucial importance to humankind, this paragraph signals the need for special care in conserving them, and, in this particular instance, the need to take into consideration potential effects of LMOs on such centres. This is a particular concern for States which host centres of origin and centres of genetic diversity. This concern is also echoed in Annex I and Annex II, which require information on the centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms, to be provided by the Party of export in the notification and information required under Articles 8 and 11 respectively.

Box 9. Centres of origin and centres of genetic diversity

A centre of origin is the area where a particular organism was first domesticated and brought into use by humans. Centres of origin may still retain a very high diversity of the genetic resources base and wild relatives from which the organism concerned was domesticated.

A centre of genetic diversity is an area where there is a high diversity present amongst a particular group of related species – either within a family, genus, or sub-species, varieties, cultivars, strains, or other sub-categories within a species.

Taking into account **the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,**

142. This paragraph points to the need for capacity-building for biosafety, which is reflected in several operative provisions of the Protocol, in particular Article 22.

Recognizing **that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,**

Emphasizing **that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,**

Understanding **that the above recital is not intended to subordinate this Protocol to other international agreements,**

143. The three paragraphs above address the relationship between the Protocol and any other international agreements which relate to the same subject matter as the Protocol. They can be read to guide the interpretation of the Protocol in circumstances when a Party's rights and obligations under the Protocol overlap with its rights and obligations under any "existing" or "other" international agreements. It is clear from the Protocol's negotiating history that these paragraphs were added to the preamble in order to address concerns arising from Parties' obligations under the World Trade Organization.

144. The combined effect of these three paragraphs is ambiguous, and produces a counterbalanced logic that leaves the interpreter little specific guidance as to how to resolve any conflict that may arise between the Protocol and any other international agreement. Ultimately, these paragraphs may be taken to reflect the Parties' awareness of the potential for conflict and their aspiration that any such conflict be resolved in a manner that respects both instruments.

145. A more detailed analysis of the relationship between the Protocol and the WTO is provided in the Appendix.

Relationship between the Protocol and other international agreements

146. During the negotiations, various delegations were concerned that the Protocol's efforts to regulate the international trade in LMOs could either undermine, or be undermined by, existing WTO rules. WTO rules regulate the trade in all products between its Members, including trade in LMOs. For example, the WTO requires Members to ensure that trade measures do not unnecessarily discriminate between like products, and that health and safety restrictions on imports have a scientific basis. Trade-related issues may arise from the implementation of the Protocol if Parties have conflicting perceptions of the differences between LMOs and conventional products, and of the risks associated with LMOs.

147. The Protocol was negotiated in the context of an international debate on the desirability, necessity, and safety of LMOs, their means of production and their by-products. Many governments were in the process of developing domestic and regional rules and procedures designed to regulate the trade, sale and use of LMOs. Although no dispute related to LMOs had been brought to the WTO, in the mid-1990s other conflicts related to food safety were working their way through the WTO's new and powerful dispute settlement system. During the course of the Protocol negotiations, the WTO heard disputes between the US and the EC over European bans on the import of hormone-treated beef,[42] between Canada and Australia over Australian restrictions on the import of fresh salmon,[43] and between the US and Japan over Japanese techniques to control pest infestations in fruit.[44] Each dispute involved a challenge of the WTO compatibility of a trade measure put in place to regulate threats to human, animal or plant life or

[42] *European Communities – Measures Affecting Meat and Meat Products*, complaint by the USA (EC – Hormones), WT/DS26, WT/DS26/AB/R, 13 February 1998.

[43] *Australia – Measures Affecting the Importation of Salmon*, complaint by Canada (Australia – Salmon), WT/DS18, WT/DS18/AB/R, 6 November 1998.

[44] *Japan – Measures Affecting Agricultural Products*, complaint by USA (Japan – Varietals) WT/DS76/AB/R, 19 March 1999.

health. Each dispute involved questions of the adequacy of scientific assessments of risk, and, in each case, the judgement of a domestic regulator was overturned as having an insufficient scientific basis and as violating a WTO discipline.

148. Concerned about the potential for a similar clash over the regulation of LMOs, different groups of negotiators sought *either* (i) to shield measures taken in accordance with the Protocol from a WTO challenge, *or* (ii) to ensure that, should a conflict arise, the WTO rules would prevail. This is not unusual in the design of treaties. Through the inclusion of "savings" or "conflicts" clauses, new international agreements can specify that they are subject to an earlier or later treaty. The compromise that emerged from the Protocol's negotiation follows closely the approach taken by the negotiators of the 1998 Rotterdam Convention on Prior Informed Consent (the "Rotterdam Convention"). The result is three paragraphs of preambular text that seek to counterbalance and accommodate the concerns of various delegations, in a manner that is intended overall to avoid conflicts between the Protocol and existing international law.

Recognizing *that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,*

149. The ninth paragraph reflects the aspiration of Protocol Parties that trade agreements (for example, the WTO Agreements) and environment agreements (for example, the Protocol, the CBD and other MEAs) "should be mutually supportive." This paragraph seeks to direct both domestic authorities and any relevant international body, to interpret and apply the Protocol and trade agreements in a manner that achieves the goals of both regimes.[45] The provision reflects a general rule of treaty interpretation that agreements between the same States and covering the same subject matter should be interpreted in such a way that promotes their compatibility.

150. The term "mutually supportive" has, furthermore, taken on a particular meaning within the trade and environment context. The term is drawn from the work of the WTO's Committee on Trade and Environment (WTO-CTE), which has been reviewing the relationship between the WTO and MEAs since 1995. In 1996, the WTO Ministerial Conference endorsed the report of the WTO-CTE which had concluded that:

> WTO Agreements and multilateral environmental agreements (MEAs) are representative of efforts of the international community to pursue shared goals, and in the development of a mutually supportive relationship between them, due respect must be afforded to both.[46]

151. In 2001, the WTO Ministerial Conference adopted the Doha Development Agenda, which mandates the WTO-CTE to revisit the relationship between the WTO and MEAs. Ministers agreed, with a view to enhancing the mutual supportiveness of trade and environment, "to negotiations, without prejudging their outcome, on:

> … the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs). The negotiations shall be limited in scope to the applicability of such existing WTO rules as among parties to the MEA in question. The negotiations shall not prejudice the WTO rights of any Member that is not a party to the MEA in question."

It is not yet clear what the implications of these negotiations, if any, will be for Parties to the Protocol.

Emphasizing *that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,*

Understanding *that the above recital is not intended to subordinate this Protocol to other international agreements,*

152. The tenth and eleventh paragraphs anticipate cases where the spirit of "mutual supportiveness", described in the ninth paragraph, is not sufficient to avoid or resolve a conflict

[45] The Protocol text is nearly identical to the text in the 8th preambular paragraph of the Rotterdam Convention which reads: "Recognizing that trade and environmental policies should be mutually supportive with a view to achieving sustainable development."

[46] Report of the Committee on Trade and Environment, WT/CTE/1, 12 November 1996, para. 171; Section VII of the Report of the General Council to the 1996 Ministerial Conference, WT/MIN(96)/2, 26 November 1996.

between the Protocol and any "existing" or "other" international agreement. While these paragraphs apply generally to *all* international agreements to which Protocol Parties are also party, they were also designed with the WTO Agreements specifically in mind. The tenth paragraph emphasizes that by joining the Protocol, a Party does not intend to give up its rights or obligations under any existing international agreement.[47]This text resembles a "savings" or "conflict" clause.[48]When such a clause appears in the operative text of a treaty, it can indicate which treaty – the existing treaty or the new treaty – the Parties intended to prevail in the case of a conflict.[49]

153. The tenth paragraph needs to be understood in the context of general principles of treaty interpretation. When it was adopted the Protocol was, of course, later in time than any "existing" international agreements, including the WTO Agreements. General principles of treaty interpretation could support an argument that as the more recent agreement, the Protocol was intended to prevail over any existing agreement between the same States and governing the same subject matter.[50] Furthermore, supplementary rules of treaty interpretation could suggest that the most recent agreement would, implicitly, reflect most accurately the will of the Parties.[51]

154. The Protocol is arguably more specific than trade rules, because it applies to an identified category of products, LMOs, while the WTO applies to all products in international trade. Supplementary rules of treaty interpretation could be taken to suggest that, in the event of a conflict, the Protocol Parties intended the more specialized rules in the Protocol to prevail over more general WTO rules.[52]

155. The tenth paragraph is thus intended to anticipate and to counterbalance arguments that the Protocol should be interpreted as an implicit decision by Parties to modify their obligations under the WTO and other existing international agreements. The provision could also be used to counterbalance arguments that the Parties implicitly intended the Protocol to prevail based on the fact that it is later in time, and contains specific rules related to LMOs.

156. The eleventh paragraph, is, on the other hand, intended to counterbalance any implication from the tenth paragraph that the WTO and other existing agreements would necessarily prevail in the case of a conflict.[53]It clarifies that the tenth paragraph is not intended to "subordinate" the Protocol to other international agreements, either existing agreements or those developed in the future. The reference here to "other international agreements" rather than only "existing" international agreements may be important. It implies that the tenth paragraph, will apply only to the Parties' rights and obligations under the WTO and other international rules as they currently exist, and not to new international agreements that may be developed later, either under WTO auspices or elsewhere.

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47 The Protocol text is similar to the text in the 9th preambular paragraph of the Rotterdam Convention which reads: "Emphasizing that nothing in this Convention shall be interpreted as implying in any way a change in the rights and obligations of a Party under any existing international agreement applying to chemicals in international trade or to environmental protection."

48 Vienna Convention on the Law of Treaties, Article 30(2), which provides that "when a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail.

49 The Protocol language is similar to, but departs from, the text in the CBD, which was also included, in part, to deal with potential conflicts with the WTO (then GATT). The CBD language, which is contained in operative rather than the preambular text, states that the "provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement". It goes on to provide an exception, suggesting that the CBD will prevail over existing treaties "where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity" (CBD, Article 22(1).

50 Vienna Convention on the Law of Treaties, Articles 30(3), 59(1)(b), 59(2).

51 This "supplementary rule" of treaty interpretation is known as "lex posterior derogat legi priori".

52 This "supplementary rule" of treaty interpretation is known as "lex specialis derogat legi generali".

53 The Protocol text is similar to the 10th preambular paragraph of the Rotterdam Convention, which reads: "Understanding that the above recital is not intended to create a hierarchy between this Convention and other international agreements."

Related Protocol provisions

157. In addition to these preambular references, negotiators included in the Protocol's operative text other provisions that are relevant to the Protocol's relationship to other international agreements:

- Article 2(4) reflects the same counterbalanced logic of the tenth and eleventh paragraphs of the Preamble. Article 2(4) reserves the right of a Party to take measures that are more "protective" than those provided for in the Protocol. However, it then constrains the exercise of that right to action consistent with the "objective and the provisions" of the Protocol, as well as Parties' "other obligations under international law" (see commentary on Article 2).[54]
- Article 14(1) applies to any future bilateral, regional and multilateral agreements the Parties may enter into "regarding intentional transboundary movements of LMOs". Such agreements must be "consistent with the objective of this Protocol" and may "not result in a lower level of protection than that provided for by the Protocol". This provision aims to ensure the Protocol provides an agreed minimum standard of protection and these standards would, presumably, apply to later international agreements, including those developed under the WTO (see commentary on Article 14).
- Article 18(1) and 18(3), which requires Parties to take into consideration relevant international rules and standards when dealing with the handling, transport, packaging and identification of LMOs (see commentary on Article 18).
- Article 24, which authorizes Parties to enter into agreements and arrangements with non-Parties if they are consistent with the objective of the Protocol (see commentary on Article 24).
- Article 26(1) which allows Parties when implementing the Protocol to take into account, consistent with their international obligations, socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities (see commentary on Article 26).

158. Further references to international agreements and institutions in the Protocol include:

- Article 2(2) which refers to the relationship between the Protocol and international law and instruments related to the law of the sea (see commentary on Article 2).
- Article 2(5), which refers to "instruments . . . undertaken in international forums with expertise in the area of risks to human health" (see commentary on Article 2).
- Article 5 of the Protocol provides that it shall not apply to human pharmaceuticals that "are addressed by other relevant international agreements" (see commentary on Article 5).
- Article 17(1), which requires Parties to notify, where appropriate, "relevant international organizations", when a release of LMOs occurs that may have transboundary consequences (see commentary on Article 17).

[54] Article 2(4) is similar in spirit to references in the WTO TBT and SPS Agreements.
The TBT Agreement, in its sixth preambular paragraph provides:
Recognizing that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement.
The first preambular paragraph to the SPS Agreement provides:
Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.

Article 1. Objective

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.

159. *The objective provision sets out what the Protocol is designed to achieve: simply put, why was the Protocol negotiated and adopted? What is it for?*

160. *The objective also has a legal effect. States that sign the Protocol must not act against the objective, and the implementation of the Protocol must conform to the objective. Several operative provisions of the Protocol refer back to the objective in terms of the standard of conduct required by Parties (see for example Articles 2(4), 14, and 24)*

161. A provision on the objective is found in most modern multilateral environmental agreements. The purpose of such a provision is to state, in fairly general terms, the aim that the treaty is meant to achieve: the reason for its existence. The provision on the objective establishes the frame within which actions have to be taken, setting the basis for the subsequent provisions with their more specific obligations. It also provides a point of reference or benchmark against which to measure activities undertaken under the treaty. The implementation of the treaty, as well as its further development, must conform to the objective. Suspected or alleged failure to conform to the objective when implementing the Protocol could be a matter for consideration by the compliance mechanism to be established in accordance with Article 34. In this spirit, other provisions of the treaty often state that specific rights of States are to be exercised "consistent with the objective" of the treaty. The Protocol contains such references in Article 2(4) in relation to the right of a Party to take more protective action than prescribed by the Protocol; Article 14(1) in relation to the right to enter into separate agreements on transboundary movements of LMOs; and Article 24 in relation to transactions with non-Parties. Although these provisions do not contain a direct reference to Article 1, the phrase "consistent with the objective of this Protocol" indicates that the objective as set out in Article 1 is to be adhered to in exercising the relevant rights and carrying out related activities.

162. Under the international law of treaties, a State that has signed a treaty but has not (yet) ratified it is under an obligation not to act contrary to the objective of that treaty, pending its entry into force.[55] To give a concrete example: while a signatory State cannot be required to apply the AIA procedure as set out in the Protocol, it is obliged to refrain from transactions involving LMOs that would result in unacceptable risks to biological diversity, for example to permit uncontrolled release of LMOs in an ecologically sensitive area.

163. By the phrase "in accordance with the precautionary approach as contained in Principle 15 of the Rio Declaration, the objective of this Protocol is …" in the first sentence, Article 1 of the Protocol declares the precautionary approach to be the basis and point of reference for the Protocol. In other words, the objective as set out in Article 1 is understood to be in accordance with Principle 15 of the 1992 Rio Declaration. The spirit of Principle 15 thus underlies the Protocol in its entirety. The essence of the precautionary approach as laid down in Principle 15 is that lack of full scientific certainty is not to be used as a reason for postponing measures to prevent environmental damage, where there is a threat of serious or irreversible damage. The inclusion of precaution in the Protocol, and the form in which it should be included, was the subject of considerable controversy.[56]

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[55] Vienna Convention on the Law of Treaties, Article 18; see also Glowka *et al. A Guide to the Convention on Biological Diversity* (IUCN, Gland and Cambridge, 1994), p. 15 . On entry into force see Article 37 of the Cartagena Protocol.

[56] See Introduction for further discussion of Principle 15 Rio Declaration.

164. The main elements of the objective of the Protocol as set out in Article 1 are:

to contribute to ensuring an adequate level of protection

165. The Protocol does not set an absolute standard of protection against adverse effects of LMOs. There is a double qualification built into the provision. Firstly, the Protocol is intended to *contribute* to ensuring protection. It is thus not to be the only means of ensuring protection, but should be supplementary to protective action undertaken in other forms and within other frameworks. This presupposes that other relevant action is being taken, or that it needs to be taken, in addition to the action taken under the Protocol. Such other action may be taken in accordance with the applicable national legislation of countries, or under other existing and future international legal instruments. Secondly, an *adequate level* of protection is envisaged, a wording which is subject to interpretation. This may imply that the level of protection should be adjusted to the specific activity undertaken and to the particular risks associated with it. In other words, the more risky the activity, and the more serious the potential consequences if the damage materializes, the higher the level of protection required.

... in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology

166. The objective of protection is to be met with respect to a range of activities involving LMOs resulting from modern biotechnology, namely transfer, handling and use. These terms are not defined in Article 3. Accordingly, they are to be understood in their everyday meaning.[57] The reason why these three activities were singled out is that they appear in Article 19(3) of the CBD, which formed the basis of the mandate for the negotiation of the Protocol. By contrast, the list of activities set out in Article 2(2) (General Provisions) is much broader, the idea being that every possible situation involving LMOs should be addressed (see commentary on Article 2(2)). Article 4, setting out the scope of the Protocol, refers to "transboundary movement, transit, handling and use" (see commentary on Article 4).

167. The terms "living modified organism" and "modern biotechnology" are defined in Article 3 (see commentary on Article 3). This component of the objective is qualified in the last part of the sentence, which provides for a specific focus on LMOs subject to transboundary movement.

... that may have adverse effects on the conservation and sustainable use of biological diversity

168. Protecting biological diversity against possible adverse effects of LMOs was the first consideration underlying the mandate to negotiate the Protocol. In the negotiations on Article 1, it was clear at quite an early stage that the protection of biodiversity against potentially negative aspects of LMOs would be the essential element of the objective. The use of the wording "biological diversity" in the context of Article 1 indicates a fairly narrow definition of the object of protection. By contrast, a number of existing national laws extend the scope of protection to the environment as a whole, including not only biological diversity but also other parts of the environment such as air, water and soils. The reference to "conservation and sustainable use" of biological diversity takes up the first two elements of the objective of the CBD (Article 1, CBD). The phrase "may have adverse effects" indicates adherence to the precautionary approach: protection is called for not only if the adverse effects are a certainty, and have been established as such by full scientific evidence, but also if there is a threat of adverse effects. Some take the view that the reference in Article 1 (and in Article 4) to LMOs "that may have adverse effects" serves to limit the scope of the Protocol since it is only those which may have adverse effects to which the Protocol will apply. However, there is no specific mechanism in the Protocol for exempting LMOs from its scope on this basis. By contrast, under Article 7(4), it is possible for the COP/MOP to exempt from the AIA procedure (but not from the Protocol as a whole) LMOs identified as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

... taking also into account risks to human health[58]

169. In addition to potential damage to biological diversity, the risks to human health that LMOs may pose must also be taken into account in assessing and managing risks associated with LMOs. The wording "taking also

[57] Vienna Convention on the Law of Treaties, Article 31.

[58] See section on human health in the Introduction for a further discussion of this issue.

into account …" constitutes a compromise between those who wanted to see protection of human health included in the objective of the Protocol, and those who felt that the objective should be limited to conservation and sustainable use of biological diversity. It is not certain what the effect of the wording "taking also into account risks to human health" implies in legal and practical terms for implementation of the Protocol. For example, what kinds of risks to human health will be taken into account: is it only those that result from some impact on biological diversity, or also more "direct" effects on human health (e.g. effects caused by consumption of LMOs or products containing LMOs)? Are these potential effects to be assessed in the same way as risks to biological diversity under the Protocol? Might potential effects on human health alone be sufficient to justify a restriction of imports of LMOs under the Protocol?

170. There seems to be widespread agreement that protection against indirect effects on human health i.e. resulting from effects on biological diversity, is part of the objective of the Protocol. Whether protection of direct effects on human health (e.g. effects caused by consumption of products containing LMOs) is also part of the objective is controversial, although the phrase "taking into account risks to human health" could support this interpretation.

171. During the negotiations some countries also proposed that other possible effects of LMOs be mentioned in the objective – for example socio-economic impacts or effects on animal health. These proposals are not reflected in the objective. There is, however, a separate provision in the Protocol on socio-economic considerations (Article 26).

… and specifically focusing on living modified organisms that are subject to transboundary movement

172. Article 1 provides for a specific focus on LMOs that are subject to transboundary movements, although the use of the term "specifically" indicates that the objective is not limited solely to transboundary movements of LMOs. Article 4 (on Scope) expresses a broader approach in that it lists "transboundary movement" as one of several activities involving LMOs to which the Protocol applies.

173. This somewhat convoluted wording reflects a compromise on a fundamental controversy that dominated the early negotiations of the Protocol: developing countries in particular favoured a Protocol covering *all* aspects of management and use of LMOs, which could to some extent compensate for the fact that at the time of the Protocol negotiations many developing countries did not have national legislation in place regulating LMOs. Most developed countries, on the other hand, were in favour of clearly limiting the scope of application of the Protocol to transboundary movements of LMOs.

174. The Protocol reflects both approaches. A number of provisions apply to transboundary movements only, most notably Articles 7-14 related to the AIA procedure. But there are also provisions covering transboundary movements as well as other forms of management and use. These include, among others, Article 16 (Risk Management), Article 22 (Capacity-Building), and Article 23 (Public Awareness and Participation). The broader approach is also reflected in the General Provisions (Article 2(2)), which go beyond the issue of transboundary movements by obliging Parties to ensure that "the development, handling, transport, use, transfer and release" of LMOs are carried out in a manner that prevents or reduces risks (see commentary on Article 2).

Box 10. Provisions relating to transboundary movements only and provisions addressing a broader scope of activities

Whether or not a provision applies only to transboundary movements of LMOs or has a broader scope may be subject to interpretation and it is not possible to give definitive guidance here at this stage. The table below makes an initial attempt to identify provisions of the Protocol applying to transboundary movement only and those with a broader application. The distinction is made on the basis of whether or not the core of the provision is limited to transboundary movements; in other words, looking at the general content of a provision rather than at whether or not the wording contains the specific term "transboundary movement". In some instances, one paragraph of an article relates to transboundary movement only, while another one has a broader scope.

Provisions related to transboundary movements (TBM) only		**Provisions with a broader scope**	
Article	**Content**	**Article**	**Content**
5	Exemption from the Protocol of TBM of certain pharmaceuticals for human use	1	Objective
6	Exemption from AIA procedure of transit TBM and of TBM of LMOs destined for contained use	2	General provisions
7	Application of the AIA procedure	3	Use of terms
8	Notification	4	Scope: TBM, transit, handling and use of LMOs
9	Acknowledgement of receipt	11(1)–(3)	Procedure for LMOs intended for use as food/feed for processing
10	Decision procedure	15(1)	Risk assessment general
11(4)–(9)	Procedure for LMOs intended for use as food/feed for processing	16	Risk management
12	Review of decisions	18(3)	Handling, transport, packaging and identification
13	Simplified procedure	19	Competent authorities and focal points
14	Bilateral/regional/multilateral agreements/arrangements on TBM	20	Information sharing /Biosafety Clearing-House
15(2),(3)	Risk assessment for TBM	21(3)	Confidential information
17	Unintentional TBM	22	Capacity building
18(1),(2)	Handling, transport, packaging and identification	23	Public awareness and participation
21(1),(2), (4)–(6)	Confidential information	24(2)	Encouragement of non-Parties to join Protocol
24 (1)	TBM with non-Parties	26	Socio-economic considerations
25	Illegal TBM	28	Financial mechanism
		33	Monitoring and reporting
		34	Compliance
		35	Assessment and review

Article 2. General provisions

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

175. *Article 2 sets out certain general rules and principles that Parties must observe in implementation of the Protocol. It addresses a diversity of issues which are not addressed in detail elsewhere in the Protocol.*

176. *This is a fairly common type of provision in modern multilateral environmental agreements. Such provisions may restate generally recognized rules of international law, or refer to established principles of cooperation between Parties. The purpose of the provision is not to create new obligations as such, but to emphasize general rules that are considered especially important in the context of this particular Protocol, thus providing guidance to Parties for its implementation.*

177. *Article 2 sets out five general provisions.*

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

178. This provision is a restatement of a general rule of international treaty law. A State that is a Party to an international treaty is bound by that treaty[59] and must comply with its obligations under the treaty. For this purpose, it must ensure that activities carried out within areas under its jurisdiction or control are in accordance with the pertinent obligations. The Party may itself decide on the legal, institutional and other means through which to achieve implementation. The tools generally used by States for this purpose are a national legal framework setting out rights and obligations of persons (natural and legal) under its jurisdiction which aim at ensuring the implementation of the international instrument, and an institutional framework to apply and enforce the national legislation. The obligation on Parties to develop a national framework has a catalytic role: without it, many Parties might not have developed such a framework in the near future.

[59] Vienna Convention on the Law of Treaties, Article 26.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

179. This obligation refers to the main component of the objective of the Protocol set out in Article 1, namely the conservation and sustainable use of biological diversity, taking also into account risks to human health (see Introduction). By stating that activities involving LMOs are to be carried out "*in a manner that prevents or reduces risks",* Article 2(2) relates directly to the need for prior risk assessment as addressed in Articles 15 and 16. The provision reflects the preventive approach, which is widely recognized in modern international law. It emphasizes that legal rules should be designed to prevent damage from occurring rather than attempting to remedy damage after it has occurred.

180. Article 2(2) provides that Parties should be guided by the preventive approach in relation to the following activities involving LMOs:

- development;
- handling;
- transport;
- use;
- transfer; and
- release.

181. These terms are not defined in Article 3 of the Protocol. Accordingly, they are to be understood in their everyday meaning.[60] The list of activities set out here is very broad, the idea being that every situation involving LMOs should be covered. By contrast, Article 1 (Objective) only mentions "transfer, handling, and use", which are the terms that appear in Article 19(3) of the CBD. Article 4, setting out the scope of the Protocol, refers to "transboundary movement, transit, handling and use" (see commentary on Article 4).

182. Article 2 covers activities which are not expressly included within the provision on scope of the Protocol in Article 4 – i.e. the "development", "transport" and "release" of LMOs. Article 2 is thus wider in its application than other provisions of the Protocol. It establishes a requirement that Parties carry out any of the activities mentioned in accordance with the preventive approach. This ties in with the obligation on countries to develop the necessary mechanisms to carry out risk management, as laid down in Article 16(1). A similar approach is reflected in Article 8(g) of the CBD, which requires Parties to that Convention to control the risks associated with the use and release of LMOs that could have adverse effects on biological diversity.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

183. This provision basically states that the rights and freedoms of States under the international law of the sea will not be affected by the provisions of the Protocol. This applies in particular to the provisions addressing the transit of LMOs through a third country and potential rights and obligations of the transit State in this context.

[60] Vienna Convention on the Law of Treaties, Article 31.

Box 11. Navigational rights and freedoms and transboundary movements of LMOs

The issue of navigational rights and freedoms is potentially relevant for any international legal instrument that sets out restrictions on international transfer or trade in a substance or product, or allows Parties to impose such restrictions. In accordance with customary international law as reflected in the 1982 UN Convention on the Law of the Sea (UNCLOS),[61] States have sovereignty over their territorial sea and the airspace above their territory. They also have rights with respect to certain sea areas that are not part of their territory but that are adjacent to it, notably the exclusive economic zone and the continental shelf.

The territorial sea is considered part of the territory of the coastal State. It extends to 12 nautical miles beyond the "baseline" (which, roughly, follows the shoreline). Within its territorial sea, a State exercises sovereignty and thus, among other things, it has the right to adopt measures for the protection of the marine environment.[62] The exclusive economic zone, which extends to 200 nautical miles beyond the baseline, is *not* a part of the coastal State's territory. However, in accordance with customary international law and UNCLOS, the coastal State has the exclusive right to exploit, manage and conserve natural resources within this zone. This includes the right to adopt measures to protect the environment, e.g. to control pollution.[63]

At the same time, customary international law and UNCLOS establish the right of innocent passage through the territorial sea, and the right of overflight.[64]

In the case of transit of potentially hazardous substances through the relevant areas, there is room for conflict between the rights of a coastal State and those of a State wishing to exercise its right of innocent passage or overflight. On the one hand, the coastal State has the right to adopt measures to reduce and control pollution in the relevant areas. This may include restrictions regarding substances that are potentially harmful to the environment. On the other hand, other States have the right of innocent passage or overflight with respect to these areas. This may include transit of potentially hazardous substances through the areas in question, as long as there is no attempt to deposit the substances. Article 2(3) of the Protocol simply reaffirms these rights, and states that the Protocol shall not affect them. It does not address or attempt to resolve any potential conflict between the coastal State and other States. An indication that the right to protect the environment within the relevant zones may take precedence over transit rights can be found in Part XII of UNCLOS, which establishes a general obligation of protecting the marine environment, including in particular rare or fragile ecosystems, as well as the habitat of depleted, threatened and endangered species.[65] This can be understood to include protection against adverse effects of LMOs. Accordingly, States must always respect the obligation to protect the marine environment when exercising navigational rights and freedoms, and rights over marine areas.

The wording of Article 2(3) of the Protocol is taken verbatim from Article 4(12) of another international agreement, the 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal ("Basel Convention"). The Basel Convention was the first international legal instrument to address at the global level environmental aspects of transboundary movement of potentially hazardous materials. Many of the underlying issues are similar to those of the Protocol. For this reason, the Basel Convention served as a reference for a number of provisions of the Protocol, including Article 2(3). In the negotiations on the Basel Convention, the rights of transit States were among the most contentious issues in the negotiations. The resulting provision was criticized as inadequate at the time of adoption of the Basel Convention. The legal implications of the issue have never been resolved, and there appears never to have been a concrete case where a conflict arose.[66]

The wording of Article 4(12) of the Basel Convention is based on the understanding that the transit State is given an active role in a proposed transboundary movement. Under the Basel Convention, this is indeed the case: the prior informed consent procedure for hazardous wastes (i.e. the equivalent to the AIA procedure under

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61 In matters pertaining to rights of states over certain marine areas as well as to navigational rights and freedoms, UNCLOS is widely held to reflect customary law in the relevant areas.

62 Recognition of the international law principle of State sovereignty over the territorial sea can be found in Article 2 of UNCLOS.

63 The extent of a State's rights and jurisdiction over its exclusive economic zone and continental shelf is defined in Parts V and VI, respectively, of UNCLOS.

64 The extent and limits of the right of innocent passage by ships through a State's territorial sea are defined by Articles 17 to 32 of UNCLOS. Article I, sections 1-5, of the International Air Services Transit Agreement lay down the extent and limits of the freedom to transit through the airspace of States of aircraft pursuant to scheduled international air services.

65 UNCLOS, Article 192 and 194(5).

66 For a discussion of Article 4(12) of the Basel Convention, and the negotiations leading to its adoption, see Kummer, K. *International Management of Hazardous Wastes – The Basel Convention and Related Rules* (Oxford University Press, 2000), p.52 *et seq*.

Box 11. Navigational rights and freedoms and transboundary movements of LMOs (cont.)

the Protocol) is applicable to transit States. In the negotiations on the Protocol, application of the AIA procedure to transit States was also considered. However, the final text of Article 6(1) expressly states that the AIA procedure is not applicable to transit of LMOs. It merely refers to *"any right of a Party of transit*" to control transit unilaterally (see commentary on Article 6). As the Protocol does not accord transit States an express right to oppose transit movement in accordance with the AIA procedure, the relevance of Article 2(3) of the Protocol is even more limited than Article 4(12) of the Basel Convention. In fact, during the negotiations on the Protocol, there was disagreement as to whether this provision was needed at all.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

184. This paragraph establishes that the rules contained in the Protocol are a "floor" rather than a "ceiling" – i.e. they are the minimum standard for achieving the objective of the Protocol that States could agree during the negotiations.[67] Some countries wished to impose more protective measures, or indeed already had more protective measures in place or under development. Parties will implement the Protocol through an appropriate legal and institutional framework at the national level. In enacting or adapting this framework, Article 2(4) reserves the right for Parties to adopt protective measures that go beyond the agreed minimum standard.

185. This freedom is not unlimited, however:

- First, Article 2(4) requires that any more protective action taken by a Party must be "consistent with the objective and provisions" of the Protocol. The objective of the Protocol is set out in Article 1. Protective action that goes further than those specified in the Protocol must support this objective, not counteract it.
- Second, any such action must also be "in accordance with that Party's other obligations under international law". For most Parties to the Protocol, other relevant obligations under international law here will include their obligations as a Member of the World Trade Organization. The interaction between rights and obligations under the Protocol and those under relevant WTO Agreements is considered in the Preamble and in detail in the Appendix to this Guide. It should not be forgotten, however, that the WTO Agreements are not the only international legal instruments to which this provision applies.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

186. This provision recalls the issue of risks to human health (see Introduction and commentary on Article 1) and "encourages" Parties to take into account available expertise, instruments and work in other forums. The provision is not couched in mandatory terms, but serves as a reminder of the numerous efforts by other organizations to address the protection of human health in the context of LMOs, which might be integrated into the work under the Protocol but not duplicated. There are a number of organizations dealing with this issue, e.g. WHO and FAO: among other things, the two organizations jointly operate the *Codex Alimentarius* (see Introduction and Box 12).

[67] Stec, S., Casey-Lefkowitz, S. and Jendroska, J. *The Aarhus Convention: an Implementation Guide*, UNECE/CEP/72 (United Nations, New York and Geneva, 2000) p. 45.

Box 12. *Codex Alimentarius* and Genetically Modified Foods

The *Codex Alimentarius* Commission is a FAO/WHO body which elaborates standards, general principles, guidelines and recommended codes of practice in relation to food safety. As of 2002, there are at least three processes underway in the *Codex Alimentarius* Commission of relevance to the safety assessment and labelling of foods derived from modern biotechnology.

In 1999, the *Codex Alimentarius* Commission decided to establish a *Task Force on Foods derived from Biotechnology*. The Task Force met for the first time in March 2000 and decided to elaborate (a) a set of broad general principles for risk analysis of foods derived from biotechnology; (b) specific guidance on the risk assessment of foods derived from biotechnology; and (c) a list of available analytical methods including those for the detection or identification of foods or food ingredients derived from biotechnology. The Task Force is due to present its final report to the Commission in 2003. At its third meeting in March 2002 the Task Force agreed to advance Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and a Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants for consideration by the *Codex Alimentarius* Commission in 2003.

In the meantime, the *Codex Committee on General Principles* is undertaking work on Draft Working Principles for Risk Analysis. These may address, among other things, the role of precaution in risk management.

The *Committee on Food Labelling* is in the process of considering draft recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification/Genetic Engineering.

Other Codex Committees undertaking work relevant to foods derived from modern biotechnology include the Committee on Food Import and Export Inspection and Certification Systems and the Committee on Methods of Analysis and Sampling.

Domestic food safety measures that are in conformity with standards, guidelines and recommendations of the *Codex Alimentarius* are (rebuttably) presumed to be consistent with the WTO Agreement on Sanitary and Phytosanitary Measures (see Appendix).

Further information on the work of the *Codex Alimentarius* Commission is available at http://www.codexalimentarius.net

Relevant work is also underway in other fora, such as the Interim Commission on Phytosanitary Measures of the International Plant Protection Convention (see Introduction).

Article 3. Use of terms

For the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) "Export" means intentional transboundary movement from one Party to another Party;

(d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) "Import" means intentional transboundary movement into one Party from another Party;

(f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "Modern biotechnology" means the application of:

a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. 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;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

187. *The inclusion of an article defining certain terms used in the text of an international instrument is a legal technique often used in multilateral environmental agreements. This is intended to achieve a high degree of clarity and accuracy in describing the meaning attached to the term defined. It also facilitates the drafting of the subsequent articles, which then may use the term without any further explanation – as the term may only be understood as defined. Legal definitions are specific to a particular legal text, and only meant to facilitate its drafting. Thus they may depart from scientific or technical definitions, and often do so.*

188. *Many words and phrases used in the Protocol are, of course, not specifically defined in Article 3. Under Article 31 of the Vienna Convention on the Law of Treaties, the terms used in a treaty, in the absence of special*

meaning of the term expressed in the treaty by the parties, are to be "interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

189. As described in the Introduction, the Protocol was adopted under the auspices of the 1992 CBD. Article 29 of the Protocol stipulates that the Conference of the Parties to the CBD shall serve as the "meeting of the Parties to this Protocol".

(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

190. Contained use is addressed in Article 6(2) of the Protocol, which excludes from the advance informed agreement procedure the transboundary movement of LMOs destined for contained use, provided that the contained use is undertaken in accordance with the standards for contained use that have been set – for example, in domestic legislation – by the Party of import. Documentation requirements for LMOs destined for contained use are addressed in Article 18(2)(b).

191. The emphasis in the definition is on characteristics which effectively limit both contact with the external environment, and (as a result) the impact thereon, as is normally the case in a laboratory.

192. However, what constitutes an appropriate barrier was the subject of much debate during the negotiations, in particular whether physical barriers were required or whether chemical or biological barriers would be sufficient. The essence, however, of such barriers is that they should *effectively* limit the contact, and the impact, of the LMOs intended for contained use on the external environment. In this respect, the definition provides some flexibility for national legislation for purposes of Article 6, but it does not provide clear guidance in order to harmonize the use of this term in national legislation. Several examples of national legislation on contained use adopted to date require chemical or biological barriers, where used, to be used in combination with physical barriers (see Box 13 below).

Box 13. Examples of definition of "contained use" in national legislation

Philippines Administrative Order No. 8 of 3 April 2002 on Rules and Regulations for the Importation and Release into the Environment of Plants and Plant Products derived from the Use of Modern Biotechnology

Contained Use means the use of a regulated article for research and development inside a physical containment facility intended to limit its contact with, and to provide for a high level of safety for, the general population and the environment which has been inspected and approved by NCBP (the National Committee on Biosafety of the Philippines).

Norway's Gene Technology Act No. 38 of 2 April 1993

The term contained use means any operation in which genetically modified organisms are produced, grown, stored destroyed or used in some other way in a closed system which physical barriers are employed, either alone or together with chemical and/or biological barriers, to limit contact between the organism on the one hand and humans and the environment on the other.

Swiss Ordinance on the Contained Use of Organisms (Containment Ordinance 814.912) of 25 August 1999

Contained use shall mean any containment measure using physical barriers or a combination of physical and chemical or biological barriers to limit or prevent contact between organisms and people or the environment.

(c) "Export" means intentional transboundary movement from one Party to another Party;

(d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) "Import" means intentional transboundary movement into one Party from another Party;

(f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

193. The cluster of definitions on import, export, importer and exporter is at the core of many Protocol provisions. Only intentional, i.e. deliberate, transboundary movements constitute export or import, and exclusively those respectively from and to Parties. Unintentional, or accidental, transboundary movements are dealt with in Article 17.

194. It is important to note that both export and import are defined as "transboundary movement", with the result that the use of the term "transboundary movement" in the Protocol may mean either export or import. The definition of exporter and importer refers to persons carrying out these activities under the jurisdiction of a Party.

195. A "natural" person is an individual; a "legal" person is a company or any other institution which, according to the national legislation under which it is constituted, has a separate legal personality.

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

196. The definition of LMO is central to defining the scope of the Protocol itself. During the negotiations a special working group was established to consider technical definitions and the annexes to the Protocol.

197. The definitions in Article 3(g) and (h) are closely intertwined, and their elements are considered together below. The term "genetic material" is considered first, as this is an important concept in the subsequent consideration of the terms "living organism" and "modified organism".

Genetic material

198. Genetic material is not defined in the Protocol. The CBD, however, provides a definition in Article 2, which reads: "*Genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity.*" In biological and genetic terms, functional units of heredity are made up of nucleic acids containing genetic information: the functioning of the unit as a whole is affected by any change that occurs within the unit – for example, a change modifying the unit by altering, inserting or deleting one or more nucleotides within the unit. A further description of genetic material, and of chromosomes, genes and nucleic acids which comprise such material, is provided in Box 14.

199. The definition provided in the CBD therefore covers nucleic acids of plant, animal, microbial or other origin, that contain genetic information; but, in addition, also covers any material of plant, animal, microbial or other origin – such as whole organisms or parts of organisms – which contains nucleic acids that contain genetic information. This reflects the CBD's concern to address access to genetic resources and benefit sharing (Article 1 and Article 15, CBD).

200. The context in which the term "genetic material" is used in Articles 3(h), 20(3)(c), Annex I(i) and Annex III(5) of the Protocol suggests that the term is being used specifically to refer to nucleic acids that contain genetic information. Article 3(h) refers to a

"biological entity capable of … replicating genetic material". In biology and genetics, replication is a term that is applied specifically to the process of making copies of nucleic acids – therefore "replicating genetic material" would only be possible if the material being replicated were a nucleic acid. Similarly, Article 20(3)(c), Annex I(i) and Annex III(5), refer to "replicable genetic material" – again, in biological and genetic terms, the only material that is replicable is nucleic acid.

201. The term "genetic material" is therefore used in the Protocol in a manner that is consistent with the definition provided in Article 2 of the CBD, but refers specifically to nucleic acids containing genetic information. Based on this, it is suggested that the term "genetic material" in the Protocol can be understood to refer to nucleic acids that contain functional units of heredity.

Box 14. Genetic material: chromosomes, genes and nucleic acids

Genetic material in organisms is mostly contained in structures called chromosomes. Within each chromosome, genetic material is divided into genes, including various control elements and other elements of currently unknown function. Genes represent functional units of heritable genetic information present within an organism or a cell.

The genetic information of each gene is coded in a nucleic acid molecule: for all organisms (other than some viruses and viroids) this nucleic acid molecule is DNA – for some viruses and viroids the genetic information is stored on molecules of the nucleic acid, RNA. These nucleic acid molecules contain and transmit genetic information. The collective term "genome" is applied to all the nucleic acid molecules carrying heritable genetic information that are present within an organism or a cell. This may include sequences of "junk" or "nonsense" DNA, which on the basis of current knowledge and understanding of genetics, is not believed to have any functions.

The nucleic acid molecules are made up of sequences of nucleotides. The overall sequence of nucleotides in chromosomes – comprising genes including control elements, and other nucleotide sequences – can affect gene activity and expression; changes to this overall nucleotide sequence can therefore result in changes to gene activity and expression. It is also important to note that chromosomes incorporate a variety of proteins and other biological molecules which provide important structural components and control mechanisms that participate in the regulation of gene activity.

For all organisms (except for bacteria, blue-green algae, viruses and viroids) the chromosomes are contained in a cellular structure called the cell nucleus, which also contains various proteins and other biological molecules. While the chromosomes contain most of the genetic material of such organisms, some further genetic material is contained in other organelles (such as chloroplasts and mitochondria) and in the cytoplasm (including plasmids and other discrete genetic elements, termed episomes, that are not part of the chromosomes in the nucleus).

For bacteria or blue-green algae, the chromosomes are found free in the cytoplasm, and are of a much less complicated structure – and usually are a single circular structure formed of either single or double-stranded DNA. In viruses, the chromosome is either single or double-stranded DNA or RNA, which may be packaged in an envelope of proteins and other molecules.

Cellular structures and controls of all organisms and their genetic material, including bacteria and blue-green algae, are complex, and there remains a long way to go in understanding the way in which genes are controlled and expressed. This is one of the reasons for invoking the precautionary provisions in relation to LMOs covered by the Protocol.

Living organism

202. A living organism is defined in Article 3(h) as a biological entity that can replicate and/or transfer genetic material.

203. Replication is the process whereby exact copies of nucleic acids – the molecules which contain genetic information – are produced.

204. The phrase "or transfer genetic material" was included in Article 3(h) to ensure that entities such as viruses and viroids, which by themselves cannot actively replicate genetic material, are nonetheless covered by the definition of living organism in the Protocol. Viruses are non-cellular micro-organisms which consist of protein and of nucleic acid (DNA or RNA) containing genetic material, which are incapable of self-replication, and which can insert their genetic material into other (animal, plant or microbial) cells where it is then replicated by the machinery of those

cells.[68] Viroids are plant pathogenic infectious agents comprising small, naked RNA molecules (i.e. not encased in protein) that contain approximately 240–380 monomer units in a closed circle.[69] Viroids, like viruses, use the cells of host organisms to replicate their genetic material. Viruses and viroids are both explicitly mentioned in Article 3(h), reflecting the intention of the negotiators that they be included.

205. Sterile organisms are also explicitly mentioned. Although such organisms cannot reproduce themselves through the processes of sexual reproduction, they can replicate their genetic material, and may be able to reproduce themselves through non-sexual or vegetative processes. A sterile plant growing in the field is most certainly alive, and many plants used in agriculture – such as potatoes and bananas – are often not grown from seed, but are propagated by vegetative means.

Naked DNA and plasmids

206. There was consensus not to include plasmids[70] and naked DNA[71] as such within the definition of living organism in Article 3(h).

207. However, where a novel combination of genetic material is introduced into a recipient living organism through the use of naked DNA or plasmids as part of a technique of modern biotechnology, the resultant organism will qualify as an LMO as defined in Article 3(h). The same goes for a living organism in which a plasmid created by modern biotechnology and which contains a novel combination of genetic material is present, even where the plasmid is not integrated into the chromosomes of that organism.

Living modified organism

208. The term "living modified organism" is defined in the Protocol to include only those living organisms that:

- contain novel combinations of genetic material; and
- have been produced using the techniques of modern biotechnology.

Novel combination of genetic material

209. A novel combination may be regarded as a combination that was not previously known to exist at the time it was first produced. Based on the Protocol's usage of the term "genetic material" (see paragraphs 198–201), it is suggested that the Protocol's references to "novel combination of genetic material" can be understood to refer to a novel combination of nucleic acid containing functional units of heredity.

210. It is important to note that the novel combination relates solely to a combination of genetic material; it does not depend on any other changes that may or may not occur to material in a LMO, other than its genetic material. Even if a novel combination of genetic material did not result in an observable change in, for example, the phenotype or appearance and behaviour of an organism, the combination would still be novel.

211. The novelty of a combination could arise through the presence of a novel form of a functional unit of heredity – resulting from a change that modifies the unit by altering, inserting or deleting one or more nucleotides within the unit, so that the overall sequence of nucleotides is changed within the unit – or as a novel arrangement of functional units of heredity. Such novel arrangements arise, for example, from introduction of genetic material from different species into a recipient organism. Novel arrangements could also arise from rearrangement of genetic material of the same species.

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[68] *Dictionary of Microbiology and Molecular Biology* (Second Edition) (1987, Reprinted 1989) A. Wiley Interscience Publications, Editors Diana Sainsbury and Paul Singleton, pp. 945–946.

[69] *Dictionary of Microbiology and Molecular Biology* (Second Edition) (1987, Reprinted 1989) A. Wiley Interscience Publications, Editors Diana Sainsbury and Paul Singleton.

[70] Plasmids are linear or circular molecules of DNA which can replicate autonomously and which may encode products and/or functions that modify the phenotype of the host cell. They do not form part of the chromosome of an organism, but incorporate functional units that are heritable (Dictionary of Microbiology and Molecular Biology (Second Edition) (1987, Reprinted 1989) A. Wiley Interscience Publications, Editors Diana Sainsbury and Paul Singleton, pp. 682-683). Plasmids may either be maintained by incorporation within appropriate vector organisms, such as bacteria, or they may be kept as isolated DNA in which case they are not incorporated into any organism.

[71] 'Naked DNA' is DNA that is not attached to or in close association with other biological molecules.

212. A novel combination could arise from a change to even just a single nucleotide in a nucleotide sequence, as well as from larger changes, such as the introduction of genes hundreds or thousands of nucleotides in length.

Obtained through the use of modern biotechnology

213. The novel combination of genetic material must be "obtained through the use of modern biotechnology", the term "modern biotechnology" being defined by the Protocol (see article 3(i)).

214. This fundamental criterion for definition of LMO applies irrespective of whether the resulting genotype or phenotype could have arisen naturally or not. The question as to whether the genotype or phenotype of an organism could also have occurred naturally has no bearing on whether an altered organism is a LMO under the Protocol or not. Whether an organism is, or is not, a modified organism under the Protocol, is only dependent on the use of specific techniques defined by the Protocol as techniques of modern biotechnology (see Article 3(i)), to create a novel combination of genetic material. Furthermore, any organism into which such a novel combination of genetic material that has been obtained through the use of modern biotechnology, is subsequently transferred, even if that transfer is achieved through traditional breeding and selection techniques, will also be a LMO under the terms of the Protocol.

Box 15. Comparison of the term LMO in the CBD and in Article 3 of the Protocol

The term "LMO resulting from *biotechnology*" is used in Article 8(g) and 19(2) of the CBD. The term had been interpreted as covering all organisms resulting from biotechnology that are alive. During the CBD negotiations there had been seen to be two distinct categories of LMOs: the first being those modified using traditional techniques; and the second being "genetically modified" organisms, a sub-set produced using modern biotechnology, particularly recombinant techniques.[72]

In the negotiations on the CBD, there was a great deal of discussion as to whether to refer to "LMOs resulting from biotechnology" or to "genetically modified organisms". The former term is much wider in that it does not require the insertion of genetic material. Because some of the concerns directed towards GMOs – such as the risk of invasiveness, the spread of introduced traits, selection for resistant organisms from bio-pesticides, and displacement of traditional methods of agriculture and traditional crops – might be, under some circumstances, equally applicable to traditionally developed or bred organisms, it was decided to use the wider term.[73]

However, in CBD COP decision II/5 which provided the terms of reference for the negotiation of the Protocol and, therefore in the Protocol itself, the definition has been narrowed by the reference to *modern biotechnology*, the term being defined in the Protocol in such a way as to exclude LMOs produced using traditional breeding methods.

In many countries, the terms "genetically modified organism", "genetically engineered organism", and "transgenic organism", are widely used, including in domestic legislation, to describe LMOs covered by the Protocol.

(i) Modern biotechnology" means the application of:

a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. 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;

72 Glowka *et al*, p.45.

73 Glowka *et al*, p.45.

215. The Protocol defines modern biotechnology as both the application of *in vitro* nucleic acid techniques, and fusion of cells beyond the taxonomic family. This includes, but is not limited to, *in vitro* nucleic acid techniques applied to insertion of genetic material, deletion of such material or the alteration of genetic material (see Box 16). The techniques applied must also overcome natural physiological reproductive or recombination barriers.

216. *In vitro* nucleic acid techniques, or cell fusion, are techniques which allow very large evolutionary barriers to be crossed, and for genes to be moved between organisms which have not been known to have genetic contact.[74] It is now possible directly to insert genetic material using laboratory techniques.

Box 16. Description of gene constructs used in *in vitro* nucleic acid techniques

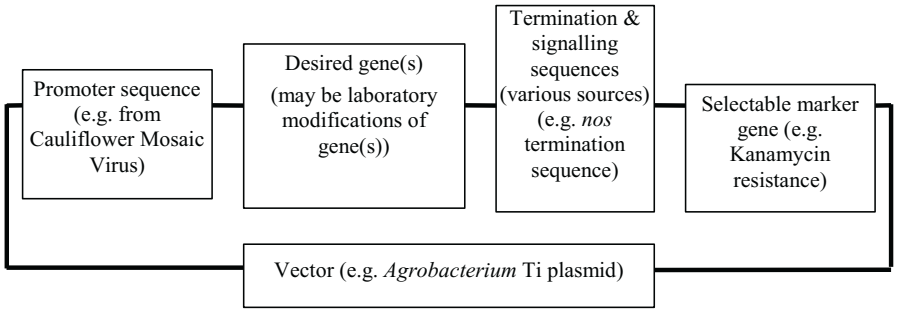
Once a gene has been isolated from a donor organism, it is modified in the laboratory so that it can be inserted effectively into the intended recipient organism. The modifications include making a large number of copies of the gene to be introduced, and possibly introducing changes to the sequence of nucleotides in the isolated gene in specific ways to enhance the expression of the gene once it is introduced into the intended recipient organism.

Following this, the gene to be introduced is built into a "gene construct". The gene construct includes a "promoter sequence" which is necessary to ensure that the gene is expressed correctly in the recipient organism. Different promoter sequences control gene expression in different ways – some allow continuous expression of the gene, while others switch expression of the gene on or off at different stages of the life-cycle of the organisms, or control the particular tissues or organs in which the gene will be expressed. "Termination" and "signalling" sequences are also incorporated into the gene construct. The termination sequence acts as a signal that flags where the end of the introduced gene is located: like the promoter sequence, the termination sequence is also important in ensuring that the introduced gene is expressed correctly. The signalling sequence provides information about the processing of the product produced from the gene construct.

A "marker gene" is often incorporated into the gene construct – this helps to make it easier to identify which individuals of a recipient organism have been modified by the introduction of the gene construct. Commonly used markers genes are those for antibiotic resistance: following introduction of the gene construct, individuals of the recipient organism are grown in the presence of antibiotics, and under these conditions, only those individuals that have been modified by the gene construct will show antibiotic resistance and therefore will be able to grow. Marker genes may be removed from the LMOs formed by this process at a later stage. Because of concerns over possible spread of antibiotic resistance traits, the use of antibiotic resistance marker genes is being phased out.

Finally, a vector may be incorporated into the gene construct. The purpose of the vector is to assist transfer the gene construct into the recipient organism. An example of a gene construct including a bacterial DNA vector (*Agrobacterium* plasmid), is shown below.

The following diagram gives an example of a very simple gene construct:



(Note: Gene constructs currently used may include multiple elements – for example, several promoter sequences and desired genes)

The gene construct is built from genetic material isolated from several different organisms, for example, a promoter from the Cauliflower Mosaic Virus, a bacterial DNA vector (*Agrobacterium* plasmid), one or more genes that may have been modified artificially in the laboratory, termination and signalling sequences, and a selectable marker gene, for example for resistance to the antibiotic kanamycin.

[74] Sidney Brenner (1978), from Wright, S. in *Molecular Politics – Developing American and British Regulatory Policy for Genetic Engineering 1972–1982* (University of Chicago Press, 1994), p. 76.

A gene or genes may be copied from any (donor) organism, modified so as to look like a gene from an organism similar to the recipient organism, and inserted into the recipient. Even without crossing evolutionary barriers, these techniques allow for rearrangements of genetic material into combinations that would not occur through recombination events during normal cell and organism reproduction.

217. New techniques of modifying the genetic information within organisms are being discovered all the time. The negotiators of the Protocol recognized that it was necessary to provide a definition of "modern biotechnology" that would cover new techniques not yet envisaged at the time that the Protocol was adopted, but which may emerge in the future. Any definition, therefore, needed to be drafted so as not to exclude new technological processes not yet identified but which may give rise to novel combinations of genetic material through the use of modern biotechnology.

218. The negotiators agreed that it would not be possible to cover future developments by including detailed lists of existing techniques in the Protocol. Indeed, such lists would tend to have the effect of excluding future techniques. The definition in Article 3(i) seeks to reflect the need to cover future techniques, by using the wording "*in vitro* nucleic acid techniques", giving two existing examples of such techniques, and leaving open whether new techniques will be regarded as "*in vitro* nucleic acid techniques" or not; and by referring to fusion of cells.

Box 17. Cell fusion

Cell fusion involves cells from two different organisms that are fused resulting in an organism containing the genetic information from both parental cells. Recombination between the two sets of genetic material becomes possible before the fused cell once again splits into two cells each containing a part of the genetic information from the fused cell. This produces hybrid cells in which a variety of things may occur, including recombination and segregation, or a chromosome doubling to allow segregation in subsequent cell divisions. Cell fusion can be applied to bacterial, fungal, plant or animal cells, using a variety of techniques to promote fusion.

219. The insertion of specific foreign DNA into a bacterial, fungal, plant or animal cell – which is one of the techniques included covered by the term "*in vitro* nucleic acid techniques" – is discussed in Section III of the Introduction and described in Box 18 below.

Box 18. Stages in making a new LMO using insertion of recombinant DNA

There are usually at least four stages in making a new LMO using insertion of DNA, which is currently the most commonly applied *in vitro* nucleic acid technique. It should be noted that other techniques of modern biotechnology, some of which also involve application of *in vitro* nucleic acid techniques, and others which involve cell fusion, may also be applied to produce LMOs.

Stage 1

An organism (the "donor") with a desired characteristic (trait) is found, and a gene (or more than one) is identified that confers that trait. The characteristic may be found in micro-organisms, plants or animals. An example might be tolerance of a particular herbicide or a particular pesticidal property. These genes are abstracted from the "donor organism".

Stage 2

Copies of the gene are made, possibly changing the sequence to take into account the preferential codon usage found in the intended recipient organism.[75] Other genes including control elements that may be needed for the system to work may be added to form a package, termed a "gene construct": the new genes including their control units may be derived from different organisms.

Cont.

[75] The genetic code has many redundancies; it uses a three letter code constructed from the four units that make up the polymeric nucleic acid, hence there are 64 possible combinations. Approximately twenty of these combinations are actually needed, hence there may be many different combinations coding for the same 'amino-acid' that will be incorporated into a protein. It was found that different organisms use different sets of these codons preferentially.

Box 18. Stages in making a new LMO using insertion of recombinant DNA (cont.)

Stage 3

The 'gene construct' is usually inserted into some form of transfer system that is used to introduce the modification into the recipient organism.

There are a number of methods used to insert the genetic material, depending on the recipient. In bacteria and fungi changes are easily accomplished. The single-cell organisms are transformed[76] – genes are usually inserted into a plasmid that is then inserted into the cell, effecting the desired change in phenotype. This results in a change to the characteristics of the single-cell organism which is heritable and also separable from the main genetic information.

The most common method for modifying animals is micro-injection. This involves the injection of the foreign DNA into a fertilized egg, which is then inserted into a mother (in the case of mammals) and allowed to develop to term. The DNA may be incorporated into a chromosome or exist as an autonomous DNA fragment which may be replicated and passed on to offspring which may express the inserted characteristics. The first animal modified in this way was made in the early 1980s and the technique has been applied to many animals, including cattle, pigs, sheep, fish and insects.

Another method for modifying animals uses retroviruses – a widespread group of viruses – as vectors for transferring information into animal cells. Retroviruses contain information which causes part or all of their sequence to be inserted into the genome of the animal they infect; it is possible to remove genes that make these viruses virulent and introduce genes that are likely to provide the desired characteristics. Retroviruses have been isolated from a wide variety of vertebrates, including mammals, birds and reptiles and similar organisms have been found in insects. They are ribonucleic acid (RNA) molecules that are copied to form a complementary DNA molecule that is then transported to the cell nucleus and one or more copies inserted into the recipient's DNA. This integrative step is apparently an essential step in virus replication and appears to occur at random sites in the recipient DNA.

For plants two principal methods are currently used to introduce new genetic material into the cells. The first, often called *biolistics* is a non-biological method of insertion. It involves the direct insertion of the nucleic acid package using a ballistic method. Very small metal particles (usually gold) are coated with the nucleic acid and fired at a high velocity into plant cells. For reasons not fully understood, some of the DNA enters a tiny proportion of the cells and is incorporated into the genome. A whole plant can be regenerated from a single cell, hence some selection system is used where one of the inserted genes codes for tolerance to a particular chemical or stress. If the cells that have been subjected to the bombardment are separated and grown under these conditions, only those that have not been badly harmed and which contain the package are able to grow. Traditional methods may then be used to select from those cells (or plants) that have successfully been modified those that might be commercially (or scientifically) useful.

The second method is microbiological. It uses a bacterium, *Agrobacterium tumifaciens*, that infects plants by inserting a small plasmid (or circular piece of DNA) into the plant. The genes that this plasmid contains then become incorporated into the genome of the plant. Scientists have adapted the system that this bacterium has evolved, to provide a tool to insert novel genetic material, modified by *in vitro* nucleic acid techniques, into plants. The cells are separated, and as for biolistics, selection of those that have been successfully modified and have the right agronomic characteristics follows. There are many plants that are susceptible to infection by *Agrobacterium*.

Stage 4

A selection marker is often introduced into the modified organisms. Whatever technique is used to modify the organism, the number of cells that have been effectively modified may be very small. A technique which detects un-transformed cells is essential. Transformed cells may also have been irreparably harmed by the process, and even if they contain the desired characteristics, may now not be viable or have unwanted characteristics, so further selection is essential.

In the case of plants, the cells are treated and cultured under appropriate conditions (including chemical treatments) so that they grow into a complete plant. These modified plants and their offspring may be grown for several generations to ensure that they are stable and maintain the inserted characteristics over a period of time. During this stage many individual modified organisms may be excluded from further use as they display unwanted characteristics or the change introduced is not as effective as desired. Changes that work in the laboratory may also not be effective when tested in the field.

[76] Transformation is a process whereby DNA is taken up by a cell or organisms from outside and is incorporated into the genetic material of the organism.

220. The definition of modern biotechnology is qualified by the requirement that the techniques applied should be techniques that *overcome natural physiological reproductive or recombination barriers*. Descriptions of these various barriers are provided in Box 19 below.

Box 19. Description of natural physiological reproductive and recombination barriers

A natural physiological barrier is one where the physiology of the individuals concerned would normally prevent exchange of genetic material – an example is where physiological conditions would prevent fertilization of a female gamete by a male gamete, even though those gametes could come into contact with each other through the reproductive process; another example is where fertilization occurs, but physiological factors prevent the full development of an embryo into a viable individual.

A natural reproductive barrier is one where various mechanisms, which could include, but are not limited to, physiological mechanisms, prevent exchange of genetic material. Natural reproductive barriers also include geographical separation, separation in time of the reproductive periods of individuals, or separation in the ecology of the individuals concerned.

A natural recombination barrier is one beyond which recombination would not be possible under normal conditions for an organism's genetic system. Recombination under natural conditions is associated with the ordered pairing of gene sequences, such that like genes pair with each other along the arms of chromosomes, and segments of gene sequences may be exchanged between the chromosome pair. This exchange process is called recombination. Since genes for various traits can exist in various forms (termed "alleles"), the exchange of genes during recombination results in new combinations of alleles of the genes on each chromosome.

221. The definition of modern biotechnology is also qualified by the requirement that the techniques *are not techniques used in traditional breeding and selection.* Traditional breeding methods are based on selecting and using those individuals – within a species, or amongst closely related species – which exhibit desired traits, as breeding stock for new varieties. Traditional breeding methods include methods that involve use of inter-specific hybrids, which may form under natural conditions. They also include methods which can be used to assist exchange of genetic material between species that would not normally come into contact and which are not normally sexually compatible. Other traditional techniques used for breeding and selection include the use of vegetative (non-sexual) reproduction through a variety of mechanisms, including the use of tissue culture.

222. The initial and most important technique used was the selection of those organisms displaying desired characteristics, their multiplication and subsequent use. A simple example would be the retention of the best produce obtained in a season for use as seed for a following season rather than its consumption. "Best", however, will have depended upon where the product was grown. The "best" seed selected by a grower in one climatic region may not be the best for use elsewhere. Techniques that subject the organism to "stress" allow for selection of those individuals most adapted to the harsh conditions that stress implies. These stresses could include cold, heat, disease, insect depredation, competition with weeds, drought or excess water, too much or too little sunlight.

223. Cross-breeding techniques are important in assuring that a variety of desired characteristics may be incorporated into an organism used in agriculture. These techniques include crossing and subsequent backcrossing to achieve the desired set of characteristics and various forms of aided pollination or insemination. Modern breeding techniques inlude embryo rescue and haploid techniques.

224. Methods to assist exchange of genetic material between species mostly are applied with plants, especially in taxonomic groups within which interspecific hybridization occurs naturally. In some cases, mutagenic agents, such as certain chemicals or ionizing radiation, have been used to cause mutations in an organism's genetic material, following which selection and further breeding are undertaken to select those changes that are both non-lethal and which appear to provide a desired improvement in the behaviour of the organism.

225. Thus, there are now many techniques available to the plant breeder by which to seek to introduce and select for desired improvements to particular organisms. With care, it is possible to make crosses, and achieve hybrids between organisms which are less closely related, and which would not interbreed under natural conditions, by techniques which are accepted as part of traditional breeding.

226. It should be noted that selection techniques are used, following use of *in vitro* nucleic acid techniques, or of cell fusion techniques, to select those individuals that exhibit desired traits; and that these individuals are used for further reproduction using a variety of techniques, which may include techniques of traditional breeding. The criterion that determines whether an organism is a LMO under the terms of the Protocol is the application of an *in vitro* nucleic acid technique, or a cell fusion technique beyond the taxonomic family, to obtain an organism that contains a novel combination of genetic material. Any organism into which such a novel combination of genetic material is subsequently transferred, even if that transfer is achieved through traditional breeding and selection techniques, will also be a LMO under the terms of the Protocol.

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

227. This definition reproduces the definition of this term in Article 2 of the CBD. The European Union is so far the only "regional economic integration organization" to satisfy the definition. The transfer of competence is particularly relevant, in the context of this Protocol, to the right to vote, as described in Article 31(2) of the CBD, applicable to Protocols concluded thereunder.

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

228. The purpose of this definition is to indicate that, generally, the term transboundary movement in the Protocol is restricted to movements of LMOs between Parties to the Protocol – except for the purposes of two specific articles. Article 17 addresses unintentional transboundary movements of LMOs, and Article 24 addresses transboundary movements of LMOs involving non-Parties. In these Articles, transboundary movement does not have, and logically cannot have, the meaning provided in the definition in Article 3(k).

Article 4. Scope

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.

229. *Article 4 specifies the activities and organisms to which the Protocol applies: i.e. in what circumstances must a Party apply the provisions of the Protocol.*

230. *Articles 4, 5, and 6 of the Protocol are closely linked to each other.*

- *Article 4 states the general rule as to the Protocol's areas of applicability;*
- *Article 5 exempts, under certain conditions, the transboundary movement of one specific class of LMOs – i.e. LMOs "which are pharmaceuticals for humans" – from the applicability of the Protocol; and*
- *Article 6 provides a more limited exception – it exempts LMOs "in transit" and LMOs "destined for contained use" from the application of the advance informed agreement (AIA) procedure laid down in Articles 7 to 10 and 12 of the Protocol.*

231. *Some of the terms used in Article 4 are specifically defined in Article 3 – so the applicability of the Protocol to specific organisms and activities also depends upon these definitions – in particular the definitions of "LMO" (including the terms "living organism" and "modern biotechnology") and "transboundary movement".*

232. *The scope of the Protocol was the subject of intense negotiations among States as early as the 1995 negotiations at CBD COP2 on the mandate to negotiate a Protocol. It was a major issue in the meetings of the BSWG and in the two sessions of ExCOP. Generally speaking, developing countries pushed for the application of the Protocol to all LMOs. Developed countries in general pushed for a more limited scope to the Protocol. Among the major issues in dispute here was the applicability of the Protocol to LMOs that are pharmaceuticals, and to the transit and contained use of LMOs. The structure and content of Articles 4, 5, and 6 of the Protocol reflects the compromises finally agreed upon during the resumed session of the ExCOP in Montreal, Canada, in January 2000.*

Box 20. Understanding the concept of "scope" in the Protocol

In many ways, the scope of the Protocol is a function of how the Parties eventually defined the many technical terms in the text. Through its definitions of "LMO", "living organism", "modern biotechnology" and "transboundary movement", the Protocol effectively defines its areas of applicability.

"Scope", in the context of the Protocol should always be understood by distinguishing between the scope of the Protocol (Article 4) and the scope of the Advance Informed Agreement procedure (Articles 6 and 7 provide for exemptions from this procedure). Through this distinction, competing interests found ways to accept the Protocol. On one hand, those who wanted a broad application of the Protocol could legitimately claim that all LMOs were covered by Article 4. On the other hand, those who wanted a limited scope for the Protocol found comfort in the limitations on the application of the provisions of the Protocol as exemplified by Articles 5, 6 and 7. This "innovative mathematics" – the balancing between these two concepts of scope – made it possible for the debate on this issue to be resolved in a satisfactory fashion.

233. The concept of scope in Article 4 has two elements:

(1) the *activities* to which it is applicable; and

(2) the *subject matter* to which it is applicable, i.e. to which organisms it applies.

234. The Protocol is made applicable to the following *activities*:

- *transboundary movement* – this term is defined in Article 3(k) as follows. *"the movement of a LMO from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties"*. This appears to exclude from the scope of the Protocol any movement of a LMO from the territory of one Party into an area beyond national jurisdiction, e.g. the high seas. The Protocol addresses both intentional and unintentional transboundary movement of LMOs although, as will be seen, most of its operative provisions are concerned with intentional transboundary movements. Unintentional transboundary movements are specifically addressed in Article 17.
- *transit* – the Protocol does not contain a definition of "transit". However, the ordinary meaning of "transit" within the context of the Protocol and in the light of the Protocol's objective and purpose is the passage of a LMO across or through the territory of one or more States.[77]
- *handling and use* – the Protocol also does not contain any definition of the terms "handling" or "use". The ordinary meaning of "handling" would appear to refer to the manual or mechanical process or method by which LMOs are moved, carried, transported, delivered, or worked with. The term "use" is also not defined, although Article 3(b) provides a definition of "contained use". Seen in its ordinary meaning and within the context of the definition of "contained use" in the Protocol and in the light of the Protocol's objective and purpose, the term "use" would appear to refer to any operation involving LMOs.

235. As to *subject matter,* the Protocol applies to "all living modified organisms". The term "living modified organism" is expressly defined in the Protocol as containing three essential elements (see commentary on Article 3(g)–(i)):

(1) it must be a "living organism";

(2) it must possess a "novel combination of genetic material"; and

(3) such genetic material must have been "obtained through the use of modern biotechnology".

236. For the implications on the scope of the Protocol of the phrase "that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health", see commentary on Article 1.

[77] The terms used in a treaty, in the absence of a special meaning of the term expressed in the treaty by the parties, are to be "interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose". Article 31(1) in relation to Article 31(4), 1969 Vienna Convention on the Law of Treaties. For similar definitions or expressions of "transit" in other treaties, see e.g. Article 124(1)(c) of the 1982 UN Convention on the Law of the Sea, defining "traffic in transit"; and Article 2(12) of the 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, defining "State of transit".

Article 5. Pharmaceuticals

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

237. *Article 5 exempts from the application of the Protocol the transboundary movement of LMOs that are pharmaceuticals for humans. LMOs that are pharmaceuticals for humans are principally genetically engineered vaccines (e.g. micro-organisms genetically modified to transmit the hepatitis B vaccine). In order to be exempt, such LMOs must be addressed by other relevant international agreements or organizations. The principal relevant international organization in this area appears to be the World Health Organization.*

238. *Despite this exemption, Article 5 recognizes the rights of Parties to subject all LMOs to risk assessment prior to any decision on import. – i.e. although the transboundary movement of the LMOs mentioned in Article 5 is not subject to the provisions of the Protocol, Parties may still decide to subject such LMOs to risk assessment prior to import.*

239. *The exemption in Article 5 refers only to the transboundary movement of LMOs that are pharmaceuticals for humans. Thus, Articles 7, 8, 9, 10 and 12 clearly do not apply to such LMOs. Other provisions of the Protocol, such as those on capacity building and public awareness and participation, however, do apply.*

240. *The issue of exempting pharmaceutical LMOs from the scope of the Protocol was the subject of much discussion during the negotiations. Early proposals, especially from developed countries, involved expressly excluding pharmaceuticals within the text of the general provision on scope of the Protocol (i.e. what is now Article 4). Many developing countries opposed such proposals, arguing that the general scope of the Protocol should cover all LMOs, but they were amenable to including such an exemption in a separate provision. This accounts for the present structure of Articles 4 and 5.*

Box 21. Why were pharmaceuticals a controversial issue?

Article 5 is the result of intense negotiations in the BSWG meetings and during the Cartagena and Montreal sessions of the ExCOP. During these negotiations, many developing country delegations raised concerns about exempting pharmaceuticals for humans from the scope of application of the Protocol. Some stressed the need for the Protocol to take into account future developments in gene therapy and the use of genetically modified plants and animals to produce pharmaceutical substances, as well as the potential adverse effects of genetically modified pharmaceutical viruses and micro-organisms on human health and the environment**.** Article 5 clearly applies to pharmaceuticals for humans but not to the use of genetically modified plants and animals to produce them. The cultivation of such plants and the propagation of such animals and their transboundary movement is not exempt under this Article.

Article 5 reflects a compromise formulation, in which only transboundary movements of LMOs which are pharmaceuticals for humans and which, as such, are also subject to other international agreements (see Box 22) or organizations (such as the World Health Organization), will be exempt from the scope of application of the Protocol.

241. For the Article 5 exemption to be applicable as an exception from the general rule on scope of the Protocol expressed in Article 4, the following elements must be present:

- there must be a "transboundary movement" (see Article 3(k));
- the transboundary movement must involve LMOs "which are pharmaceuticals for humans"; and
- the LMOs concerned must be "addressed by other relevant international agreements or organizations".

242. The transboundary movement of such LMOs is not subject to the AIA procedure and to the other provisions of the Protocol that are relevant to transboundary movement, except for the right of a Party to subject the LMO to risk assessment prior to import. Other provisions of the Protocol will still apply.[78]

243. The following categories of LMOs, however, do not satisfy the conditions in Article 5 and will be subject to the Protocol's provisions on AIA and those relevant to transboundary movement, depending upon their intended use (see commentary on Articles 6, 7 and 11):

- LMOs which are not pharmaceuticals *for humans* (e.g. LMOs that are intended for veterinary purposes);
- LMOs which are intended to serve as raw material for the *production* of pharmaceuticals for humans (e.g. genetically modified plants, animals and micro-organisms);
- LMOs which are pharmaceuticals for humans but which are *not addressed* by relevant international agreements or organizations – e.g. those on which no action has been taken as yet under a potentially relevant international agreement or organization.

244. In relation to the last of these elements, the Protocol does not make clear what is meant by "are addressed" – for example, to what extent must the agreement or organization in question explicitly address the issues and activities addressed by the Protocol? Nor does Article 5 specify what would constitute an international agreement or organization for the purposes of satisfying the exemption. While Article 14 of the Protocol allows Parties to enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of LMOs, these must be consistent with the objective of this Protocol and must not result in a lower level of protection than that provided for by the Protocol.

245. The exemption in Article 5 of pharmaceuticals for humans is qualified in that it is without prejudice to the right of any Party to subject the LMO in question to risk assessment "prior to the making of decisions on import". Thus, Parties may still subject such pharmaceutical LMOs to a risk assessment process prior to allowing the importation. The right of a Party to subject LMOs that are pharmaceuticals for humans to risk assessment is a right which is inherent in every country, which can regulate such LMOs consistent with national standards on human health.

246. While there are relevant international agreements that are applicable to pharmaceuticals for humans, many of these agreements deal with human health concerns but do not yet directly address the environmental and biodiversity impacts of LMOs. A Party may, in the context of a particular import of a pharmaceutical for humans, wish to assess the adequacy of these agreements and require appropriate additional risk assessment as provided for in its national legislation.

[78] See Box 10, under Article 1 above, for an analysis of the provisions of the Protocol which are relevant only to transboundary movement of LMOs, and those that apply more generally.

Box 22. Transboundary movement of pharmaceuticals for humans

The cross-border movement of pharmaceuticals for humans in general is governed by the World Health Organization's (WHO) "Certification Scheme on Pharmaceutical Products Moving in International Commerce". This Scheme is an administrative instrument that is applicable to finished dosage forms of pharmaceutical products intended for administration to human beings or to food-producing animals, and requires the pharmaceuticals regulatory authority of the exporting country to attest to its counterpart in the importing country, upon application by a commercially interested party, that:

(a) "a specific product is authorized to be placed on the market within its [exporting country] jurisdiction or, if it is not thus authorized, the reason why that authorization has not been accorded";

(b) "the plant in which it [the pharmaceutical product] is produced is subject to inspections at suitable intervals to establish that the manufacturer conforms to GMP ["Good Practices in the Manufacture and Quality Control of Drugs"] as recommended by WHO"; and

(c) "all submitted product information, including labelling, is currently authorized in the certifying country".

The phrase "pharmaceutical products" is defined for purposes of the Scheme above as "any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form or as an active ingredient for use in such dosage form, that is subject to control by pharmaceutical legislation in both the exporting State and the importing State".

It should be noted that in the Protocol negotiations, many countries initially opposed to exempting pharmaceuticals for humans were reassured by the incorporation of risk assessment in this certification mechanism. It would be necessary to verify whether this is in fact part of the practice in the implementation of the mechanism.

(See WHO, Guidelines on the Implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, http://www.who.int/medicines/teams/qsm/certifguide.html)

The 1970 Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products ("Pharmaceutical Inspections Convention," available at: http://www.austlii.edu.au/au/other/dfat/treaties/1993/2.html) defines "pharmaceutical product" in Article 1(2) thereof as:

(a) "any medicine or similar product intended for human use which is subject to control by health legislation in the manufacturing Contracting State or in the importing Contracting State; and

(b) "any ingredient which the manufacturer uses in the manufacture of a product referred to in subparagraph (a) above".

The 1970 Pharmaceutical Inspection Convention provides for mutual recognition of pharmaceutical inspection and quality control standards among the participating States, and promotes the exchange of information related thereto. The "Pharmaceutical Inspection Cooperation Scheme" provides the institutional framework for such information exchange and standards harmonization (available at http://www.picscheme.org/index.htm). The WHO Certification Scheme described above is consistent with the provisions of the 1970 Pharmaceutical Inspection Convention.

Article 6. Transit and contained use

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

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

247. *Article 6 provides for two limited and qualified exceptions from the general scope of applicability of the Protocol provided for in Article 4. These apply to:*

- *LMOs in transit through the territory of a Party; and*
- *LMOs destined for contained use in the importing Party.*

248. *These LMOs are within the scope of the Protocol. But Article 6 exempts them from the application of the Protocol's provisions on the advance informed agreement procedure (see commentary on Articles 7, 8, 9, 10, and 12). All other provisions of the Protocol remain applicable to such LMOs. Moreover, Article 6 recognizes the right of Parties to regulate the entry of such LMOs into their territory.*

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

249. Article 6(1) identifies the first category of LMOs to be exempt from the application of the AIA procedure. These are LMOs that are "in transit" – i.e. LMOs that are moving or passing through or across the territory of one or more Parties to the Protocol. Thus, the Protocol's specific AIA rules do not apply to LMOs in transit. However, the Protocol does not affect the rights of a State of transit under general international law to regulate activities within its territory. In this regard, a Party (or a non-Party) through whose territory a LMO in transit is passing may regulate the transport and handling of that LMO while it is on its territory – e.g. it may impose handling and other transport safety and health precautions and regulatory measures on transiting LMOs.

250. With regard to transit of LMOs through the territorial sea or exclusive economic zone of a coastal State, Article 2(3) of the Protocol is also relevant. Article 2(3) of the Protocol recognizes the sovereignty of States over their territorial sea, their sovereign rights and jurisdiction over their exclusive economic zones, and the exercise by ships and aircraft of navigational rights and freedoms provided for under international law (see commentary on Article 2(3) and Box 11).

251. In sum, subject to international law, Parties (and non-Parties as well) can require prior notification of transit through their national

law. While Article 6(1) exempts LMOs in transit from the AIA procedure, there is nothing in the Protocol which prohibits Parties from imposing such regulatory and safety rules as they deem necessary, including requiring risk assessment, and positive consent by State authorities before transit is permitted. These rights arise under general international law (and the law of the sea) and thus are also available to non-Parties to the Protocol.

252. Any decision made by a Party with respect to the transit of LMOs through its territory should be made available to the Biosafety Clearing-House established under Article 20 of the Protocol.

253. Although the AIA provisions of the Protocol do not apply to LMOs in transit, other provisions of the Protocol remain applicable. In particular it should be noted that Article 18, which provides the rules for handling, transport, packaging and identification of LMOs, applies to LMOs in transit.

254. Finally, if a LMO moves from one Party to another through a transit State, subject to the terms of Article 7 (see below), that LMO may still be subject to the AIA procedure as between the Party of export and the Party of import. Article 6(1) simply provides that the AIA procedure does not apply as between the Party of export and the transit Party.

255. During the negotiation of the Protocol, specific concerns were raised by some countries, particularly small island developing States, regarding transshipment of LMOs. Simply put this is where LMOs are moved from one ship (or mode of transport) to another whilst on the way to their final destination. There was some discussion as to whether this activity should be subject to special notification, consent or documentation requirements. It appears to be addressed now within the general provision in Article 6, i.e. the AIA procedure does not apply, but the right of a Party (or non-Party) through whose territory a LMO is being transshipped may, in accordance with its rights under general international law, regulate the handling of that LMO while it is on its territory.

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

256. Article 6(2) of the Protocol identifies the elements for a second category of LMOs to be exempted solely from the coverage of the AIA procedure, but not from the other provisions of the Protocol. The conditions to be fulfilled for this exception to apply are:

- there must be a "transboundary movement of a LMO";
- that LMO must be "destined for contained use" (see Article3(b)); and
- the contained use must be "undertaken in accordance with the standards of the Party of import".

257. All of these must be present for the exception to be applicable. Thus, if the LMO is not destined for contained use, or if the contained use is not undertaken in accordance with the importing Party's standards relating to such contained use of LMOs, the LMO in question will continue to be subject to the AIA procedure under the Protocol.

258. A number of countries have adopted standards for contained use of LMOs. For example, in the European Union Directive 90/219/EEC (as amended by Directives 94/51/EC, 98/81/EC and Council Decision 2001/204/EC)[79] lays down common measures for the contained use of genetically modified micro-organisms (GMMs) with a view to protecting human health and the environment. The Directive requires users of GMMs to carry out an assessment of the contained use as regards the risks to human health and the environment that the contained use may incur, using as a minimum the elements of assessment and the procedure set out in an annex to the Directive. This

[79] OJ L 117/1, 8 May 1990; OJ L 297/29, 18 November 1994; OJ L 330/13 5 December 1998; OJ L 73/32, 15 March 2001.

assessment "shall result in the final classification of the contained uses in four classes applying the procedure set out in Annex III, which will result in the assignment of containment levels". These four classes refer to activities of no or negligible risk, activities of low risk, activities of moderate risk and activities of high risk. Prior to the contained use of the GMMs the user shall submit a notification, which varies according to the classification of the contained use to the competent authorities, including the information listed in Annexes to the Directive. The competent authorities will in turn "examine the conformity of the notification,…the accuracy of the information,…the correctness of the assessment,…the class of contained uses and, where appropriate, the suitability of the containment and other protective measures, the waste management, and emergency response measures".

259. Despite Article 6(2), Parties (and non-Parties) still have the right to subject all LMOs to risk assessment and to set standards and regulations for the contained use of LMOs within their territorial jurisdiction. Serious concerns were voiced during the final negotiations regarding the potential implications of the contained use provisions of the Protocol. The AIA procedure in the Protocol is essentially triggered by the exporter (see commentary on Article 7). However, there is no specific obligation in the Protocol on the exporter or the Party of export to ensure that the final use of the LMO in the Party of import conforms to the intended use. Thus if an exporter intends to export a LMO for contained use in the Party of import, it is not required to ensure that the LMO is subsequently used only in containment nor that standards of containment in the Party of import are adequate. In cases where there is a possibility or where it is likely that a LMO initially imported for contained use may subsequently be introduced into the environment, the Party of import may be justified in requiring the application of the AIA procedure prior to the first import.

Article 7. Application of the Advance Informed Agreement procedure

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

260. *Article 7 identifies those LMOs which will be subject to the advance informed agreement procedure set out in Articles 8–10 and 12. It also identifies a specific category of LMOs which will be subject instead to a separate procedure, set out in Article 11. Finally, it provides a procedure for the possible future exclusion of specific LMOs from the AIA procedure by a decision of the COP/MOP (see commentary on Article 29).*

Box 23. What is AIA?

Advance informed agreement requires that *before* the first intentional transboundary movement of a specific LMO into its jurisdiction, the Party of import:

- is notified of the proposed transboundary movement;
- receives information about the LMO and its proposed use; and
- is given an opportunity to decide whether or not to allow the import of the LMO, and upon what conditions (if any).

261. While Article 7 is titled "Application of the Advance Informed Agreement Procedure", it is important to recall that other provisions of the Protocol are also relevant to determining whether or not the AIA procedure in Articles 8–10 and 12 of the Protocol applies to a particular transboundary movement of a LMO. These are:

- Article 4, which determines the scope of the Protocol as a whole;
- Article 5, which excludes the transboundary movement of certain pharmaceutical LMOs from the scope of the Protocol;
- Article 6, which exempts two categories of transboundary movements of LMOs from the application of the AIA procedure, namely:
  - LMOs in transit (Article 6(1)); and
  - LMOs destined for contained use undertaken in accordance with the standards of the Party of import (Article 6(2));
- Article 13(1)(b), which allows a Party of import, subject to conditions, to specify that imports of certain LMOs to it will be exempted from the AIA procedure;
- Article 14(3), which exempts from the provisions of the Protocol intentional transboundary movements of LMOs that take place pursuant to bilateral, regional or

multilateral agreements or arrangements (as provided under Article 14), as between Parties to those agreements and arrangements;

- Article 14(4), which allows a Party to determine (and notify to the Biosafety Clearing-House) that its domestic regulations shall apply with respect to specific imports.

262. It should be noted that some of the Articles listed above provide exemptions from the AIA procedure that are applicable as between *all* Parties to the Protocol (Articles 4, 5, 6 and 7), whereas some allow for *potential* exemptions at the discretion of the Party of import, and subject to certain conditions (Articles 13 and 14). More detail on each of these Articles is provided in the relevant sections of this Guide.

What is the Advance Informed Agreement procedure?

263. The central procedural mechanism set out in the Protocol to regulate transboundary movement of LMOs is the advance informed agreement procedure. Article 7 (taken together with the other Articles listed above) establishes the scope of the application of the AIA procedure – i.e. to which transboundary movements the procedure applies. The AIA procedure itself is then set out in Article 8, 9, 10 and 12. Other provisions of direct relevance to the AIA procedure include:

- Article 15 (Risk Assessment);
- Article 19 (Competent National Authorities and National Focal Points);
- Article 21 (Confidential Information);
- Article 26 (Socio-economic Considerations);
- Annex I (Information Required in Notifications under Articles 8, 10 and 13); and
- Annex III (Risk Assessment).

264. The AIA procedure essentially requires that before the first transboundary movement of a LMO that is subject to the AIA procedure, the Party of import is notified of the proposed transboundary movement and is given an opportunity to decide whether or not the import shall be allowed and upon what conditions. This decision must be based upon a risk assessment. The provisions in Articles 8, 9, 10 and 12 of the Protocol and related provisions in Articles 15, 19, 21 and 26, as well as Annexes I and III to the Protocol attempt to address and clarify a number of important aspects of the AIA procedure.

265. The AIA procedure is modelled loosely on existing mechanisms in international law for the transboundary movement of hazardous substances, for example the prior informed consent (PIC) procedures in the Basel Convention on the transboundary movement and disposal of hazardous wastes and the Rotterdam Convention on chemicals in international trade. However, the AIA procedure in the Protocol differs from previous models in certain important respects. In addition, as noted in more detail below, the Protocol allows a significant degree of flexibility to Parties as to whether they apply the AIA procedure set out in the Protocol or instead use a different domestic regulatory procedure which must, nonetheless, be consistent with the Protocol (see, for example, Article 9).

266. The flexibility and discretion accorded to Parties under the Protocol means that the procedure to be followed by the Party of export, the exporter, the importer and the Party of import in any given case may vary significantly depending upon, for example:

- the identity of the countries involved in the transboundary movement (i.e. the importing and exporting countries, as well as any transit countries);
- the LMO in question; and
- the intended use of that LMO in the Party of import.

267. In order to ensure that it is complying with the Protocol and with the relevant national legislation of the Party of import in relation to AIA, the Party of export of a LMO (and indeed a non-Party exporting a LMO) will need to consider (or require the exporter to consider) a number of questions (see Box 24).

268. As noted above, the provisions in Articles 8, 9, 10 and 12 of the Protocol and related provisions in Articles 15, 19, 21 and 26, as well as Annexes I and III to the Protocol, attempt

Box 24. Is this transboundary movement of this LMO subject to the AIA procedure?

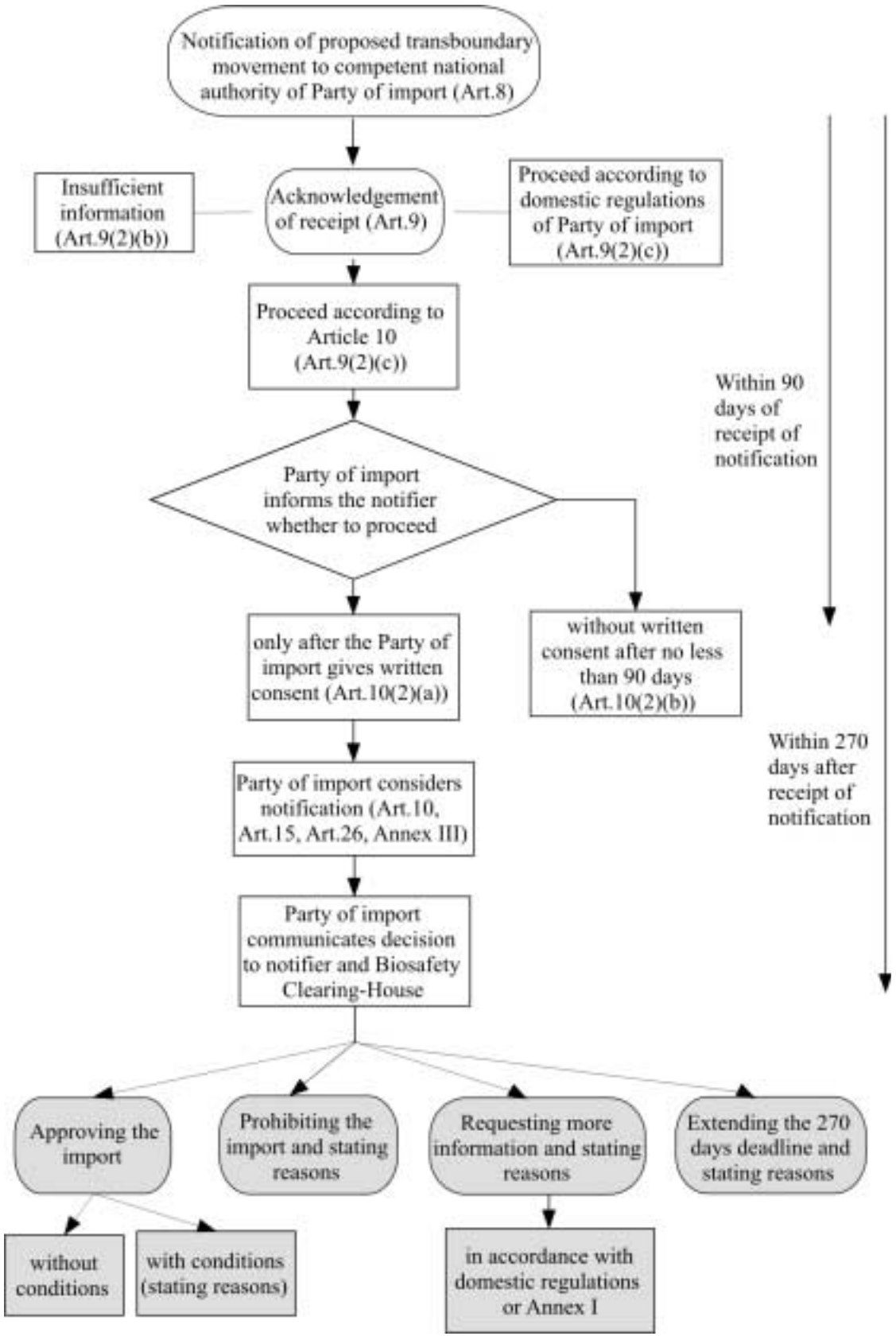
- *What type of LMO is involved?*
  - Is it within the scope of the Protocol (Articles 4 and 5)?
  - Is it within the scope of application of the Protocol's AIA procedure (Article 7)?
  - Has it subsequently been exempted from AIA by the COP/MOP (Article 7(4))?
  - Is the LMO being imported into the Party of import for the first time(Article 7(1))?
  - Is it a LMO to which the Party of import has decided to apply simplified procedures (Article13)?
- *What is the country of import?*
  - Is it a Party to the Protocol?
  - Is it a party to a relevant bilateral, regional or multilateral arrangement with the Party of export under Article 14?
  - Has it indicated that it will apply the Protocol's AIA procedure to potential imports of LMOs, or its own domestic regulatory framework instead?
  - Has it indicated through the Biosafety Clearing-House that it will apply simplified procedures to certain LMOs (Article 13)?

to address and clarify a number of aspects of the AIA procedure. For example:

- Who initiates the AIA procedure – i.e. who notifies the Party of import of the proposed import of a LMO (Article 8)?
- What information must be provided with the notification (Article 8; Annex I)?
- Is the Party of import under any obligation to keep information received in the AIA procedure confidential (Article 21)?
- How long does the Party of import have to make a decision whether to allow or to prohibit the import of the LMO (Articles 9 and 10)?
- On what basis must the decision be made (Articles 10 and 15; Annex III)?
- Who is responsible for undertaking the risk assessment? And who will pay for it (Articles 10 and 15)?
- What factors should be taken into account in the risk assessment process (Article 15; Annex III)?
- What happens if the Party of import fails to respond to a notification, or fails to make a decision on import within the time period allowed in the Protocol (Articles 9 and 10)?
- Under what circumstances can import decisions be reviewed (Article 12)?

269. However, the flexibility accorded to Parties under the Protocol, and the terms of the AIA provisions of the Protocol themselves, may give rise to some ambiguity and uncertainties in practice. Parties to the Protocol will need to implement the AIA provisions, or similar, in their domestic laws and regulations in order to give effect to them. In this respect, transparent and comprehensive domestic regulations and procedures can assist in clarifying some of the areas left unclear in the Protocol.

Box 25. Advance Informed Agreement Procedure



1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

First intentional transboundary movement

270. During the negotiation of the Protocol, there was some debate as to whether the AIA procedure should apply to *every* transboundary movement of a LMO into a Party or only to the *first* transboundary movement of a specific LMO into a Party of import. Article 7(1) appears to resolve this issue, providing that AIA shall only apply to the "first intentional transboundary movement of LMOs into the environment of the Party of import". However, on the face of Article 7(1), it may be somewhat unclear whether AIA will be required each time a particular LMO is imported into a Party for the first time from a "new" Party of export, or whether it only applies the first time a particular LMO is imported into the Party of import from *any* Party – after which, assuming the first import is allowed, imports of the same LMO should be allowed under the same conditions from all Parties. The former interpretation could be supported by a strict reading of the definition of "transboundary movement" in Article 3(k) which indicates that this term means the "movement of a LMO from *one* Party to *another* Party". In this interpretation, "one Party" in Article 3(k) refers to a specific Party of export – so each time a new Party of export is involved in a transaction with the Party of import, it would constitute the "first" transboundary movement for the purposes of Article 7.

271. A plain reading of Article 7(1) may provide more support for the interpretation that the AIA procedure applies where a particular LMO is to be introduced into the Party of import for the first time from any other Party to the Protocol, and that AIA does not apply automatically each time the same LMO is subsequently imported from other Parties. However, such an interpretation may give rise to some difficulties for the Party of import. If it approves the first import of a specific LMO from another Party, then for subsequent imports from that Party or from other Parties, the Party of import will need to be sure that what is being imported is in fact the "same" LMO that has already been approved under the AIA procedure. In the absence of unique identification mechanisms (see Box 34) this may not be a simple matter. The Party of import will need to be aware of subsequent imports, which suggests a need for some notification procedure so that the Party of import can confirm that the LMO to be imported is the same as that which has been approved. This issue may be appropriately addressed under the provision in Article 10(3)(a) for conditions to be attached to import approvals, or by the provision in Article 12(4) which allows a Party of import to require a risk assessment for subsequent imports. In these provisions, the Protocol provides a "safety net" for Parties of import in that they may require approvals for subsequent imports of LMOs.

272. The use of the word "intentional" in Article 7(1) also raises certain interpretative difficulties.

- First, in the phrase "intentional transboundary movement of LMOs", the word "intentional" might be interpreted as referring *either* to the transboundary movement *or* to the LMOs, or to *both*. By way of practical example, suppose an exporter intends to make a shipment not of LMOs but of conventional (non-modified) seeds, but knows or suspects that the shipment may have unintentionally become contaminated with a small percentage of LMOs. Would this constitute an intentional transboundary movement of LMOs for the purpose of triggering the Protocol's AIA procedure?
- Second, Article 7(1) and 7(2) refer to "intentional introduction into the environment", but do not specify whose intention is relevant here: for example the exporter, the importer or the Party of import. In this regard, it is significant that it is the exporter or Party of export which triggers the AIA procedure by making the notification of the proposed transboundary movement to the Party of import. However, the exporter and Party of export are unlikely to be involved in the final use of the LMO in the Party of import (see further paragraph 275 below).

Intentional introduction into the environment of the Party of import

273. This phrase further limits the application of the Protocol's AIA procedure. Article 7(1) removes from the AIA provisions of the Protocol any LMO which is not destined for *intentional introduction into the environment* of the Party of import.

274. The phrase "intentional introduction into the environment" is not defined. However, paragraph 2 of Article 7 makes it clear that it excludes LMOs which are intended for direct use as human food or animal feed, or for processing (see commentary on Article 11). Intentional introduction into the environment may include for example: the use of the LMO in question in field trials in the Party of import; the commercial scale growing of agricultural LMOs; the release of transgenic fish; or the deliberate release of genetically modified micro-organisms into the environment. In general, the term "introduction into the environment" may be contrasted with "contained use" in Article 3(b).

Box 26. Intentional introduction into the environment of a LMO

As noted above, this phrase is not defined in the Protocol. Some examples of national legislation or regulations on biosafety incorporate similar terms, but tend to use the word "release". For example:

- EU Directive 2001/18 on the deliberate release into the environment of GMOs defines "deliberate release" as "any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment".
- Australia's 2000 Gene Technology Act provides that "a dealing with a GMO involves the intentional release of the GMO into the environment if the GMO is intentionally released into the open environment, whether or not it is released with provision for limiting the dissemination or persistence of the GMO or its genetic material in the environment".
- Colombia's Resolution 3492 of 22 December 1998 regulating and establishing a procedure for the introduction, production, release and commercialization of genetically modified organisms uses the term "release into the environment" defined as "the use of a product manipulated outside the limits of a normal physical confinement in a closed area, laboratory, greenhouse, fermented, or any other closed structure under established biosafety conditions".
- Norway's Gene Technology Act No. 38 of 2 April 1993 goes into more detail. It provides that "deliberate release" means any production and use of genetically modified organisms that is not considered to be contained use [as defined in the Act].

  The following are among the activities that are considered to be deliberate release under the Act:

  a) deliberate release of genetically modified organisms for research purposes (field experiments);

  b) deliberate release of genetically modified organisms for commercial purposes, for remedial purposes and the like;

  c) use of genetically modified organisms in greenhouses, aquaculture facilities, animal accommodation and the like, unless the facility in question is approved for contained use as part of an approved laboratory or other installation;

  d) routine release of genetically modified organisms from contained use;

  e) disposal of waste containing living genetically modified organisms;

  f) placing on the market of a product consisting of or containing genetically modified organisms;

  g) import of genetically modified organisms;

  h) transport of genetically modified organisms.

275. It is notable that the Protocol does not expressly require the exporter or the Party of export to seek confirmation that exported LMOs are or will only be used only for their intended purpose once in the Party of import. This may be contrasted with, for example, the Basel Convention on the Transboundary Movement of Hazardous Wastes and their

Disposal which contains provisions designed to ensure, before any transboundary movement of hazardous wastes takes place, that arrangements are in place for environmentally sound management in the State of import. However, it might be argued that both Parties of export and Parties of import are bound in this respect to take into account the objective of the Protocol, in Article 1, and their general obligation in Article 2(2) to ensure that activities involving LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking into account risks to human health. The obligations of the Party of import under Article 8(g) of the CBD and Article 16 of the Protocol are also relevant here.

2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

276. The treatment of LMOs intended for direct use as food or feed, or for processing, or "LMO-FFPs", was the subject of intense debate during the Protocol negotiations. The debate centred on potential exports of agricultural commodities (e.g. grains from genetically modified crops) which, while fulfilling the legal definition of LMO in Article 3 of the Protocol, are intended to be used directly for food, feed or processing use and are not intended to be introduced into the environment of the Party of import.

277. During the negotiation of the Protocol, some argued that to include LMO-FFPs within the scope of the Protocol's AIA provisions could be unworkable and have severe implications for trade in agricultural commodities. They argued that since LMO-FFPs were not intended to be introduced into the environment they were not properly within the remit of the Protocol which was intended primarily to address potential risks to biological diversity. On the other side, it was argued that, whatever the *intended* use of a LMO shipment in the Party of import, in practice LMO-FFPs might in fact end up being released into the environment, particularly in developing countries, and thus should be equally subject to AIA and risk assessment if adequate safeguards for biological diversity were to be put in place. It was also noted that LMO-FFPs might accidentally be introduced into the environment of the Party of import during shipment and processing.

278. The differences of view on the treatment of LMO-FFPs threatened the conclusion of the Protocol as a whole. The resolution found was to include LMO-FFPs within the scope of the Protocol, but to subject transboundary movements of LMO-FFPs to a separate and less onerous procedure in the Protocol, which is set out in Article 11. Articles 8-10 and 12 do not therefore apply to LMO-FFPs. Shipments of LMO-FFPs are also subject to different documentation and identification requirements under the Protocol than those of other LMOs (see commentary on Article 18).

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

279. Article 7(4) allows the COP/MOP (see commentary on Article 29), at a later date, to decide collectively to exclude additional LMOs or categories of LMOs from the application of the AIA procedure. This will require a decision of the COP/MOP, taken in accordance with its rules of procedure. Any such LMOs must first be identified as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The Protocol gives no guidance as to what information or evidence might be required to support such a conclusion. Nonetheless, any such decision would need to be taken in the light of the precautionary approach in Principle 15 of the Rio Declaration which is referred to in the Protocol's objective in Article 1 (see Introduction).

280. This provision for the "collective" exclusion of additional LMOs from the AIA procedure is distinct from the provision in Article 13 which allows individual Parties to exempt imports of particular LMOs from AIA at domestic level, provided that adequate measures are applied to ensure the safe intentional transboundary movement of LMOs in accordance with the objective of the Protocol (see commentary on Article 13).

Article 8. Notification

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

281. *Article 8 addresses the first step in the AIA procedure: the notification of the proposed transboundary movement to the Party into which the LMO is to be imported. Article 8 establishes:*

- *Who makes the notification?*
- *To whom is the notification addressed?*
- *What is the content of the notification?*

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

Notification

282. As noted above, Articles 8, 9, 10 and 12 set out the procedure to be followed under AIA. The first step in the AIA procedure is the notification to the Party of import of a proposed transboundary movement to it of a LMO that falls under the scope of application of the AIA procedure.

283. Of course, the notification must take place *before* the first transboundary movement of the LMO into the Party of import is initiated.

Who notifies?

- The Party of export has the legal obligation to ensure that the Party of import receives notification of the proposed transboundary movement.
- In practice, the "notifier" is likely to be a private entity, the exporter.

284. During the negotiation of the Protocol, there were extensive discussions as to who should provide notification of a proposed transboundary movement to the Party of import. Three options were considered:

(i) the importer; or

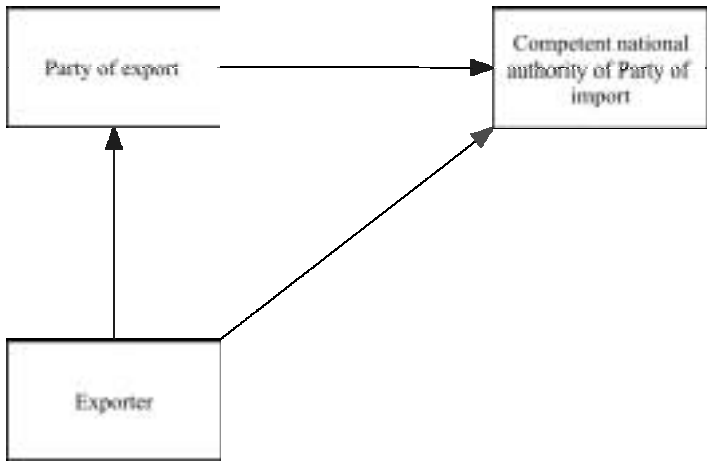
(ii) the exporter; or

(iii) the Party of export.

285. As adopted, Article 8 places the primary obligation regarding notification on the Party of export – i.e. the State Party from which the transboundary movement of the LMO in question originates. The Party of export may in turn, through its national law, require the exporter (most often a private entity) to provide the notification. In practice, depending upon the circumstances of the transboundary movement, other entities may also be in contact with the competent national authority of the Party of import during the AIA procedure, for example, the importer of the LMO or some other entity. However, it is clear that under the Protocol it is the Party of export that has a legal obligation to ensure that the Party of import receives proper notification of a proposed transboundary movement of a LMO.

286. In later provisions of the Protocol, the term "the notifier" is used, for example in Articles 10, 12 15 and 21. This term is not defined in the Protocol. However, on the basis of Article 8, the "notifier" will be either the Party of export itself or the exporter.

Box 27. Possible notification 'routes' under Article 8



Who receives the notification?

- Notification must be made to the competent national authority of the Party of import (see commentary on Article 19).
- Under Article 19, each Party must designate one or more competent national authorities to perform the administrative functions under the Protocol.
- Details of the competent national authorities will be available through the Biosafety Clearing-House.

Content of notification

- The notification must contain, at a minimum, the information specified in Annex I of the Protocol.
- The Party of export must ensure that it imposes a legal requirement for the accuracy of information provided by the exporter.

287. Article 8 does not specify in what language the notification should be made – whether it is the language of the Party of export, the Party of import, or some other language. In practice, this issue is likely to be dealt with in national legislation of the Party of import on import procedures for LMOs.

288. The requirement that the notification must contain "at a minimum" the information specified in Annex I of the Protocol could imply that:

- the notifier may provide additional information if available;
- a Party of export may require additional information to be provided to the Party of import in respect of exports of LMOs from its territory; and/or
- the Party of import may require additional information to be provided in respect of LMO imports into its territory.

289. A Party of import may also request additional information at a later stage, prior to making a decision on import, under Article 10(3)(c).

290. As part of the information to be made available under Annex I, the notifier must describe the intended use of the LMO or products of that LMO (Annex I(i)). It should be noted that the AIA procedure relates to approval of *imports* (or transboundary movements) of LMOs (in accordance with Article 7). It does not expressly relate to approval for specific final uses of the LMO once it is in the Party of import: for example, for field trials, commercial growing or placing on the market. (Nonetheless, the final intended use of the LMO would need to be known in order to initiate the appropriate procedure under the Protocol). Depending upon the national legislation of the Party of import, and the request made by the notifier, approval of specific final uses of the LMO in the Party of import may be dealt with as part of the import approval procedure, or it may be subject to a

subsequent and separate approval. This is a matter which will need to be clarified in the domestic legislation of Parties of import.

291. Information provided under Article 8 may be subject to confidentiality requirements in accordance with Article 21.

National implementation

292. As with other provisions of the Protocol, in order to be effective, Article 8 will need to be implemented in the domestic law of Parties – in relation to both exports and imports of LMOs. In relation to exports, Parties will need to ensure that there is an obligation to provide notification to a Party of import of proposed first exports of LMOs that are within the scope of the AIA procedure. The type of information to be provided by the notifier should also be specified. In relation to proposed imports, Parties may wish, in their domestic regulations, to require prior notification to be made to the competent national authority (or authorities); to specify the information to be provided in the notification; and to specify the form and language in which that information should be submitted.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

293. The Party of export is under a general obligation under Article 2(1) to take the necessary measures at the national level to implement its obligations under the Protocol. Article 8(2) places a specific obligation on the Party of export with regard to notifications. It obliges the Party of export to require the exporter to provide accurate information about the LMO under national law. The information referred to here is that required for the notification, i.e. as indicated in Annex I. The requirement applies whether or not, under the domestic law of the Party of export, it is the Party of export itself or the exporter who is required to notify the Party of import of the proposed transboundary movement of LMOs.

Article 9. Acknowledgement of receipt of notification

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, *prima facie*, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

294. *Under Article 9, the Party of import must acknowledge receipt of the notification to the notifier within 90 days of receipt. The acknowledgement of receipt of the notification is important as it:*

- *confirms, on a preliminary basis, that the required information has been provided by the notifier;*
- *identifies the next steps in the process (i.e. either the specific AIA procedure in Article 10 or the domestic regulatory framework of the Party of import); and*
- *confirms the date upon which the 270-day period begins within which the Party of import should reach a decision on the proposed import.*

295. *However, if the Party of import fails to acknowledge receipt of a notification within the 90-day deadline, its consent to the proposed transboundary movement is not implied (Article 9(4)). If a Party has difficulties responding to a notification, assistance may be available under the procedures and mechanisms to facilitate decision-making that are to be developed under Article 10(7) (see commentary on Article 10).*

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, *prima facie*, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

296. The purpose of the acknowledgement of receipt of notification is to confirm receipt to the notifier and to confirm on a preliminary basis whether the notification is in order – i.e. that it contains the required information. The acknowledgement of receipt of notification also identifies the next steps in the process, in that it indicates whether the AIA procedure in the Protocol will be applied to the import of the LMO or whether the Party of import will apply its own domestic regulatory framework in dealing with the import. This regulatory framework need not exactly replicate the procedure set out in Article 10 of the Protocol, but it must be "consistent with this Protocol" (see Article 9(3)).

297. Confirmation of the date of receipt of the notification is important in that it is this date

which marks the beginning of the 270-day period within which the Party of import should reach its import decision under Article 10 (see commentary on Article 10).

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

298. As noted previously, countries that become Parties to the Protocol will need to put in place regulatory procedures to implement it at the domestic level. Thus, a decision by a Party on the proposed import of a particular LMO will take place within a domestic regulatory framework.

299. The effect of Article 9(2)(c) is to allow *any* Party to the Protocol *either*:

- to implement new domestic measures to implement the procedure set out in Article 10; *or*
- to use its existing national biosafety regulatory framework, provided it is consistent with the Protocol; *or*
- to implement new domestic measures which are consistent with the Protocol, but which do not exactly replicate the procedure set out in Article 10.

300. The right to use a domestic regulatory framework consistent with the Protocol, rather than be bound to use its specific AIA procedure, was insisted upon during the Protocol negotiations by a number of developed countries which had existing biosafety regulatory frameworks in place which they wished to continue to use.

301. The phrase "consistent with this Protocol" is not defined, and is not made subject to any specific oversight mechanism in the Protocol. In other provisions of the Protocol, the phrase "consistent with the objective of this Protocol" is used (for example, in Articles 11(4), 14(1) and 24(1)). The requirement of consistency with "this Protocol" would appear to place more limits on the flexibility accorded to the Party than a requirement of consistency only with the objective of the Protocol.

302. From a review of Article 1, one might expect that the consistency of a domestic regulatory framework with *the objective* of the Protocol would be assessed in terms of the following issues:

- Avoidance of adverse effects on the conservation and sustainable use of biological diversity;
- Risks to human health;
- Provision of an adequate level of protection in the field of the safe transfer, handling and use of LMOs;
- Reference to the precautionary approach referred to in Article 1.

303. On the basis of the broader content of the Protocol, and particularly its AIA provisions, a domestic regulatory framework consistent with *the Protocol* (as required under Article 9(3)) might be expected to reflect, in addition, for example:

- Decision-making based on risk assessment carried out in a scientifically sound manner and taking into account recognized risk assessment techniques (and the guidance provided in Annex III);
- Decision-making within a predictable time frame (perhaps not exceeding 270 days);
- Procedures for review of decisions in light of new scientific information;
- Procedures for public consultation and for confidential information, in view of Articles 23 and 21 respectively.

304. Thus, it might be expected that while any domestic regulatory framework followed under Article 9(2)(c) may differ somewhat in procedural terms from the AIA procedure specified in Article 10, the core elements of the decision-making procedure should be similar. In accordance with Article 2(4), a Party's domestic regulatory framework may be more protective of the conservation and sustainable use of biological diversity than called for in the Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

305. During the Protocol negotiations, there were extensive discussions over whether, in the absence of any response to a notification from a Party of import, the proposed transboundary movement of a LMO could proceed as if the Party of import had in fact consented. Article 9(4) provides that, in such circumstances, no consent to the transboundary movement shall be implied – i.e. the exporter cannot simply assume that the transboundary movement can go ahead.

306. A similar provision is contained in Article 10 below, with regard to the failure of a Party of import to communicate a decision to the notifier within 270 days (see commentary on Article 10).

307. Procedures and mechanisms developed under Article 10(7) of the Protocol may be relevant to the acknowledgement of receipt of notifications under Article 9 (see commentary on Article 10). The Intergovernmental Committee for the Cartagena Protocol, after consideration of appropriate procedures, has recommended to the COP/MOP a procedure whereby a Party of import may, after receiving a notification, contact the Secretariat to seek assistance from the roster of experts,[80] among other mechanisms, in order to deal with the notification. Under the ICCP recommendation, a Party of export may also facilitate the Party of import to obtain assistance from the roster of experts where the Party of import does not acknowledge receipt of a notification within ninety days.[81]

308. Another provision which may potentially be relevant in the context of a continued failure to acknowledge receipt of notifications is Article 34 on compliance.

[80] A roster of experts was established by the CBD COP under Decision EM-I/3 and its functions have been elaborated by the ICCP. See commentary on Article 10(7).

[81] ICCP Recommendation 2/7, UNEP/CBD/ICCP/2/15, Annex I.

Article 10. Decision procedure

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant 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 Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

309. *Article 10 sets out the procedure to be followed by the Party of import in reaching its decision on whether to allow the first transboundary movement of a LMO into its territory for intentional introduction into the environment. The Article addresses:*

- *the basis on which the Party of import should take its decision;*
- *the time limit within which the decision should be taken; and*
- *the consequences of a failure to communicate a decision to the notifier within the specified time limit.*

310. *Article 10 needs to be read in conjunction with Article 15. Article 10 provides that the decision of the Party of import must be based on a risk assessment. Risk assessment is addressed in more detail in Article 15 and Annex III to the Protocol.*

311. *It is the responsibility of the Party of import to base its decision on a risk assessment (see commentary on Article15(2)). However,*

- *the Party of import can require the exporter to carry out the risk assessment (Article 15 (2)); and*
- *the Party of import can require the notifier to bear the cost of risk assessment (Article 15(3)).*

312. *In reaching a decision on whether to allow the import of a specific LMO, the Party of import can also take into account:*

- *the precautionary approach, under certain circumstances (see commentary on Article 10(6), and Introduction);*
- *certain socio-economic considerations (see commentary on Article 26).*

313. *Article 23 on public awareness and participation also imposes obligations on Parties which are relevant during the decision-making process in Article 10 (see commentary on Article 23 below).*

314. *Essentially, under Article 10 the Party of import has to communicate to the notifier (and to the Biosafety Clearing-House) its decision on whether to allow the import within 270 days of receiving the notification of the proposed transboundary movement (see commentary on Articles 8 and 9). If the Party of import does not communicate its decision within this period, the import cannot go ahead – i.e. the Party of import's consent cannot be implied.*

315. *The decision of the Party of import may:*

- *Approve the import, with or without conditions;*
- *Prohibit the import;*
- *Request additional information from the notifier; or*
- *Extend the time period for the decision to be taken.*

316. *The Party of import has to give the notifier reasons for its decisions, unless it unconditionally approves the import.*

1. Decisions taken by the Party of import shall be in accordance with Article 15.

317. The decision of the Party of import on the proposed transboundary movement must be based on a risk assessment carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Article 15 sets out the risk assessment requirements in more detail. Annex III contains guidance on the objective of risk assessment, general principles of risk assessment, the methodology to be applied, and points to consider in risk assessment.

318. The Party of import may also take into account certain socio-economic considerations pursuant to Article 26 of the Protocol, in reaching a decision on the proposed import.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

319. Under Article 9, when a Party of import receives notification of the proposed transboundary movement of a LMO, it has 90 days within which to acknowledge receipt of the notification. Under Article 10(2), the Party of import is also required at that stage to tell the notifier in writing whether the import can only take place once written consent has been given. In practice, a Party of import may select to impose a general requirement in its national legislation for written consent prior to the first import of a specific LMO.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

320. Paragraph 3 defines the time limit for an import decision and the possible content of that decision.

Time limit

321. The 270-day period specified in the Protocol is a maximum (subject to Article 10(3)(c) and (d)). There is nothing to prevent Parties from specifying a shorter decision period in their national biosafety legislation if they so wish and if they have the capacity to reach a decision within a shorter time. If not, then the 270-day period will apply.

322. Moreover, in certain circumstances, the 270-day period may be extended. These circumstances are:

- Where additional information has been requested from the notifier, the time during which the Party of import is waiting for the additional relevant information is "added to" the 270-day period. (Article 10 (3)(c)).
- Where the Party of import informs the notifier that an additional defined period of time is required (Article 10(3)(d)). Where the Party of import requires additional time in which to assess the proposed transboundary movement of a LMO, it may so inform the notifier. This provision may not be used by the Party of import simply to extend the decision period indefinitely – the Party of import must specify the amount of additional time that is required.

Content of decision

323. As specified in Article 10(3), the Party of import may approve the transboundary movement, with or without conditions, prohibit the import, request additional information, or specify an additional time period within which the decision will be taken. Conditions attached to a consent may address, for example, risk management measures, including monitoring, that may be required in relation to Article 16.

324. The focus of the AIA procedure is on the transboundary movement of LMOs. The decision to be taken by a Party of import under Article 10 is a decision on whether or not to allow the *import* of a particular LMO and under what conditions (if any). As noted in paragraph 290 above, this decision of the Party of import may not necessarily cover the final use of a LMO in the Party of import once it has been imported. Any proposed use of the LMO may thus potentially be subject to a separate approval procedure in the Party of import. This is a matter for clarification in the relevant national legislation.

Notification of decision

325. The decision on whether or not to allow the import of LMOs must be communicated in writing to the notifier, i.e. the exporter or the Party of export (see commentary on Article 8) and to the Biosafety Clearing-House (see commentary on Article 20).

326. Notification to the Biosafety Clearing-House allows other Parties, as well as exporters, importers and others, to find out which LMOs have been approved for import for intentional introduction into the environment by a Party to the Protocol, and under what conditions (if any).

Subsequent imports of the same LMO

327. If the Party allows the import of the LMO in question, it must, in its decision, specify how that decision will apply to subsequent imports of the same LMO. For example, the Party of import may simply permit future imports of that LMO, under the same conditions, without further administrative requirements. Alternatively, it may, for example:

- require notification of future imports of the same LMO; or
- attach conditions to future imports, such as shipment through a specified entry point.

328. As mentioned previously in relation to Article 7(1), it may not always be simple to determine whether a LMO being imported into a Party of import is the "same" as one that has already been approved for import (see paragraph 271).

329. Under Article 12(4), a Party of import may in any event require risk assessment for future imports of the same LMO. This may be relevant where the circumstances under which the LMO is imported change – for example, there is a change in the intended use, or in the receiving environment, or in the quantities of the LMO being imported into the Party of import.

330. A Party of import may also wish to consider at this stage the need to impose an ongoing obligation on the notifier, and/or on other persons/entities such as the importer, to inform the Party of import of any new information which may become available about the LMO in question, for example as to its potential effects upon the environment or human health (see commentary on Article 12(4)). New information may necessitate a review of any risk assessment and/or of an import decision.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

331. A Party of import must give reasons to the notifier for its decision. Under the Protocol, reasons are not required where an unconditional consent is given. The reasons given for a decision are likely to be important in the event that the notifier wishes to challenge the decision (or conditions attached to an import) under any available domestic procedures in the Party of import. They will also be important if the notifier subsequently requests the review of the decision (see commentary on Article 12).

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

332. As noted in relation to Article 9(4), there were extensive discussions during the Protocol negotiations as to whether, and if so in what circumstances, consent to an import of a LMO could be implied, or whether in all cases *explicit* consent of the Party of import should be required before a transboundary movement could proceed.

333. Article 10(5) addresses the situation where a notifier submits a notification to the Party of import of a proposed transboundary movement of a LMO subject to the AIA procedure, but does not receive any response from the Party of import within 270 days. Under the AIA procedure established in the Protocol, there can be no implied consent to a transboundary movement of a LMO into a Party of import. If the Party of import does not communicate its decision in accordance with Article 10, i.e. within 270 days, the exporter is not authorized under the Protocol to proceed with the export.

334. This provision is largely intended to protect countries which may, for whatever reason, have been unable to communicate a response within the 270-day period specified. However, it is not intended to make way for an open-ended delay. Where a Party of import has difficulties in reaching a decision, it may be able to avail itself of the procedures and mechanisms established under Article 10(7) – for example utilizing assistance of the roster of experts.

335. As noted in relation to Article 9, the Protocol is not entirely clear as to what the consequences of non-response in these circumstances are. It is not explicitly stated in the Protocol that transboundary movement of LMOs for intentional introduction into the environment *cannot* take place without

written consent. Article 10(7) provides only that a failure by a Party of import to communicate its decision within 270 days "shall not imply its consent to an intentional transboundary movement". However, in this regard, it is interesting to compare the wording of Article 10(5) with that of Article 11(7), which deals with the failure to communicate a decision on the proposed import of LMO-FFPs. Article 11(7) provides that a failure by a Party to communicate its decision "shall not imply its consent *or refusal* to the import" (emphasis added). It might be argued that this difference in wording can be understood to imply that a failure to communicate a decision under Article 10 can be taken as implied *refusal* of the import.

336. In any case, the Protocol makes it possible for Parties to make explicit written consent a precondition for imports through their domestic regulations (see commentary on Article 10(2)(a)), and this seems to accord with the intent of an AIA procedure. Once again, clarity can be achieved through a Party's national implementing legislation. For the sake of certainty, Parties could consider incorporating into their national law a clear requirement for explicit consent prior to the first import of a LMO.

337. A related question is whether there is any obligation upon Parties of export to specify in their national legislation that a transboundary movement of a LMO covered by the AIA procedure must not proceed without the express written consent of the Party of import. This is complicated by the fact that the definition of "transboundary movement" in the Protocol (see commentary on Article 3 (k)) does not specify when a transboundary movement has actually occurred – i.e. is there a transboundary movement as soon as the LMO *leaves* the Party of export, or only when that LMO *arrives* in the Party of import? And, in practical terms, can the transboundary movement begin *before* the consent of the Party of import has been received, as long as it is given before the LMO arrives in the Party of import? (Although in such circumstances the notifier would bear the risk that approval may not be given). The Protocol does not explicitly require Parties of export to hold back exports of LMOs until the consent of the Party of import has been received. Nonetheless, such a measure on the part of exporting Parties may promote full implementation of the Protocol, and would also promote certainty.

338. In terms of its obligations under the Protocol, the Party of import would *prima facie* be in breach of its obligation under Article 10 if it failed to respond within 270 days in one of the ways identified in Article 10(3)(a)–(d), even if such a failure would not result in consent to the import being implied.

6. Lack of scientific certainty due to insufficient relevant 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 Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

339. Article 10(6) is generally taken to reflect the precautionary approach (see Introduction). The inclusion of operative provisions in the Protocol on the right of Parties to take precautionary measures in relation to imports of LMOs was among the most contentious issues in the Protocol negotiations.

340. Article 10(6) addresses the situation where, having carried out a risk assessment based on information provided in accordance with Annex I, and on the basis of Article 15 and Annex III, the Party of import concludes that there remains a lack of certainty about the extent of potential adverse effects of the LMO on the conservation and sustainable use of biological diversity, taking also into account risks to human health. It is also relevant to a situation where there is insufficient information to carry out a risk assessment. The basic question addressed during the negotiation was: in such circumstances, should a Party be able to prohibit the proposed import, or attach conditions to it, on the basis of the precautionary approach?

341. As adopted, Article 10(6) represents one of the most explicit examples of the implementation of the precautionary approach in any multilateral environmental agreement. Where the conditions in Article 10(6) are met, a Party of import has the right under the Protocol to base its import decision on the precautionary approach.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

342. This provision requires the first meeting of the COP/MOP (see commentary on Article 29) to decide on procedures to facilitate decision-making on imports. The potential scope of this provision remains somewhat unclear. On the one hand, it could relate primarily to building capacity in countries which have yet to put in place or implement national biosafety frameworks, and which need assistance in developing the legal, institutional or technical capacity to do so. On the other, it might conceivably extend to the development of supplementary procedural standards under the Protocol, such as the development of standard notification and import decision formats, decision guidance documents, or other technical guidelines.

343. In preparation for the first meeting of the COP/MOP, Article 10(7) was addressed at the first and second meetings of the ICCP. The ICCP has made a recommendation to the COP/MOP setting guidelines for procedures and mechanisms to facilitate decision- making, as well as procedures relating to access to the roster of experts, which was established in accordance with decision EM–I/3 of the CBD COP.[82] The ICCP has recommended that procedures and mechanisms to facilitate decision-making should be demand-driven by Parties of import. The main mechanisms envisaged to provide support for decision-making are the roster of experts and the Biosafety Clearing-House.

[82] ICCP Recommendation 2/7, UNEP/CBD/ICCP/2/15, Annex I.

Article 11. Procedure for living modified organisms intended for direct use as food or feed, or for processing

1. **A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.**
2. **The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.**
3. **Any Party may request additional information from the authority identified in paragraph (b) of Annex II.**
4. **A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.**
5. **Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.**
6. **A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:**
   (a) **A risk assessment undertaken in accordance with Annex III; and**
   (b) **A decision made within a predictable timeframe, not exceeding two hundred and seventy days.**
7. **Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.**
8. **Lack of scientific certainty due to insufficient relevant 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 Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.**

9. A Party may indicate its needs for financial and technical assistance and capacity- building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

344. *As noted under Article 7, while they fulfil the definition of "living modified organism" in Article 3 of the Protocol, living modified organisms for direct use as food or feed or for processing (LMO-FFPs) are not intended to be introduced into the environment. They are intended to be used directly as food for humans, as animal feed, or processed. Examples of LMO-FFPs are genetically modified fruits or vegetables for human consumption (i.e. for direct use as food) or genetically modified soya or corn intended for processing into edible oils. Non-food examples include genetically modified grain intended for feeding to animals. LMOs may also be used in industrial processing, for example in the production of plastics and oils.*

345. *During the negotiations, arguments centred first on whether LMO-FFPs should be within the scope of the Protocol at all. Once it was agreed that they would be, debate focused on whether they should be subject to the Protocol's AIA procedure. Those in favour of subjecting LMO-FFPs to the AIA procedure, along with other LMOs, argued that notwithstanding their intended use in the Party of import, in practice, such LMOs may end up being released in the environment of the Party of import either accidentally, for example where there is spillage during a shipment or in processing operations, or deliberately, where the LMO in question is planted in the environment. They also noted that the objective of the Protocol refers to risks to human health. Most developing countries argued in favour of subjecting transboundary movements of LMO-FFPs to AIA. Those who opposed the application of AIA to LMO-FFPs argued that since they were intended for direct consumption by humans or animals or for processing use, LMO-FFPs posed no threat to the biological diversity in the Party of import, and thus were properly outside the scope of Protocol. They also argued that subjecting LMO-FFPs to AIA would subject trade in agricultural commodities to prohibitive delays and expense.*

346. *Negotiations and consultations in the period between the Cartagena session of the ExCOP in February 1999 and the resumed ExCOP in Montreal in January 2000 focused on finding a solution to differences over LMO-FFPs. In the end, LMO-FFPs were exempted from the Protocol's AIA procedure (see commentary on Article 7). But the provisions of Article 11 in effect provide a special, and in principle simpler, procedure for transboundary movements of LMO-FFPs. Essentially, in contrast to the "bilateral" AIA procedure, Article 11 establishes a multilateral information exchange mechanism for LMO-FFPs, centred around the Biosafety Clearing-House. It places the onus on an importing Party to check the Biosafety Clearing-House for information on new LMO-FFPs which may enter international trade, and, if it wishes, to subject such imports to domestic regulation. Article 11 explicitly permits Parties to subject first imports of LMO-FFPs to prior risk assessment and approval.*

347. *It is important to note that Article 11 applies to LMO-FFPs, and not to all foods and feeds derived from LMOs. Thus, while Article 11 is* ***relevant*** *to regulation of transboundary movement of what are commonly referred to as "genetically modified foods", it is* ***applicable*** *only where the product being exported and imported fulfils the definition of "living modified organism" in Article 3 of the Protocol. Article 11 does not apply directly to processed food products derived from, but not consisting of or containing a LMO (e.g. a refined processed oil derived from genetically modified soya). It* ***does*** *however apply to transboundary movement of LMOs destined for use in the production of processed foods, as well as to LMOs for direct use as food or animal feed. Issues related to the safety assessment and labelling of foods derived from modern biotechnology are being addressed in another intergovernmental forum, the Codex Alimentarius (see Box 12).*

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

348. Under Article 11(1), where a Party makes a final decision regarding the commercial growing or placing on the market of a LMO at the domestic level, and that LMO may be exported for direct use as food or feed, or for processing, then that Party must notify the Biosafety Clearing-House (and thereby other Parties) within 15 days of reaching the decision. In some cases, the Party may have to inform competent national authorities of other Parties directly, as well as the Biosafety Clearing-House.

349. The minimum information to be provided to the Biosafety Clearing-House at this stage is set out in Annex II, and corresponds in large part to the information required in notifications made under Article 8 of the Protocol, although there are some significant differences.

350. The obligation to notify the Biosafety Clearing-House in Article 11(1) will apply where, for example, a Party decides to permit the commercial growing or marketing of a genetically modified corn, soya or oilseed rape within its territory which may subsequently be exported for animal feed or for processing for food or other use. It would also apply to a decision permitting the growing and/or marketing of genetically modified tomatoes, which may be exported for direct use as food, or for processing.

351. The requirement to inform other Parties through the Biosafety Clearing-House does not apply where the Party concerned has approved the LMO in question only for field trials – i.e. for research and development purposes. However, if the same LMO were to be sent to *another* Party for field trials then, subject to the provisions of Article 7, it would likely be subject to the Protocol's AIA procedure (since it would be then intended for introduction into the environment of the Party of import).

352. The reference to "direct" use in Article 11(1) suggests that Article 11 will only apply where there is no intermediate use of the LMO in question in a Party of import.

353. During the negotiations, the controversy over Article 11 centred on agricultural commodities. However, Article 11 as adopted also applies to LMOs for direct use for processing. Examples of such LMOs may include those used in industrial processes for the production of plastics or oils.

354. The purposes of the notification to the Biosafety Clearing-House under Article 11(1) are:

- to put other Parties "on notice" that the LMO in question may be exported for food, feed or processing use; and
- to provide relevant information on that LMO that another Party can use when deciding whether or not to allow the import of that LMO for food, feed or for processing in its territory.

355. It is therefore essential that all Parties have access to this information. It was recognized during the negotiation of Article 11 that for some Parties access to the Biosafety Clearing-House may be problematic, particularly where it depends upon regular and reliable internet access (see commentary on Article 20). Thus, if the national focal point (see commentary on Article 19) of a Party does not have access to the Biosafety Clearing-House it should inform the Secretariat of this fact. It should then receive instead a written copy of the information on any new LMO-FFP direct from the Party which has approved that LMO for domestic use. Although Article 11(1) states that this facility is available to a Party that "does not have access to the Biosafety Clearing-House", it presumably extends beyond those that have *no* access to those Parties that have limited or unreliable access to the Biosafety Clearing-House. It may therefore be prudent for any Party which may experience difficulties accessing the Biosafety Clearing-House through the internet on a regular and reliable basis to notify the Secretariat upon entry into force of the Protocol, so that it will receive hard copies of any information on new LMO-FFPs.

356. In contrast to the AIA procedure, Article 11 of the Protocol does not require a Party exporting a LMO-FFP, or an exporter of a LMO-FFP, to provide any notification or information *directly* to the importing Party. Any such obligation needs to be triggered by the domestic regulations of the *importing* Party (see commentary on Article 11(4) and (6)). In practice, however, in some instances the domestic requirements of the importing Party may result in first imports of a LMO-FFP being subject to procedures similar to AIA – e.g. the importing country may well require prior notification of a first import of a LMO-FFP, as well as a risk assessment, and explicit approval.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

357. As in Article 8(2) of the Protocol, Parties are required to ensure that under their domestic law there is a requirement for accuracy of information provided in relation to the LMO-FFP. The "applicant" is not defined in the Protocol, but will presumably be the person or entity which submits the application relating to the domestic use of the LMO-FFP in the Party that makes the final decision on such use.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

358. Once the Annex II information has been conveyed to the Biosafety Clearing-House by the Party which has made a final decision regarding domestic use of a LMO-FFP, any Party may request additional information from the national authority responsible for taking that decision.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

359. Article 11(4) asserts the right of Parties to require prior approval of imports of LMO-FFPs. Thus although LMO-FFPs are outside the scope of application of the Protocol's AIA procedure, in their domestic regulatory framework Parties may still choose to require advance notification and approval of a proposed transboundary movement of a LMO-FFP. The domestic regulatory framework must be consistent with the objective of the Protocol. As discussed in relation to Article 9, on the basis of Article 1, consistency with the *objective* of the Protocol might be considered in terms of the following kinds of issues:

- Avoidance of adverse effects on the conservation and sustainable use of biological diversity;
- Risks to human health;
- Provision of an adequate level of protection in the field of the safe transfer, handling and use of LMOs;
- Reference to the precautionary approach referred to in Article 1.

(See commentary on Article 9, paragraph 302).

360. A number of countries already have in place domestic regulatory frameworks which require prior approval for the import or placing on the market for the first time of a LMO for food, feed or processing use, or for some such uses. In general terms, these frameworks provide for the risk assessment of the LMO-FFP in question, taking into account the characteristics of the LMO, and its intended use.

361. Beyond consistency with the objective of the Protocol, Article 11 does not specify any particular procedural requirements to be reflected in domestic regulatory frameworks applicable to imports of LMO-FFPs. Of course, a Party may also be subject to other relevant international obligations, including those under the WTO Agreements (see Appendix). In addition, a Party may decide to take action that is more protective of the conservation and sustainable use of bioogical diversity than that called for in the Protocol, subject to the proviso set out in Article 2(4).

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

362. Article 11(5) is intended to promote transparency and predictability, by requiring Parties to notify through the Biosafety Clearing-House relevant national frameworks that they will apply to imports of LMO-FFPs. Thus domestic regulatory frameworks under Article 11(4) should be notified to the Biosafety Clearing-House under Article 11(5). In this way, a Party or person who intends to export a LMO-FFP to a Party to the Protocol should be able to find out through the Biosafety Clearing-House what national regulations of the importing Party will apply to the proposed export.

363. The Protocol does not specify in which language or format the information on relevant national regulations is to be made available. This is an issue which will need to be resolved by the COP/MOP if the system envisaged in Article 11 is to be workable, and it is currently being addressed in discussions on the operation of the Biosafety Clearing-House (see commentary on Article 20).

364. Similar notification requirements apply under WTO agreements, for example in relation to notification of sanitary and phytosanitary measures and technical regulations.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

365. Article 11(6) was intended to ensure that developing country Parties and Parties with economies in transition which do not yet have in place a domestic regulatory framework addressing imports of LMO-FFPs could nonetheless subject such imports to prior notification and approval procedures in a manner consistent with the Protocol's objective.

366. Any such Party which does not have a domestic regulatory framework for LMO-FFP imports in place, but which wishes to subject such imports to prior assessment and approval, should indicate this to the BCH. In practice, any Party which does not have such a framework in place upon entry into force of the Protocol for it, may wish to consider making such a declaration. For practical purposes, a Party making such a declaration should also indicate the national authority to which notification of any proposed import should be made – this will be the competent national authority of the importing Party under Article 19 (or one of them).

367. One question which arises here is whether the "domestic regulatory framework" referred to here must be a national biosafety framework or a framework specifically designed to address LMO-FFPs, or whether it could also include more general import procedures, such as existing quarantine measures. The better view would appear to be that where a Party does not have a comprehensive domestic framework addressing LMO-FFPs, then it may make a declaration under Article 11(6).

Risk assessment and predictable time frame

368. Article 11(6) provides that decisions on imports are to be undertaken in accordance with a risk assessment under Annex III of the Protocol, and within a predictable timeframe not exceeding 270 days. In effect this provision allows an importing Party to utilize an AIA-type procedure for reaching a decision on the first import of a LMO-FFP. However,

some potential difficulties might be noted here:

- First, Annex III addresses risk assessment guidelines for LMOs intended for intentional introduction into the environment. Since the Protocol itself differentiates between LMOs and LMO-FFPs one might expect certain different or supplementary criteria to be applicable for risk assessment for LMO-FFPs. For example, while Annex III sets out primarily an environmental risk assessment rather than addressing food safety and related issues, risk assessment for LMO-FFPs, in addition to potential risks associated with their introduction into the environment, might address in more detail human health aspects of the food, feed and processing use of the LMO in question. In this regard, principles and methodologies such as those adopted under the *Codex Alimentarius* may be of relevance (see Box 12) In addition, the reference in Annex III to risks associated with products of LMOs ("products thereof") may be of particular relevance to risk assessment for LMO-FFPs.
- Second, in relation to the time frame for decision-making, unlike Article 10, Article 11(6) does not explicitly allow for an extension of the 270-day time period where the importing Party has either requested additional information about the LMO-FFP or where it simply requires additional time in order to reach a decision. This might create difficulties for an importing Party which does not have a full domestic regulatory framework in place within which to reach its decision. In particular, the lack of a provision to extend the time period for decision-making may be problematic given the language of Article 11(7). On the other hand, there is also nothing in Article 11 which indicates when the 270-day period *begins* in relation to decision-making on imports of LMO- FFPs.

369. Although Article 11(6) is intended as a proective measure for developing country Parties and Parties with economies in transition, it may be challenging in practice for a country which does not have a domestic regulatory framework in place to take a decision on the potential import of a LMO-FFP based on a risk assessment in accordance with Annex III and within a predictable time frame of not more than 270 days. It is perhaps feasible that interim guidelines and procedures could be applied. However, in practical terms, it may make sense for a Party developing a national biosafety framework to deal with LMO-FFP imports within the same framework as LMOs, while taking into account that different or supplementary considerations relating to food safety may need to be taken into account in relation to LMO-FFPs. As in the case of the AIA procedure, gaps and ambiguities in the Protocol may best be resolved through clear national regulations.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

370. Article 11(7) reflects the approach taken in Articles 9 and 10 of the Protocol in relation to AIA, that consent to a transboundary movement of a LMO cannot be implied.

371. Article 9(4) and Article 10(5) provide that failure by a Party of import to acknowledge receipt of a notification or to communicate a decision respectively "shall not imply its consent" to an intentional transboundary movement of a LMO. In contrast to Article 9(4) and Article 10(5), Article 11(7) states that failure by a Party to communicate a decision shall not imply its consent *or refusal* to the import of the LMO-FFP. Since this additional wording was added intentionally, it is to be presumed that the negotiators intended the consequences of a failure to communicate a decision under Article 11 to be different to a failure under Article 9 or Article 10. It cannot be presumed that the words "or refusal" are simply redundant.

372. Nonetheless, the practical implication of the additional wording remains unclear. In these circumstances, for practical purposes and to enhance certainty and predictability, a Party may wish to put in place a domestic regulatory framework for imports of LMO-FFPs under Article 11(4) rather than rely on Article 11(6) and (7). This domestic regulatory framework could then set out the procedure and time frame by which an import decision on LMO-FFPs would be reached, and specify

whether explicit written consent is required prior to the first import of a LMO-FFP.

373. In the event that a Party of import has difficulties in assessing potential imports of LMO-FFPs, it may be that some assistance would be available through the procedures and mechanisms to facilitate decision-making adopted by the COP/MOP under Article 10(7).[83] Strictly speaking, it would appear that Article 10, and hence Article 10(7), is not applicable to LMO-FFPs as it relates to the Protocol's AIA procedure. Nonetheless, it seems likely that similar types of assistance may be required in relation to LMO-FFPs.

8. Lack of scientific certainty due to insufficient relevant 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 Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

374. Like Article 10(6), Article 11(8) allows Parties of import to take a precautionary approach to decision-making on imports. While the debate over the inclusion of precautionary language in Article 10 was protracted, once the language of Article 10(6) was agreed it was also included in Article 11 without additional debate.

9. A Party may indicate its needs for financial and technical assistance and capacity- building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

375. Article 11(9) appears to recognize that there may be additional specific capacity-building needs in Parties regarding LMO-FFPs – for example regarding risk assessments. Although Parties may "indicate" these needs, Article 11(9) does not specify to whom such needs should be indicated. The reference to Article 22 and Article 28 would appear to suggest that such capacity-building needs should be addressed through the COP/MOP and the financial mechanism as well as through bilateral, regional and multilateral channels.

[83] ICCP Recommendation 2/7, UNEP/CBD/ICCP/2/15, Annex I.

Article 12. Review of decisions

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or

(b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

376. *Article 12 addresses the changing state of knowledge about LMOs and their potential impacts on biological diversity and human health. It provides for the review of decisions on imports of LMOs in the light of new information or circumstances. It addresses:*

- *Who can initiate a review of a decision of the Party of import? and*
- *On what basis?*

377. *Under Article 12 a review of an import decision relating to a particular LMO can be initiated by either:*

- *the Party of import;*
- *the Party of export; or*
- *the notifier (see commentary on Article 8).*

378. *A request for a review of a decision may be made at any time provided the requirements of Article 12 are met.*

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or

(b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

379. Paragraphs 1 and 2 of Article 12 set out the circumstances which may give rise to a review of a decision.

380. For the *Party of import* to initiate a review, there must be:

- new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

381. This suggests that scientific information must be available which was not available at the time the original decision was taken. While not explicitly stated in Article 12, it appears that the Party of import may review any type of decision, i.e. an approval of an import; a prohibition of import; or conditions attached to the import of a LMO.

382. For a *Party of export or notifier* to request a review, there must be *either:*

- a change in circumstances that may influence the outcome of risk assessment on which the original decision was based; or
- additional relevant scientific or technical information.

383. Again, a Party of export or notifier may presumably request any type of decision to be reviewed. It can be envisaged that various factors may give rise to a change in circumstances for the purposes of Article 12 such as to prompt a request to review a decision. Presumably, the types of factors to be considered in determining whether or not such a change in circumstances has occurred are the factors reflected in Annexes I and III – i.e. information provided in the notification, and the guidance on risk assessment. For example, one relevant change in circumstances which might occur could be a change in the proposed receiving environment of the LMO in question. Others might be the availability of improved detection and identification methods for the LMO, or a change in the intended use of the LMO.

384. If the Party of export or notifier does request review of a decision, the Party of import has 90 days in which to respond to that request with reasons. In order to fulfil the requirement to give reasons the Party of import is likely to have to review the original decision and the risk assessment on which it was based in the light of the new information or circumstances. However, Article 12 does not provide that the decision procedure in Article 10 should apply anew to requests for review. In contrast to Article 10, Article 12 does not explicitly give the Party of import an opportunity to request additional information from the notifier during this period or unilaterally to extend the time period within which the result of its review will be communicated. Nonetheless, it may be necessary for a Party of import to request additional information from the Party of export or notifier in order to ascertain whether the change in circumstances or additional relevant scientific and technical information is such as to warrant a change to the original decision. The 90 days time limit within which to respond to requests for review may prove problematic for certain countries with limited human, technical and/or financial resources. In particular, and in contrast to Article 15(3), Article 12 does not explicitly provide that the Party of import may require the Party of export or the notifier to bear the costs of the review. This may be addressed in the domestic law of the Party of import.

385. Article 12 does not provide an "appeal" as such against the original import decision of the Party of import – i.e. the Party of export or the notifier cannot use Article 12 simply to challenge the decision of the Party of import taken in accordance with Article 10, unless they can point to changed circumstances or additional relevant scientific information, However, if they can identify such circumstances or information, the Party of export or notifier may ask for a review of the decision at any time. During the negotiations, there was discussion of including a provision in Article 12 whereby a Party of export or notifier could request a review of a decision if there was reasonable evidence that the original decision was not based on scientific principles and evidence. This provision was not agreed.[84] Of course, it is open to a Party of import to make provision for an additional appeal procedure in its national regulations or other procedures may already exist in its national law for the review of administrative decisions.

[84] Earth Negotiations Bulletin Summary of BSWG 6, pp5-6, available at: http://www.iisd.ca/linkages/download/asc/enb09110e.txt

386. The possibility to review decisions provided by Article 12 of the Protocol is an important element in assessing the compatibility of the Protocol with relevant WTO agreements (see Appendix).

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

387. As noted previously, the Protocol's AIA procedure applies to the first intentional transboundary movement of a LMO for intentional introduction into the environment of the Party of import. Article 12(4) addresses the situation in which, having taken a decision allowing the first import of a particular LMO for intentional introduction into the environment, the Party of import may nonetheless wish to subject subsequent imports of the same LMO to risk assessment. The Party of import may wish to do this where, for example, the intended use of the LMO changes, the receiving environment changes, or the volume of imports changes so as to increase the risk of adverse impacts on the conservation and sustainable use of biodiversity, taking into account risks to human health.[85] It is conceivable that a decision of a Party of import allowing the first import of a LMO could specify, as a condition of import, that if any of the above-mentioned circumstances arise (or others) then a new risk assessment would be required. However, Article 12(4) suggests that it is not necessary for the Party of import to do this in order to be able at a later stage to exercise its discretion to require a further risk assessment to be carried out.

388. During the negotiations, there was discussion on whether Article 12 should include a list of the circumstances under which the Party of import might exercise its discretion to require risk assessments for subsequent imports. However, these proposals were not included in the final text.

[85] Earth Negotiations Bulletin Summaries of BSWG 5 and 6, available at: http://www.iisd.ca/linkages/vol09/

Article 13. Simplified procedure

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

389. Article 13 represents another example of the discretion that the Protocol leaves to Parties of import in how they address potential imports of LMOs for intentional introduction into the environment.

390. Under Article 13(1)(a), a Party of import may indicate that certain transboundary movements of LMOs to it may take place on the basis of a mere notification to the Party of import.

391. Under Article 13(1)(b), a Party of import may indicate that it will exempt certain imports of LMOs from the AIA procedure.

392. Parties which intend to utilize Article 13(1)(a) or (b) must notify to the Biosafety Clearing-House the LMOs to which such procedures will apply.

393. It should be emphasized that this "exception" to AIA operates at the domestic level only – i.e. it is only proposed imports of the specified LMO to the Party of import in question that are affected. Transboundary movements of the same LMO to all other Parties remain subject to the Protocol's AIA procedure.

394. A Party may only avail itself of the simplified procedure in Article 13 if "adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol". This proviso is intended to provide a minimum level of protection below which no Party should fall. No supervisory mechanism for Article 13 is established in the Protocol. However, this may be an issue which could be addressed, if necessary, under the compliance procedures and mechanisms which are to be adopted under Article 34 of the Protocol.

Article 14. Bilateral, regional and multilateral agreements and arrangements

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

395. *Article 14(1)-(3) addresses the situation where Parties to the Protocol have concluded, or intend to conclude, a separate agreement or arrangement on intentional transboundary movement of LMOs. For example, it is possible that two neighbouring countries, with an active trade in LMOs, may decide to conclude an agreement that is more specific than the Protocol, addresses the issues in more detail, and is adjusted to those countries' particular situation and needs.*

396. *Article 14 states that the provisions of the Protocol "shall not affect" intentional transboundary movements of LMOs that take place in accordance with such an agreement or arrangement entered into by a Party to the Protocol. However, such agreements or arrangements must be consistent with the objective of the Protocol and must not result in a lower level of protection (for biodiversity and for human health) than that provided for by the Protocol.*

397. *One issue which arises in relation to Article 14 is whether it applies to agreements and arrangements between Parties only, or also to agreements and arrangements between Parties and non-Parties. This is important considering the standard that is set in Article 14(1) for such agreements and arrangements. This issue is addressed further in the commentary on Article 24.*

398. *One specific application of Article 14 relates to the special situation of the European Union and its member States. As future Parties to the Protocol, the European Community and its members will want to continue to apply the relevant EU legislation both within the internal market of the EU and to imports of LMOs from third States into the EU, in precedence over the provisions of the Protocol. Article 14 was intended to provide the basis for this. In an earlier draft of the Protocol, there was a provision dealing specifically with the issue of regional economic integration organizations applying their own legal provisions to transboundary movements of LMOs involving their region. The definition of "regional economic integration organization" in Article 3 was included in the context of that provision. In the final negotiations, the provision in question was deleted with the understanding that Article 14 would serve the relevant purpose. According to the interpretation of the European Commission, Article 14(3) provides the basis for giving precedence to EU legislation in relation to movements of LMOs within the EU, and Article 14(4) in relation to the import of LMOs into the EU from third States (see below).*[86]

[86] See Proposal for a Regulation of the European Parliament and of the Council on the transboundary movement of genetically modified organisms, COM(2002)85 final, Explanatory Memorandum.

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

399. This provision establishes a double requirement for separate agreements or arrangements regarding intentional transboundary movements of LMOs among Parties:

(i) such agreements and arrangements must be consistent with the objective of the Protocol; and

(ii) they may not result in a lower level of protection than that provided by the Protocol.

The rationale is to give Parties the opportunity to establish and apply bilateral or multilateral systems for the management of the transboundary movement of LMOs other than the system provided by the Protocol. However, at the same time, Article 14 seeks to ensure that the objective of the Protocol is not undermined by such alternative arrangements. Parties may not use a separate agreement or arrangement to avoid their obligations under the Protocol.

400. Article 14 refers to "bilateral, regional and multilateral agreements and arrangements". This wording indicates that a Party may conclude a treaty with one other Party (bilateral) or with more than one other Party (multilateral). A multilateral treaty can be limited to a particular region (regional), or it can be wider in scope.

401. The reference to "arrangements" in addition to "agreements" can be understood to mean that international legal instruments that do not assume the form of treaties but imply an engagement on the part of the States concerned are also covered. These may include for example arrangements on LMOs within the OECD or the European Union, or within other regional bodies that do not take the form of treaties.

402. The difficulty in relation to Article 14(1) lies in the interpretation of the terms "consistent with the objective of the Protocol" and "do not result in a lower level of protection", which set a standard for agreements and arrangements under Article 14. These terms are not defined and no specific mechanism is established to monitor and assess whether Article 14 agreements and arrangements have met these requirements. If difficulties should arise in relation to such agreements and arrangements, the COP/MOP or the compliance mechanisms to be adopted under Article 34 of the Protocol may be called upon to play a role in their resolution.

403. In order to be consistent with the Protocol's objective, an Article 14 arrangement or agreement would need to be in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration, contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs that may have adverse effects on biological diversity, taking also into account risks to human health. While the agreement or arrangement would not need to replicate the same procedures and techniques, such as the AIA provisions, contained in the Protocol it should provide for equivalent measures necessary to achieve an adequate level of protection. Thus, as a minimum, it should provide for a mechanism to ensure safe transfer, handling and use of LMOs, and for a method to provide the importing country with an opportunity and a basis for deciding whether or not to consent to the import of LMOs. (See also commentary on Article 9, paragraphs 302–303).

404. The requirement that such agreements and arrangements "do not result in a lower level of protection than that provided for by the Protocol" indicates that at least an equivalent level of protection must be achieved. This requirement is in conformity with the general obligations of Parties to adhere to the Protocol's objective and to ensure that activities involving LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health (see commentary on Article 2(2)). It is also consistent with the right of Parties to take action that is more protective than that called for in the Protocol, provided such action is consistent with the provisions of the Protocol and its other obligations under international law (see commentary on Article 2(4)). Parties are not entitled to take action that is less protective of the conservation and sustainable use of biological diversity than that called for in the Protocol. It should be noted that the level of

protection provided by the Protocol, as it enters into force and is applied by its Parties, may evolve over time, and may differ from LMO to LMO. An Article 14 agreement or arrangement must be similarly flexible to keep pace with developments under the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

405. The purpose of Article 14(2) is to provide transparency as regards the international legal rules that govern transboundary movements of LMOs for States that are Parties to the Protocol.

406. Article 14(2) refers to agreements and arrangements entered into by a Party before or after the date of entry into force of the Protocol. The "date of entry into force" of the Protocol is addressed in Article 37(1). The difference between agreements and arrangements entered into before or after the date of entry into force of the Protocol is primarily relevant in the case where a separate agreement does not conform to the requirements of Article 14(1). Agreements or arrangements that are compatible with the Protocol take precedence in accordance with Article 14(3) (see below). Parties that have already entered relevant agreements or arrangements before the Protocol comes into force are entitled to maintain these provided they meet the conditions set out in Article 14(1). If an incompatible agreement was entered into before the entry into force of the Protocol, the rules of international treaty law stipulate that the Protocol takes precedence over the older treaty as between Parties to both treaties. If an incompatible agreement is entered into after the entry into force of the Protocol, it would be in contravention of Article 14, and of the Party's duty to fulfil its obligations under the Protocol in good faith.[87]

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

407. This is the key provision of Article 14. It explains why the consistency requirement in Article 14(1) is important. Article 14(3) stipulates that a separate agreement or arrangement, if it fulfils the conditions of Article 14(1), takes precedence over the Protocol, but only with regard to transactions between the States that are parties to it.

- In a transboundary movement between State A and State B, both of which are Parties to the Protocol ***and*** to the separate agreement under Article 14, the separate agreement applies.
- By contrast, in a transboundary movement between State C, which is a Party to the Protocol as well as to the separate agreement under Article 14, and State D, which is a Party to the Protocol but not to the separate agreement, the Protocol applies.

408. In each case, the separate agreement must fulfil the Article 14(1) conditions. This is in fact a re-statement of a rule of international treaty law that governs the relationship between successive treaties on the same subject. Under Article 30(2) of the Vienna Convention on the Law of Treaties, a treaty may accord precedence to another treaty entered into by its parties, as the Protocol does in this instance. Article 30(4)(b) of the Vienna Convention stipulates that in a relationship between a State that is a Party to two agreements and a State that is a Party to one of the agreements only, the agreement to which both States are Parties shall apply.

409. Article 14(1)-(3) refers to agreements and arrangements regarding *intentional transboundary movement* of LMOs, and Article 14(3) provides that the Protocol provisions shall not affect *intentional transboundary movements* that take place pursuant to such agreements and arrangements. Thus other provisions of the Protocol which are not applicable only to transboundary movements of LMOs will continue to apply even as between parties to the separate agreement (see Box 10 for an analysis of the distinction between the two types of provisions).

[87] Vienna Convention on the Law of Treaties, Article 26.

410. With regard to the EU, relevant EU legislation is considered a "regional agreement or arrangement" in accordance with Article 14. This means that EU legislation shall apply to transboundary movements of LMOs within the EU in precedence over the provisions of the Protocol, in accordance with Article 14(3).[88]

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

411. This provision does not relate specifically to the title of Article 14, as it does not concern separate agreements or arrangements on the transboundary movement of LMOs. Its relevance and aim here are not immediately obvious. In order to understand the meaning and significance of Article 14(4) and the reason for its placement in this Article, one needs to look at the negotiating history of the Protocol. In fact, the placement of this provision was subject to discussion, and it was moved several times during the negotiation process.

412. The Protocol contains three provisions dealing with the possibility for Parties to subject certain imports of LMOs to domestic legislation rather than the precise requirements of the AIA procedure:

- Article 9(2)(c) provides for a decision to be taken by the Party of import, after receipt of notification of an intended transboundary movement under the AIA procedure, to apply its domestic regulatory framework to that particular movement in preference to the AIA procedure, provided that the national framework is consistent with the Protocol (see commentary on Article 9);
- Article 13(1)(b) sets out a simplified procedure by which specified LMOs may be exempted from the AIA procedure by a Party through advance notification to the Biosafety Clearing-House, provided certain requirements are met (see commentary on Article 13); and
- Article 14(4) allows for a general application of domestic regulations to specific imports in preference to the AIA procedure, also by advance notification to the Biosafety Clearing-House.

Box 28. Example of a regional arrangement

Directive 2001/18/EC of the European Parliament and the Council on the deliberate release into the environment of genetically modified organisms

Objective

In accordance with the precautionary principle, the objective is to approximate the legislation of the Member States and to protect human health and the environment in two cases:

– Deliberate release into the environment of genetically modified organisms; and

– Placing on the market of genetically modified organisms in the European Union.

General obligations

– Ensuring that appropriate measures are taken to avoid adverse effects on human health and the environment, in accordance with the precautionary principle;

– Genetically modified organisms may only be deliberately released or placed on the market in conformity with the procedures set out in the Directive.

Authorization procedures

Procedures are established for the authorization of release into the environment and placing on the market of genetically modified organisms in the European Union. Subject to a safeguard clause in the Directive, once consent has been given for the placing on the market of a GMO as or in a product, that product may be used

[88] See Proposal for a Regulation of the European Parliament and of the Council on the transboundary movement of genetically modified organisms, COM(2002)85 final, Explanatory Memorandum.

413. The negotiating history of the Protocol shows that Article 14(4) was intended to take account of the need of the EU for a mechanism to apply its own legislation to movements of LMOs taking place from third parties into the EU. By allowing the application of "its domestic regulations" (i.e. the relevant EU legislation, see Box 28), Article 14(4) takes account of this need.[89] However, the application of Article 14(4) is not limited to regional economic integration organizations. It can be invoked by any Party to the Protocol.

[89] See Proposal for a Regulation of the European Parliament and of the Council on the transboundary movement of genetically modified organisms, COM(2002)85 final, Explanatory Memorandum.

General introduction to Articles 15–16 and Annex III

414. *Articles 15 and 16, and Annex III, introduce the concepts of risk assessment and risk management into the Protocol.*

415. Risk may be defined as the likelihood that an organism introduced into the environment may cause harm to that environment. It is comprised of two factors:

- the consequence of a particular event (i.e. of a potential adverse effect, including its magnitude); and
- the likelihood of the event occurring.

416. Risk assessment is an important first step in any attempt to minimize or prevent possible adverse effects to the environment. It is intended to enable informed decisions to be made about the transboundary movement of LMOs. Risk management addresses the issue of how to manage, in an appropriate and effective manner, any risk that may have been identified during the assessment process.

417. In the context of LMOs, thorough risk assessment and effective risk management measures are particularly important since it is likely to be virtually impossible to recall LMOs once released into the environment, and since most organisms have abilities to spread or propagate, or to disseminate genes to other varieties of the same species or to other species.

418. Possible adverse effects of a LMO depend not only on the LMO itself, but also on the potential receiving environment into which the LMO is to be introduced. They also depend upon the interactions between that LMO, the receiving environment, and other organisms present in that environment. A potential receiving environment is an ecosystem or habitat, including humans and animals, which is likely to come in contact with a released organism.[90]

419. Many of the LMOs which may be considered for growing or use within the territory of a Party to the Protocol will have been produced, and possibly grown or reared commercially, in other countries which may have very different ecosystems and indigenous organisms. Although these LMOs may have been subject to risk assessment and risk management procedures in all the countries where they have previously been used (particularly in the country of manufacture and first use), these assessments and procedures may not be adequate to protect a new and different receiving environment and its biological diversity, taking also into account risks to human health.

420. Risk assessment and risk management are related processes. Risk management measures will be proposed following a risk assessment. It is likely to be necessary to reassess risks after risk management measures are applied. Therefore, it may be necessary to iterate between risk assessment and consideration of appropriate risk management measures to achieve prevention of any risk, or its minimization or reduction to an acceptable level. Assessment of risk management measures could include consideration of the possibility that risk management measures, while appropriate, may not be applied effectively, or that even where effectively applied, the risk management measures specified may not in fact sufficiently control risks.

421. Risk assessment involves a number of steps, including identification of potential adverse effects, an assessment of the likelihood that the potential adverse effects occur, and an evaluation of the consequences that may arise where these adverse effects come to be realized. As part of the risk assessment, Annex III provides for a recommendation to be made as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks.

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[90] *UNEP International Technical Guidelines for Safety in Biotechnology* (1995), Annex 2.18.

Article 15. Risk assessment

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

422. *Article 15 establishes the basic requirements for risk assessment under the Protocol, and refers to Annex III for further guidance. Article 15 and Annex III are, therefore, closely connected. The objective of the risk assessment under the Protocol is, as stated in this Article and Annex III (1), to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biodiversity, taking also into account risks to human health.*

423. *Annex III notes that risk assessment entails, as appropriate, the following steps:*

- *identification of possible adverse effects in the potential receiving environment, taking into account characteristics of the LMO concerned and of the potential receiving environment;*
- *evaluation of the likelihood of these effects occurring;*
- *evaluation of the consequences if those effects should occur;*
- *estimation of overall risk in relation to each adverse effect, based on evaluation of its likelihood and consequences;*
- *recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage the risks;*
- *in cases of uncertainty regarding the level of risk it may be necessary to request further information on the specific issues of concern or implementation of risk management strategies to take account of the uncertainties and/or to monitor the LMO in the receiving environment.*

424. *The rest of this commentary will focus on the risk assessment provisions of Article 15. A separate commentary is provided on Annex III (see paragraphs 794–843).*

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Basis for the risk assessment

425. At a minimum, risk assessment for LMOs subject to the AIA procedure is to be based on information provided in accordance with Article 8 (including Annex I), and other available scientific evidence.

426. Relevant scientific evidence to be taken into account will include scientific data (including statistical data, if available), scientific theories, models, and other sources of scientific knowledge, that assist in the

identification of possible adverse effects, and evaluation of the probability of adverse effects occurring, and of their consequences. Evidence that might not be regarded as scientific – for example, indigenous and traditional knowledge and information, as well as anecdotal information – might also be considered where relevant, provided consideration is carried out in a scientifically sound and transparent manner, such as through a scientific study of the issues raised.

427. There are, however, many variables that may change the response of an organism to an environment which have not yet been understood, and due to the complexity of the ecosystems may never be fully predictable. In some cases it may be difficult to even identify these effects, let alone predict the probability of them being realized. Furthermore, available information about ecological relationships and environmental factors in specific environments, and the response of a LMO to a specific environment, may be limited or non-existent, due to a lack of relevant research.

428. There may also be disagreement among scientists about the possible adverse effects associated with a LMO, including disagreement about the manner in which an inserted gene is likely to modify characteristics of the organism other than the intended changes, about the interpretation of data, and about the ecological and environmental effects of LMOs.

Scientifically sound manner

429. The risk assessment must be "carried out in a scientifically sound manner". Box 29, taken from the UNEP International Technical Guidelines on Biosafety, gives examples of the types of scientific expertise and information that may need to be considered in undertaking risk assessments relating to LMOs. Further developments in these and other relevant scientific fields could also be taken into account.

430. There is no definition of the phrase "scientifically sound manner" in the Protocol. Indeed, there appears to be no internationally agreed definition of the phrase "scientifically sound". Similar terms have been used in other international guidelines without definition.[91] Identifying what constitutes a "scientifically sound manner" may give rise to disagreement between States. The phrase implies that risk assessment needs to proceed in a systematic way, and to be undertaken with inputs from people with appropriate qualifications and experience in fields relevant to the nature of the possible adverse effects.

431. Possible elements of a "scientifically sound manner" might include, for example:[92] the review and evaluation of all available relevant scientific information; a case-by-case, structured and integrated approach; analysis using appropriate statistical techniques; peer review; a credible, transparent and inclusive evaluation mechanism; and the use of scientific advice from a wide variety of sources, including expertise in different disciplines and diversity of scientific schools of thought and opinion.

432. Specific guidance on the risk assessment process to be undertaken under Article 15 is provided in Annex III to the Protocol.

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91 For example, Statements of Principles concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account, Procedural Manual of the Codex Alimentarius Commission (12th edition, 2001), p. 165. Article 2(2) of the WTO SPS Agreement provides that any sanitary or phytosanitary measure must be "based on scientific principles", and the Agreement contains further references to "scientific justification" (Article 3(3)) and "scientific evidence" (Article 2(2) and Article 5(2)).

92 See e.g. "Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology", Report of the Third Meeting of the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology, Appendix II, ALINORM 03/34; A Canadian Perspective on the Precautionary Approach/Principle: Discussion Document, September 2001, pp. 14-15, available at *Health Canada online*: http://www.hc-sc.gc.ca/english/protection/ precaution.html

Box 29. Examples of the types of scientific expertise and information for undertaking risk assessments relating to LMOs

Risk assessment requires a range of expertise which should be reflected in the competence and experience of those carrying out the assessment in a scientifically sound manner.

The different fields of expertise needed for scientifically sound risk assessment may include, as appropriate:

* Nucleic acid technology
* Molecular genetics
* Population genetics
* Marine biology
* Ecology
* Taxonomy
* Microbiology
* Virology
* Zoology
* Entomology
* Plant biology/botany
* Veterinary science
* Agronomy
* Forestry
* Pathology
* Epidemiology
* Process technology
* Biochemistry
* Toxicology

This list is provided as a guide to the major fields of expertise which may be required and is not intended to be comprehensive. Not all of these are likely to be relevant in each case and, as knowledge and technology advance, other fields of expertise will be important in risk assessment.

Source: UNEP International Technical Guidelines for Safety in Biotechnology, pp.21–22

Possible adverse effects

433. The Protocol does not explain the term "possible adverse effects". The possible adverse effects of LMOs that are to be identified and evaluated are those that might affect the conservation and sustainable use of biological diversity, taking also into account risks to human health. Based on the wording of Article 15, and on the methodology for risk assessment set out in Annex III, it would appear that all such possible adverse effects are to be identified. The evaluation of each possible adverse effect that has been identified then includes an assessment of the probability or likelihood of that adverse effect occurring, and of its consequences should it occur. Possible adverse effects to be considered may include both short-term and cumulative, long-term effects, as well as direct, indirect and delayed effects. For example, this approach is taken in EU legislation on release of LMOs into the environment (see Box 30).

Box 30. Categorization of direct, indirect, immediate and delayed effects

"direct effects" refer to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events;

"indirect effects" refer to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management. Observations of indirect effects are likely to be delayed;

"immediate effects" refer to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;

"delayed effects" refer to effects on human health or the environment which may not be observed during the period of the release of the GMO but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

Source: Annex II, Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms. OJ L 106/1 (17 April 2001).

Taking into account recognized risk assessment techniques

434. Risk assessments of LMOs under Article 15 are to take into account recognized risk assessment techniques. The Protocol does not specify what constitute recognized risk assessment techniques, but they may be assumed to include those techniques that are currently applied at national, regional or international level. In addition, risk assessment techniques that may be applied or developed in other areas may also be relevant for risk assessment of LMOs (e.g. techniques relating to alien invasive species).

435. Examples of such techniques would include the UNEP International Technical Guidelines on Biosafety and the OECD's work on risk assessment.[93]

436. Risk assessment strategies related to LMOs adopted by international and national systems are very similar. They are predominantly based on familiarity (i.e. knowledge and experience) with the unmodified donor and recipient and the likely impact due to the changed characteristics of the organism; with the intended application; and with the potential receiving environment.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

437. This provision places an obligation on Parties of import to ensure that risk assessments are the basis for reaching decisions on proposed imports of LMOs that are subject to the Protocol's AIA procedure. The Party of import may perform the risk assessment, or alternatively, the Party of import may require the exporter to carry out the risk assessment.

438. In some countries, national authorities perform a risk assessment, on the basis of information provided by the applicant/ notifier. In other countries, the authority responsible for decisions acts as an auditor of the risk assessment provided by the applicant. In the latter case, the applicant must provide a dossier containing the information used in the risk assessment and on proposed risk management measures, and the authorities review the data and the assessments. National authorities may ask for further information or clarification before deciding on the validity of the assessment in relation to the potential receiving environment(s).

439. Under the procedures to be adopted under Article 10(7), the Party of import may be able to request assistance, for example, through the roster of experts to review the information and risk assessment provided by the applicant/exporter.

440. The mechanisms used by Parties for carrying out or evaluating risk assessment may vary. Whatever mechanism is used, it is important that the requirements of risk assessment are clearly defined and systematically carried out. The individuals charged with risk assessment will need to be well qualified in the area under review, be individuals of the highest integrity, and meet requirements for public disclosure of actual and potential conflicts of interest.[94]

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

441. Parties may vary as to their approach to recovering the costs of the risk assessment procedures that are to be carried out under Article 15. In some cases, no charge may be made for the regulatory processes. However many countries may require fees from the applicant to cover either part or all of the costs of risk assessment (insofar as such costs can be determined).

442. This provision enables a Party of import, if it so wishes, to recover from the notifier the cost of risk assessment of the proposed transboundary movement.

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93 See, for example Report to the Working Group on Regulatory Oversight in Biotechnology (to the G8 Heads of State and Government), May 2002, OECD Reference No. C(2000)86/ADD1.

94 See, for example, the EU-U.S. Biotechnology Consultative Forum Final Report (December 2000) http://europa.eu.int/comm./external_relations/us/biotech/report.pdf

Article 16. Risk management

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of 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; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

443. *The purpose of risk management as provided in Article 16 is to regulate, manage and control risks identified in risk assessments carried out under the Protocol.*

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

444. This Article deals with the management of risks of those organisms that fall within the scope of the Protocol (i.e. all LMOs covered by Article 4) and refers to the provisions of Article 8(g) of the CBD, which requires Parties to the CBD to:

> establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

445. Article 16(1) places an obligation on Parties to set up appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol. The obligation implies the establishment and implementation of a regulatory system with the capacity to manage and control such risks.

446. The Protocol does not give any specific guidance on how suitable risk management strategies may be identified. However in order to manage risk, risk management strategies will need to be effective when applied in practice by those who will have the responsibility for implementing them, for example, farmers or

distributors of LMOs. In the identification of risk management mechanisms, measures and strategies it is therefore important to consider the feasibility of the measures proposed in the circumstances in which they will be carried out in practice. Identification of risk management strategies could also, taking into account Article 23(2), consider the many different views of those affected by the introduction into the environment of LMOs covered by the Protocol, so as to ensure that differing technical assessments, public values, knowledge, and perceptions are considered.

447. For the release of LMOs that are plants, risk management measures that are commonly applied include the following:

- isolation distances or "buffer zones" (to the next field of the same crop and to other hybridization partners to minimize pollen transfer);
- border rows with non-transgenic plants (to catch pollen);
- after release treatment: inactivation of remaining plants and seeds, specific soil treatment after harvest (e.g. measures for early germination in order to destroy volunteers);
- after release control (e.g. removal of volunteers in the next year/s); and
- partial or full restrictions preventing planting in specified areas (e.g. to prevent horizontal gene flow).

448. Risk management measures, such as those above, have been developed and applied mainly in countries where farms are managed as large single units. They may well need to be adapted if they are to work effectively under different conditions, such as in situations where there are many small farms, each managed separately, as is common in many developing countries.

449. While the Protocol does not specifically require risk management measures to include a component for monitoring the application and effectiveness of the measures, and strategies to manage adverse effects resulting from poor implementation, or ineffectiveness, of these measures, it may be considered that these elements are part of "management and control".

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

450. "Measures based on risk assessment" refers to the measures to regulate, manage and control those risks that are identified through the risk assessment provisions of the Protocol, as described in Article 15(1) and 16(1).

451. The obligation established under this Article "to impose measures to the extent necessary to prevent adverse effects" differs from, and in the use of the word 'prevent' would appear to be stronger than, the wording and approach used in the wording of Articles 10(6) and 11(8) on application of the precautionary approach in the decision procedure, which refers to avoiding or minimizing adverse effects.

452. The management measures to be imposed here are those necessary to prevent adverse effects of LMOs on "the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import". Consistent with Article 16(1), this provision places an obligation on Parties to impose risk management to prevent adverse effects.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

453. An unintentional transboundary movement might occur by spread of LMOs through growth and dispersal, for example, where a LMO is grown close to an international border. Unintentional transboundary movement may also occur through local, informal trade, errors in handling of shipments or through illegal activities. Article 16(3) requires that the risk assessment needed before the first release of a LMO takes into

account the possibility of unintentional transboundary movements of LMOs across international borders (for further discussion of unintentional transboundary movement, see commentary on Article 17).

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

454. Article 16(4) requires each Party to endeavour to ensure that, all LMOs undergo an appropriate period of observation before being put to their intended use. The use of the word "endeavour" indicates an obligation to put in place measures to achieve the goal set out in Article 16(4).

455. The placing of this requirement in the Article 16 on risk management suggests that its provisions are in addition to provisions for risk assessment in Article 15 and Annex III.

456. The wording does not specify where this observation is to take place: it could take place in the territory of the Party concerned, or in other countries. However, if an initial risk assessment suggests that there are significant differences between the place where the period of observation has occurred, and the receiving environment, then a further period of observation, commensurate with the life-cycle or generation time of the LMO concerned, may be necessary. This would need to take place in the potential receiving environment, or in a comparable environment in another Party, in order to be able to complete the risk assessment in relation to the potential receiving environment.

457. Article 16(4) specifies that this observation is to be undertaken before the LMO is put to its intended use.

458. The "life-cycle" or generation time will depend on the LMO concerned. In the case of trees or long-lived animals, for example, a life-cycle could be measured in years or even centuries. However, the generation time – the time taken from germination or birth for the organism to produce progeny/offspring – will generally be shorter than the period of their life-cycle. The reason for the reference to a period of observation commensurate with the life-cycle is that this would permit observation of how a LMO behaves under different stages of its life-cycle, which may be associated with internal changes within the organism affecting physiology, biochemistry, gene expression, etc. associated with maturation and ageing. It also recognizes that ecological effects may take a significant period of time before they become apparent. The phrase "commensurate with its life-cycle or generation time" could therefore imply a period of observation at least as long as a generation time, or a period in which all major stages of the life-cycle are manifest.

459. It is important to note that for organisms with short life-cycles (for example, insects, bacteria or short-lived plants) the requirements for risk assessment may well necessitate observation and testing for periods that may be many times longer than their short life-cycles. In addition, many organisms, including those with short life-cycles, may produce very long-lived spores or other resting stages. For example, ancient viable microorganisms are reported to have been extracted from archaeological sites; some seeds and some invertebrates are also amongst organisms known to have long-lived resting stages. Such resting stages will need to be taken into account in the context of the period of observation.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of 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; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

460. Article 16(5) places an obligation on Parties to cooperate in two specific instances. The first relates to the sharing of information and methods of management to identify organisms or traits which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The second relates to cooperation regarding appropriate treatment of the organisms and traits identified, potentially including the development and implementation of concerted strategies to counter their adverse effects.

461. Concerns about certain characteristics introduced into LMOs, such as antibiotic resistance markers, were raised during the Protocol negotiations. A specific provision to facilitate concerted action by the Parties to the Protocol to phase out the use of antibiotic resistance markers was proposed by some countries. However, in view of the rapid developments within genetic engineering, it was felt that the general provision provided by Article 16(5) would be more appropriate. Parties may decide to take concerted action in relation to antibiotic resistance markers, but they are not specifically obliged to do so. In addition, Article 16(5) enables Parties to take concerted action in relation to any LMOs, or specific traits of LMOs, that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

462. Article 16(5) is also relevant in relation to neighbouring countries that are likely to have common interests in risk assessment and management, or countries sharing similar geographical or climatological characteristics that may wish to share information about organisms produced or grown in their territories. The information gained about the characteristics of growth and fitness within particular environments may provide guidance as to the behaviour in other similar environments, and may assist in assessing and/or managing any risks posed by LMOs or the inserted characteristics.

Article 17. Unintentional transboundary movements and emergency measures

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

463. *While much of the Protocol is concerned with the intentional transboundary movement of LMOs, LMOs can also cross national boundaries unintentionally. Article 17 deals with issues related to inter-State cooperation and preventive measures in the event of such unintentional transboundary movements of LMOs.*

464. *Article 17 recognizes that LMOs may spread across national boundaries, posing potential risks to biodiversity and human health within the jurisdiction of other States. With a view to avoiding such risks, Article 17 contains a series of obligations, which primarily address the duty to notify and to consult in the event of unintentional transboundary movements of LMOs.*

465. *Under existing general international law, States have a general obligation to prevent or minimize transboundary harm. This implies that States have an obligation to take appropriate measures to prevent incidents that may cause such harm. The obligation of prevention has a continuing character. In other words, it applies from the planning stages of the proposed activity to the operational stages. In the framework of the Protocol, Parties are required to prevent or minimize the risks of unintentional transboundary movements of LMOs.*

466. *The complement of the obligation of prevention is the duty to cooperate in matters relating to the unintentional transboundary movement of LMOs. In this respect, Chapter 16 of Agenda*

21 (Environmentally Sound Management of Biotechnology) also calls for cooperation in providing immediate assistance in cases of emergencies that may arise in relation to the use of biotechnology products.

467. *The Protocol does not include a definition of "unintentional transboundary movement". Unintentional transboundary movement can be contrasted with transboundary movements addressed in other provisions of the Protocol, which are covered by the definition in Article 3(k). The key element here is whether the transboundary movement is a deliberate one or not. Thus, an intentional introduction of a LMO into the environment of a Party (i.e. a deliberate release) may in certain circumstances give rise to an unintentional transboundary movement of that LMO to another State. Alternatively, an accidental release in a Party (e.g. from a contained use facility) may give rise to an unintentional transboundary movement.*

468. *The four paragraphs of Article 17 set out various obligations concerning notification and consultation in cases of unintentional transboundary movements. Article 17(1) deals with the obligation of the Party where the incident occurred to notify any affected or potentially affected States as well as the Biosafety Clearing-House. Article 17(2) requires Parties to designate a point of contact for receiving notifications. Article 17(3) describes the minimum information that any notification should contain. Finally, Article 17(4) refers to the obligation to hold immedconsultation to minimize any significant adverse effects on biodiversity and human health.*

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

469. Article 17(1) addresses the obligation to notify other States in the event of an unintentional transboundary movement of a LMO. It now seems to be recognized that customary international law requires a State to notify other affected States where an incident within its jurisdiction may give rise to significant harm to the environment of other States. There are a number of treaties that develop, to different degree and detail, the procedural aspects of the obligation to notify.[95] In addition, Principle 18 of the 1992 Rio Declaration on Environment and Development calls for immediate notification of any natural disasters or other emergencies.

470. In the context of the conservation and sustainable use of biodiversity, the CBD provides that Parties shall immediately notify the potentially affected States of imminent or grave danger of damage to biodiversity (Article 14(1)(d) CBD).

Box 31. Article 14(1)(d) CBD

Each Contracting Party, as far as possible and as appropriate, shall:

…

(d) In the case of imminent or grave danger or damage, originating under its jurisdiction or control, to biological diversity within the area under jurisdiction of other States or in areas beyond the limits of national jurisdiction, notify immediately the potentially affected States of such danger or damage, as well as initiate action to prevent or minimize such danger or damage.

[95] For example, the 1982 UNCLOS (Articles 198 and 211(7)); the 1986 Convention on Early Notification of a Nuclear Accident (Article 2); the 1989 Basel Convention (Article 13); the 1992 UN-ECE Convention on the Transboundary Effects of Industrial Accidents (Article 10) (which expressly excludes from its scope the cases of accidental release of genetically modified organisms); and the 1997 Convention on the Law of the Non-Navigational Uses of International Watercourses (Article 28).

471. Although Article 17 of the Protocol focuses on the issue of unintentional transboundary movements of LMOs, it is worth noting that, in certain respects, it represents a development from Article 14 of the CBD. Article 17 specifies in more detail the procedural aspects of the obligation to notify, and it does so in *mandatory* language, avoiding qualifications such as "as far as possible and as appropriate" that appear in the CBD. Additionally, the Protocol lowers the threshold that triggers the obligation to notify by referring to "significant adverse effects" instead of "imminent or grave danger or damage" as in Article 14 of the CBD.

472. Article 17(1) describes a series of conditions that have to be fulfilled before the obligation of notification arises. Its main elements correspond to the following questions:

- What kind of measures are Parties bound to take?
- To whom shall the notification be addressed?
- What conditions and circumstances are required to trigger the obligation to notify?
- When must the notification be made?

What kind of measures are States bound to take?

473. Article 17(1) indicates that "Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House, and where appropriate, relevant international organizations". The obligation to "take appropriate measures" implies a duty of due diligence which requires each Party to take the necessary legal, administrative or other measures to implement its duty of notification (see also Article 2(1)). It is up to each Party individually to decide how they will give full effect to this obligation, as long as they do it immediately after any known incident. Parties have the flexibility to decide which authority will be in charge of this function. They might mandate the designated national focal point or competent national authority (Article 19), or the point of contact under Article 17(2) to perform this task. Presumably, the notification has to be made in written form. However, if Parties so agree, through bilateral or regional arrangements, they may also make use of other modalities and more expedient means of communication.

To whom shall the notification be addressed?

474. The notification shall be sent to:

- any affected or potentially affected States,
- the Biosafety Clearing-House; and
- where appropriate, relevant international organizations.

475. Notifications have to be sent to all those affected or potentially affected States. This obligation is owed by Parties to other *States*, not only to other Parties to the Protocol. While non-Parties to the Protocol are, of course, not specifically bound by the provisions of Article 17(1), they are nonetheless also under some duty under customary international law to notify other affected and potentially affected States where an event occurs in their jurisdiction which could cause significant harm to the environment of another State (see Box 32 below).

476. The role of the Biosafety Clearing-House (see commentary on Article 20) is important here. Notification to the Biosafety Clearing- House is likely to promote effective international cooperation to deal with unintentional transboundary movements of LMOs.

477. The Party of origin may also notify relevant international organizations in the event of an unintentional transboundary movement. The relevant international organizations are not identified in the Protocol but depending upon the circumstances of the release may include organizations with appropriate expertise, such as, for example, UNEP or FAO. The term would also appear to include relevant regional organizations.

What conditions and circumstances are required to trigger the obligation to notify?

478. This part of Article 17(1) gives rise to a variety of issues. The text provides that the relevant Party shall notify

> when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.

479. The first issue is that there has to be a "known" occurrence. Only occurrences that come to the knowledge of the Party trigger the obligation to notify. The expression "when it knows" needs to be read in light of the continuing character of the obligation of prevention and of evolving scientific and technological knowledge and developments in biotechnology. Accordingly, Parties are required to take all appropriate measures to monitor existing activities concerning LMOs (see also Articles 7 and 8(g) of the CBD and Article 16 of the Protocol) during the planning and the operational stages.

480. In practice, the meaning and interpretation of the expression "when it knows" may lead to disagreement. Knowledge may be inferred from the particular facts of the relevant unintentional transboundary movement and the particular circumstances of the Parties involved. This may give rise to the question of whether a developing country Party should be subject to the same standard as a Party with advanced capacity in modern biotechnology. The effective implementation of this Article is likely to require extensive human, financial and institutional resources. In this respect, capacity-building cooperation (see commentary on Article 22), in relation to, for example, risk management and monitoring, constitutes a crucial component for the effective implementation of Article 17.

481. Article 17(1) refers to an "occurrence" under the jurisdiction of the Party. The term "occurrence" is not defined, but it may consist, for example, of an accidental release of LMOs, a failure in risk management measures, or identification of an unexpected spread of LMOs within the Party of origin. An intentional introduction of a LMO into the environment of a Party would not appear, *of itself*, to constitute an occurrence for the purposes of Article 17, unless that release has already been identified as possibly giving rise to an unintentional transboundary movement of the LMO concerned. In such circumstances, customary international law would appear to require prior consultation with potentially affected States. Article 16(3) requires each Party to take appropriate measures to *prevent* unintentional transboundary movements of LMOs, including such measures as requiring a risk assessment to be carried out prior to the first release of a LMO. More generally, Article 8(g) of the CBD requires CBD Parties to establish or maintain means to regulate, manage or control risks associated with the use and release of LMOs.

482. Under Article 17(1), the "occurrence" in question has to take place in the jurisdiction of the Party of origin. This means in any part of its territory, including its territorial sea, and other maritime zones adjacent to its territorial sea (the continental shelf and the exclusive economic zone), as well as occurrences on board its registered aircraft and on ships flying its flag.

483. Article 17(1) further requires that the known occurrence "leads or may lead" to an unintentional transboundary movement. While in some cases this may be presumed by virtue of the proximity to border of other States, in other circumstances this may be difficult to establish. Potential gaps in knowledge about the potential spread of a given LMO may call for the application of the precautionary approach in accordance with Article 1 of the Protocol.

484. The precautionary approach is also relevant for the interpretation of the expression "likely" to have a significant adverse effect on biological diversity and human health. Uncertainties regarding the impacts of LMOs on biodiversity in different environments may complicate any conclusive answer to the question of whether a particular LMO is "likely" to have a significant adverse effect in the affected or potentially affected States. In light of these uncertainties, the precautionary approach will be relevant, in particular if centres of origin and of genetic diversity are involved, or other vulnerable components of biodiversity identified in accordance with the CBD (Article 7 and Annex I of the CBD).

485. Article 17(1) also refers to "significant adverse effects" on biodiversity, taking into account risks to human health, in affected or potentially affected States. This wording

introduces a threshold that needs to be reached to trigger the obligation of notification. The term "significant" is found in a variety of international instruments. It is also found in the Preamble and other provisions of the CBD. According to the International Law Commission, the word "significant" is generally taken to refer to adverse effects which are more than detectable but not necessarily serious or substantial.[96] Its interpretation needs to be tested against the particular background and circumstances of each occurrence. In cases where it is not possible to determine if the threshold has been exceeded, the application of the precautionary approach may be relevant, again perhaps especially where centres of origin and of genetic diversity may be affected.

486. Article 17 is silent on matters related to unintentional transboundary movements of LMOs which affect or potentially affect areas beyond the limits of national jurisdiction (for example, the high seas).

When must the notification be made?

487. The last part of Article 17(1) deals with the issue of notification "as soon as" the Party of origin knows of the relevant occurrence. This formulation appears to indicate that notification has to take place immediately or without delay after the situation is known. Generally, customary international law, treaties and other instruments, require States to notify immediately or without delay in cases of transboundary environmental emergencies. Again, appropriate information management systems and adequate human and financial resources will be important factors in enabling Parties to fulfil their obligation to notify in a timely manner.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

488. Parties to the Protocol are required to make available to the Biosafety Clearing-House the details of the point of contact to receive notifications. They are obliged to do so before the date of the entry into force of the Protocol for them.

489. At the national level, the contact point might be the same body as the national focal point or a competent national authority designated under Article 19. However, it could also be some other agency.

490. Clearly, non-Parties to the Protocol cannot be required under Article 17(2) to notify a contact point for these purposes. The Protocol does not specify to which entity in an affected or potentially affected State notification should be made in the event that that State is not a Party to the Protocol. For non-Parties to the Protocol which are nonetheless Parties to the CBD, the obligations in Articles 5 and 14(1) of the CBD with regard to cooperation in respect of matters of mutual interest for the conservation and sustainable use of biological diversity may be relevant.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

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[96] Commentaries on the Draft Articles on Prevention of Transboundary Harm, adopted by the International Law Commission at its fifty-third session (2001), Article 2, para. (4), UN Document A/56/10, November 2001.

491. Article 17(3) describes the minimum information that any notification to affected or potential affected States should contain.

492. Article 17(3) (a) – (c) refers generally to information related to the particular characteristics of the LMOs concerned and the circumstances concerning the occurrence giving rise to the unintentional transboundary movement. It also requires information about the possible adverse effects on biodiversity and human health, and possible related risk management measures.

493. Article 17(3) does not specify the format or language in which the notification should be provided to affected or potentially affected States. The general obligation of due diligence to prevent harm would suggest that the Party of origin and affected and potentially affected States should cooperate to ensure that information is provided in an effective and useable form.

494. An additional issue under Article 17(3) is to what extent Article 21 of the Protocol on confidential information affects the information requirements under Article 17. However, Article 21(5)(d) of the Protocol excludes from confidentiality the information relating to any methods and plans for emergency response. This is likely to cover certain information made available under Article 17.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

495. Parties of origin of unintentional transboundary movements of LMOs do not discharge their obligations by simply notifying other States. The obligations of prevention and cooperation require States to offer any assistance to minimize any significant adverse effects to biodiversity and human health and to request immediate consultations to agree upon any applicable emergency measures.

496. Article 17(4) provides for immediate mandatory consultations. It seems clear that the Party in which the occurrence has taken place is obliged to offer consultations simultaneously with the notification. If there is more than one potentially affected State, joint consultations among all the States concerned may be more practical.

497. The main objective of this paragraph is to "minimize" any significant adverse effects. The word "minimize" implies the lowest possible level of significant adverse effects to biodiversity and human health. In order to minimize any impacts, the primary aim of consultations is to enable States concerned to assess the particular situation with a view to determining any appropriate responses and the nature and magnitude of the necessary actions, including emergency measures.

498. It is widely recognized that any consultation process needs to be conducted in good faith and with a genuine intent to arrive at agreed solutions.

499. In order to be consistent with the continuing character of the obligation of prevention, it may be necessary to maintain ongoing consultations throughout the emergency operation, and even afterwards, to adequately monitor for any possible unidentified adverse effects.

500. Finally, as part of their duties on prevention, Parties may wish to develop bilateral or regional contingency plans concerning unintentional transboundary movements. For its part, the CBD encourages the development of joint contingency plans. (Article 14(1)(e) CBD; see also Article 5 CBD).

501. The types of responses and actions that may be taken in relation to an unintentional transboundary movement are not specified but are to be determined by the States concerned, presumably in the light of the nature and scale of the transboundary movement in question and the possible adverse effects on biodiversity and human health.

Box 32. Article 17 and non-Parties

As noted above, where a relevant occurrence takes place in a Party to the Protocol, it is obliged to notify all affected and potentially affected States, whether or not those States are themselves Parties to the Protocol. This is consistent with the Protocol's objective to ensure an adequate level of protection with regard to the conservation and sustainable use of biological diversity, taking also into account risks to human health.

The situation is different where the State in which the occurrence occurs is a non-Party to the Protocol. Under general international law, a treaty does not create obligations or rights for non-Parties, without their consent. However, this general principle is without prejudice to existing obligations under international customary law (Article 38, 1969 Vienna Convention on the Law of Treaties) – i.e. if a treaty or part of it reflects customary international law then all States are bound by it (or by the relevant part of it) regardless of whether they become parties to the treaty.

Existing international law regards as customary rules the general obligations of prevention and cooperation, as well as their related procedural obligations of notification and consultation, in cases of transboundary environmental emergencies. Accordingly, even non-Parties to the Protocol are bound to notify immediately and consult with affected or potentially affected States (Parties and non-Parties alike) in the event of an unintentional transboundary movement of LMOs from their jurisdiction that leads or may lead to significant adverse effects in other States. However, they are not bound by the specific procedures established for such notifications under Article 17 of the Protocol.

Even though non-Parties are not obliged to contribute information to the Biosafety Clearing-House, it seems that by designating a point of contact for notifications, non-Parties will be contributing to ensuring an effective response to any unintentional transboundary movement. They will also be taking steps to discharge their respective obligations under customary international law. In addition, the Protocol requires the Parties to encourage non-Parties to contribute appropriate information to the Biosafety Clearing-House on LMOs released in, or moved into or out of areas within their national jurisdictions (Article 24(2)).

Article 18. Handling, transport, packaging and identification

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

502. *Article 18 addresses the handling, transport, packaging an identification of LMOs. It has two main functions:*

- *First, to ensure that LMOs are handled and moved safely – to avoid adverse effects on biodiversity and human health; and*
- *Second, to provide information to those handling LMOs and to the Party of import.*

503. *Article 18 has three elements:*

- *It requires Parties to take measures for the safe handling, packaging and transport of LMOs subject to intentional transboundary movement (Article 18(1)). This applies to all LMOs within the scope of the Protocol, whether or not they are subject to the specific AIA procedure in the Protocol – i.e. it applies to LMO-FFPs, LMOs in transit; LMOs destined for contained use in the Party of import; as well as LMOs subject to the AIA procedure.*
- *It sets out what information must be provided in documentation accompanying transboundary movements of LMO (Article 18(2)). This information provides a means to identify and track transboundary movements of LMOs; gives information to the Party of import at the border; and offers a contact point for further*

information about the consignment in question. The specific requirements vary according to the intended use of the LMOs in question. Thus there are different documentation requirements for:

- *LMO-FFPs;*
- *LMOs destined for contained use in the Party of import; and*
- *LMOs intended for intentional introduction into the environment of the Party of import.*

For LMO-FFPs more detailed requirements will be drawn up after the Protocol enters into force.

- *It addresses the possible future development of standards by the COP/MOP in relation to the handling, packaging, transport and identification of LMOs (Article 18(3)).*

504. *The ICCP has set in motion a process for further consideration of Article 18, including meetings of technical experts on this issue. One key issue for further consideration in relation to the implementation of Article 18 is to what extent existing relevant national and/or international rules might be used and adapted to address more comprehensively the handling, packaging, transport and identification of LMOs, and to what extent new specialized rules for LMOs will need to be developed and applied.*

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

505. Article 18(1) imposes a general obligation on each Party to the Protocol to require safe handling, packaging and transport of LMOs subject to transboundary movement. This obligation extends to all LMOs subject to intentional transboundary movement that are within the scope of the Protocol in accordance with Article 4 – i.e. it includes LMOs in transit, LMOs destined for contained use in the Party of import, and LMO-FFPs. (But not the transboundary movement of LMOs which are pharmaceuticals for humans that are addressed by other international agreements or organizations (Article 5)).

506. This provision is linked to more general obligations upon Parties to the Protocol and to the CBD to regulate, manage and control risks associated with LMOs (Article 8(g) CBD; and Article 16 of the Protocol). A number of countries have in place rules and standards that are relevant to ensuring safe handling, packaging and transport of LMOs.[97]

507. "Relevant international rules and standards" could be those covering handling, packaging and transport of LMOs and might extend to general international rules and standards governing health, safety and the environment or international trade. At present, specific LMOs may be covered by relevant international rules and standards on the basis of their characteristics rather than because they are LMOs as such. These may include, for example, relevant rules and standards promulgated under the International Plant Protection Convention, by the World Health Organization, or in the UN Recommendations on the Transport of Dangerous Goods. Relevant rules and standards may also be developed in the future by the Parties in accordance with Article 18(3).

[97] See for example, the synthesis prepared by the CBD Secretariat for the first Meeting of Technical Experts on Handling, Transport, Packaging and Identification of living modified organisms, based on information submitted by governments and organizations, in UNEP/CBD/BS/TE-HTPI/1/2, available at http://www.biodiv.org

Box 33. The United Nations Recommendations on the Transport of Dangerous Goods (the "Orange Book")

One of the principal collections of relevant international rules and standards in relation to handling, packaging and transport of dangerous goods is the "Orange Book", formally known as the United Nations Recommendations on the Transport of Dangerous Goods. The Orange Book contains a list of dangerous goods most commonly carried (including some LMOs) and their identification and classification; consignment procedures (labelling, marking and transport documents); standards for packing, test procedures and certification; and standards for multi-modal tank-containers, test procedures and certification.

The Recommendations adopt a system that categorizes goods by the types of risk associated with their transportation. There are nine different classes, including division 6.2 ("Infectious Substances") and division 9 ("Miscellaneous Dangerous Substances and Articles").

Infectious substances are defined as substances known or reasonably expected to contain pathogens, which are defined as micro-organisms or recombinant micro-organisms that are known or reasonably expected to cause infectious diseases in humans or animals. "Miscellaneous dangerous substances and articles" cover substances and articles not covered under the other divisions. Genetically modified micro-organisms that are not dangerous for animals or humans, but which could modify animals, plants, microbiological substances and ecosystems in a way that does not occur naturally, are included in this division. It also comprises genetically modified organisms that are known or suspected to be dangerous to the environment, and which shall be carried in accordance with conditions specified by the competent authority of the country of origin.

A review of division 6.2 provisions and Model Regulations on "Infectious Substances" is underway.

The outcome of the meetings of the ICCP has been brought to the attention of the Sub-Committee of Experts on the Transport of Dangerous Goods. Cooperation was established between the Sub-Committee and the ICCP on matters concerning handling, packaging, transport and identification. Amendment of the provisions of the relevant Model Regulations may be possible to accommodate the transport regulatory needs of the Protocol on the basis of proposals from the Protocol process.

Sources: ST/SG/AC.10/11/Rev.3; UNEP/CBD/ICCP/1/6; UNEP/CBD/ICCP/2/12; UNEP/CBD/ICCP/3/7

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

508. Article 18(2) requires Parties to take measures to ensure that LMOs subject to intentional transboundary movement are accompanied by documentation identifying the LMOs and providing contact details for individuals and institutions responsible for the movement of the LMOs.

509. The Protocol recognizes the need for the specific identification of shipments of LMOs. The documentation requirements in Article

18(2) are a means of identifying and tracking the transboundary movement of LMOs. They will be a key element in ensuring that Parties of import know when they are receiving a transboundary movement of LMOs, whether for import or in transit. In addition, in the event of accidental releases during transport, documentation can provide information that might assist efforts to reduce risk of damage. All shipments of LMOs within the scope of the Protocol must be accompanied by details of a contact point from which further information about the shipment can be sought.

510. In the initial stages of negotiation of the Protocol, documentation requirements for all LMOs were dealt with as one issue. However, under the agreed text of Article 18(2), the documentation requirements vary according to the nature of the LMO concerned and its intended use in the Party of import. These distinctions were part of the compromise agreed upon by countries in order to bring LMO-FFPs within the scope of the Protocol.

511. Article 18(2) does not specify the language of documentation accompanying LMOs. If Article 18 is to ensure safe movement of LMOs and the provision of information to those handling and importing LMOs, this issue needs to be considered by the Parties.

LMO-FFPs

512. Article 18(2)(a) addresses the documentation requirements for LMO-FFPs. These were an extremely controversial issue in the final stages of the negotiations of the Protocol, and this provision was the final element to be agreed upon before the Protocol was adopted. Some countries in the negotiations were concerned that imposing clear identification requirements for transboundary movements of LMO-FFPs would indirectly impose costly segregation or identity preservation obligations, for example requiring genetically modified and non-genetically modified crops and grains to be segregated at all stages of the production process and during shipment, and measures to be taken to avoid any accidental trace contamination by LMOs of non-modified grain shipments.

Box 34. Unique identification of LMOs

Work is underway to develop an international system of unique identifiers that would apply to each individual genetic modification. The unique identifier system is similar in concept, for example, to the ISBN system for book publishing. The unique identifier would take the form of a code that would then provide a link to a database which would include full information about the specific modification to which the unique identifier referred. Further information on progress on development of a unique identifier system for the Protocol can be found through the Biosafety Clearing-House website. The system for unique identifiers, when it is developed and implemented, will assist the identification and monitoring of LMO-FFPs that have been approved by one or more national authorities, and will also assist the flow of information between Parties and their competent authorities, and with the public.

The OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology has developed and adopted "Guidance for the designation of a unique identifier for transgenic plants".[98] The purpose of this unique identifier is to be used as a "key" to access information in the OECD product database and interoperable systems (for example, the Biosafety Clearing-House) for modern biotechnology products approved for commercial application. The Guidance was adopted at a meeting of the OECD Working Group in January 2002. The agreed alphanumeric code for a unique identifier is composed of three elements using a maximum of nine digits to designate the applicant and the transformation event (rather than other options such as a new variety), and contains a final single digit for verification. The OECD's Business and Industry Advisory Committee (BIAC) played a role in the discussions of the unique identifier through their Expert Group on Biotechnology. According to the guidance, it is the developers of transgenic products who will generate the unique identifier.

The OECD Guidance was presented at ICCP 3, which took note of the adoption of the Guidance and recommended that "OECD product database establish interoperability with the pilot phase of the Biosafety Clearing-House, incorporating the use of the OECD unique identifiers for transgenic plants, as appropriate and as they become available, and to further elaborate on its applicability for the Protocol and to report on this to the first meeting of the [COP/MOP]".[99]

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98 ENV/MONO(2002)7 reproduced in UNEP/CBD/ICCP/3/INF/12.

99 ICCP Recommendation 3/3, paragraph 2, UNEP/CBD/ICCP/3/10, 27 May 2002, Annex.

513. Article 18(2)(a) avoids this issue, temporarily at least, by providing that transboundary movements of LMO-FFPs must be accompanied by documentation identifying that they "may contain" LMOs. A contact point for further information must also be specified. The documentation must also specify that the LMO-FFPs are not intended for intentional introduction into the environment. More detailed requirements for identification of LMO-FFPs are to be decided by the COP/MOP within two years of the Protocol entering into force. This will include consideration of specification of the identity of LMO-FFPs and a system of unique identification. In practice, because of the potential timing and frequency of meetings of the COP/MOP (see commentary on Article 29), a decision under Article 18(2)(a) will likely need to be taken at the first or second meeting of the COP/MOP after the Protocol enters into force.

LMOs that are destined for contained use

514. Article 18(2)(b) sets out the basic requirements for documentation accompanying LMOs destined for contained use (see commentary on Article 3(b)). This must include:

- Identification as LMOs;
- Requirements for safe handling, storage, transport and use;
- Contact point for further information;
- Name and address of consignee.

515. Some countries already address elements of Article 18(2)(b) in their national regulations on contained use of LMOs.[100]

LMOs destined for intentional introduction into the environment

516. Article 18(2)(c) sets out the detailed information to be provided in documentation accompanying transboundary movements of LMOs intended for intentional introduction into the environment of the Party of import, as well as other LMOs within the scope of the Protocol. This must include:

- Identification as LMOs;
- Identity and relevant traits/characteristics;
- Requirements for safe handling, storage, transport and use;
- Contact point for further information;
- Name and address of exporter and importer;
- Declaration that the transboundary movement is in accordance with the Protocol's requirements.

517. The phrase "any other LMOs within the scope of the Protocol" would appear to exclude LMO-FFPs and LMOs destined for contained use, which are addressed separately in Article 18(2)(a) and (b)). However, it would appear to cover LMOs in transit, which, though excluded from the AIA procedure (Article 6(1)) are within the Protocol's scope. This phrase would also include any LMOs that may in the future be excluded from the scope of application of AIA by the COP/MOP (see commentary on Article7(4)).

The ICCP and Article 18

518. A significant amount of work on the elaboration of Article 18 was initiated by the ICCP for consideration by the COP/MOP. The ICCP mandated two meetings of experts to consider the needs and modalities for developing measures for Parties to meet their future obligations under Article 18(2)(b) and (c). It also mandated an additional meeting of technical experts to consider Article 18(2)(a).

519. ***Article 18(2)(a) (LMO-FFPs)*** ICCP 3 considered the report and detailed recommendations of the technical expert group meeting on Article 18(2)(a), but was unable to make further significant progress towards consensus.

[100] See for example, the synthesis prepared by the CBD Secretariat for the first Meeting of Technical Experts on Handling, Transport, Packaging and Identification of living modified organisms, based on information submitted by governments and organizations, in UNEP/CBD/BS/TE-HTPI/1/2, available at http://www.biodiv.org

Recommendation 3/6 of the ICCP[101] submitted the report and recommendations of the meeting of technical experts on Article 18(2)(a) to the first meeting of the COP/MOP, and invited Parties and other States to closely consider the issues and facilitate their resolution with a view to ensure the timely implementation of the requirements in the first sentence of Article 18(2)(a).

520. ***Article 18(2)(b) (LMOs destined for contained use) and Article 18(2)(c) (LMOs destined for intentional introduction into the environment)*** ICCP recommendation 3/6 sets out the information to be provided to meet the requirements of Article 18(2)(b) and (c). It also urged Parties and governments to take measures to include these information requirements into existing documentation practices accompanying LMOs supplied by the originator of the shipment (e.g. commercial invoices); and encouraged Parties to consider whether the provision of additional information especially the intended use of the LMOs (e.g. commercial or research), would facilitate implementation of Article 18(2)(b) and (c).Model templates for the inclusion of such information were developed by the technical experts meeting. These are annexed to recommendation 3/6 for further consideration by the COP/MOP.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

521. Article 18(3) requires the COP/MOP to consider whether it is necessary to develop specific standards for handling, packaging, transport and identification of LMOs. Article 18(3) is not limited to LMOs subject to transboundary movement. The ICCP has initiated preparatory consideration of this issue.

522. As discussed above, there are a number of existing rules and standards that would cover aspects of handling, packaging, transport and identification of LMOs and several international organizations are in the process of developing more relevant rules and standards such as the Codex Alimentarius Commission, the OECD, the Interim Commission on Phytosanitary Measures (under the International Plant Protection Convention) and the United Nations Economic Commission for Europe.

523. It is not clear to what extent existing or draft rules and standards cover all aspects of handling, packaging, transport and identification of LMOs under the Protocol. The Parties will need to examine the existing and draft rules and standards to determine whether they are sufficient for the purposes of the Protocol. If the Parties consider it necessary to develop specific standards for the Protocol, existing and draft rules and standards might provide useful models.

[101] ICCP Recommendation 3/6, UNEP/CBD/ICCP/3/10.

Article 19. Competent national authorities and national focal points

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

524. *Article 19 requires Parties to designate national institutions to perform functions relating to the Protocol. Each Party must designate one national focal point for the Protocol and one or more competent national authorities. The national focal point is the primary contact point between a Party and the Secretariat of the Protocol. The competent national authority (or authorities) is responsible for exercising the administrative functions required by the Protocol (for example, under the AIA procedure), and must be authorized by a Party to act on its behalf in relation to these functions.*

National focal point

525. The national focal point is the primary contact point between a Party and the Secretariat to the Protocol (see commentary on Article 31). This will be the national institution that receives, for example:

- notifications of meetings relating to the Protocol and requests to designate delegates;
- invitations to submit views on matters under discussion in international negotiations relating to the Protocol.

526. In order to facilitate the work of the ICCP, Parties to the CBD were asked to designate focal points for the ICCP in Decision EM-I/3. The national institution which fulfils this function may continue to do so after the entry into force of the Protocol, but this is not necessarily the case. In any event, a separate notification of the national focal point for the Protocol should be made to the Secretariat not later than the entry into force of the Protocol for a Party.

527. Parties to the CBD have already designated national focal points for the CBD. The focal point for the Protocol may be, but does not have to be, the same institution. Similarly, the focal point may be the same institution as the competent national authority (see below).

528. The Secretariat will place a list of national focal points on the Biosafety Clearing-House.

Competent national authority(ies)

529. The functions of the competent national authority are quite different to those of the national focal point. The competent national authority (or authorities) is responsible for exercising the administrative functions required by the Protocol, and must be authorized by a Party to act on its behalf in relation to these functions. In effect, the functions of the competent national authority are spelled out in the AIA and other provisions of the Protocol. The competent national authority will:

- receive notification of proposed transboundary movement of a LMO that falls within the scope of the AIA procedure (Article 8);
- acknowledge receipt of the notification (Article 9);
- request further information from the notifier, if necessary (Articles 9 and 10);
- communicate the decision of the Party of import to the notifier and the Biosafety Clearing-House (with reasons where required) (Article 10(3));
- respond to requests by the Party of export or notifier to review decisions (Article 12); and
- consult with the notifier, where necessary, on treatment of confidential information (Article 21).

530. The functions of the competent national authority suggest that the designated institution should be the institution which, at the domestic level, has the authority to make decisions about imports of LMOs. The designation of the competent authority at the national level may differ according to the nature of the LMO in question or its intended use. Thus, for example, in some countries the Fisheries Ministry may be responsible for imports of transgenic fish; the Ministry of Agriculture for imports of genetically modified crops or seeds; or the Ministry of Environment or some other Ministry or agency may be responsible for all LMO imports. The Protocol recognizes this, and allows Parties to designate more than one competent national authority if they wish to do so. If a Party chooses to designate more than one competent national authority, it must inform the Secretariat which authority is responsible for dealing with the different types of LMOs. The Secretariat will make this information available to all Parties, including through the Biosafety Clearing-House. Thus a notifier should be able to find out which national authority it should approach in the Party of import to notify a proposed transboundary movement of a LMO for intentional introduction into the environment.

531. While the competent national authority (or authorities) is responsible for carrying out administrative functions under the Protocol vis-à-vis other Parties, the decision-making process under a Party's national biosafety framework for reaching a decision on the proposed import of a LMO is likely to involve a wide range of national authorities. The national biosafety framework should set out the domestic level procedure, including any necessary consultations, by which any decision on a proposed import will be taken.

532. The competent national authority (or authorities) must be notified to the Secretariat at the time the Protocol enters into force for a Party (see Article 37), so that it can begin to exercise functions straight away.

Article 20. Information-sharing and the Biosafety Clearing-House

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

533. *Article 20 establishes the Biosafety Clearing-House (BCH). The BCH is an information exchange mechanism to assist Parties to implement the Protocol. It is established as part of the Clearing-House Mechanism (CHM) created under the CBD (see Box 35). The BCH is an information repository and a central vehicle for implementing the Protocol. Many provisions of the Protocol require Parties to submit information to the BCH, and it has a special role in relation to exchange of information on LMO-FFPs (Article 11).*

534. *The BCH will use electronic and other systems for the exchange of information relevant to the Protocol. It will also provide access to other international biosafety information exchange mechanisms. The BCH will be developed in stages, commencing with a "pilot phase" that aims to collect basic information and explore the mechanics of establishing and operating the BCH. This pilot phase is*

underway. After the Protocol has entered into force, the Parties will draw on the experiences of the "pilot phase" to decide at their first meeting how the BCH will function.

535. *Given the central role of the BCH in the operation of the Protocol, the availability, accuracy and accessibility of relevant information through the BCH will be crucial. In addition to practical considerations, one question which may arise is the extent to which information made available through the BCH will be moderated and/or verified. If such a function should be performed, then a further question arises as to who should fulfil this function – for example, the Secretariat, or some other body.*

536. *Article 20 addresses a number of issues:*

- *It establishes the BCH and describes the main objectives of the BCH (Article 20(1));*
- *It sets out the principal functions of the BCH (Article 20(2));*
- *It specifies what information is to be made available to the BCH (Article 20(3));*
- *It provides for the COP/MOP to determine how the BCH will operate and to keep its operation under review (Article 20(4)).*

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

537. Article 20(1) establishes the BCH as part of the Clearing-House Mechanism that was created by Article 18(3) of the CBD.

Box 35. The Clearing-House Mechanism of the CBD (Article 18(3) CBD)

Article 18(3) CBD

The Conference of the Parties, at its first meeting, shall determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.

Article 18(3) of the CBD created a mechanism to translate the goal of partnerships and cooperation into action – the Clearing-House Mechanism. The CHM was created to "promote and facilitate technical and scientific cooperation between the Parties to the CBD" and is a key to achieving the CBD's three principal objectives. It also facilitates access to and the exchange of information on biodiversity around the world. It is a network of Parties and partners working together to facilitate implementation of the CBD. The Parties directed the CBD Secretariat to take a leadership role in facilitating the implementation of the CHM, and also created an Informal Advisory Committee (IAC) to provide the Secretariat with feedback and advice through the CHM development process. The activities of the CHM are directed by the CBD COP as well as by the advice of the Subsidiary Body on Scientific, Technical and Technological Advice. The CBD COP designated 1996-1998 as the Pilot Phase of CHM operations, during which activities and services would evolve in response to the needs of countries and partners working to implement the CBD. The Parties also made a commitment to commissioning an Independent Review of the CHM after completion of the Pilot Phase. This report was published in September 1999.

The CHM depends on a decentralized process to gather and organize the information that its users need. Driving this process are networks of focal points, international centres and institutions with expertise that co-ordinate initiatives among themselves on topics of common interest. Each focal point also contributes to the Clearing- House information system, which is then made accessible to all users. In this way, focal points encourage networking among government agencies, expert groups, non-governmental organizations and private enterprise at all levels.

538. Article 20(1) sets out two main objectives of the BCH:
   - First, the BCH is designed to facilitate the exchange of information and experience concerning LMOs. The types of information to be exchanged are broadly described as scientific, technical, environmental and legal. Specific types of information are detailed in Article 20(3) and elsewhere in the Protocol (see paragraphs 551 and 552 below).
   - Second, the BCH is to assist Parties to implement the Protocol. Consistent with the Protocol's Preamble and other provisions, this second function of the BCH acknowledges the special needs of the following three groups:
     - Developing country Parties, in particular the least developed and small island developing States among them;
     - Countries with economies in transition;
     - Countries that are centres of origin and centres of genetic diversity.

539. The effective operation of the BCH will depend on the active participation of developed country Parties, developing country Parties and Parties with economies in transition. The availability of technological resources in developing country Parties and Parties with economies in transition is an important consideration in the design of the BCH and will motivate efforts to develop information exchange mechanisms within the BCH that are not internet- or electronic-based. Operation of the BCH will also depend on resources and training being provided to developing country Parties and Parties with economies in transition. Prior to the entry into force of the Protocol, the Secretariat organized regional workshops on the BCH.

540. The special role of the BCH in relation to LMO-FFPs is addressed in Article 11.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

541. Article 20(2) sets out three principal functions of the BCH:
   - First, the BCH will be the vehicle through which information is made available for the purposes of Article 20(1).
   - Second, the BCH will provide access to information relevant to the implementation of the Protocol that is made available by the Parties.
   - Third, the BCH will provide access to other international biosafety information exchange mechanisms. A number of international biosafety information exchange mechanisms already exist. However, none of these alone provide the comprehensive range of information required by the BCH. The BCH will need to be tailored to the specific requirements of the Protocol. The organizations managing other international biosafety information exchange mechanisms will be important partners in the pilot phase (see Article 20(4)) and subsequent operation of the BCH.

Box 36. Existing international biosafety information exchange mechanisms: examples

The BCH may draw on a wide variety of existing mechanisms. The following examples provide access to a range of information, including existing national regulations on biosafety.

- Organization for Economic Cooperation and Development (OECD) – Biotrack http://www.oecd.org/biotrack
- United Nations Industrial Development Organization (UNIDO) – Biosafety Information Network and Advisory Service (BINAS) http://binas.unido.org/binas/
- International Centre for Genetic Engineering and Biotechnology (ICGEB) – Biosafety Bibliographic Database http://www.icgeb.org/~bsafesrv/bsfdata1.htm
- United Nations Environment Programme (UNEP), Microbial Strain Data Network (MSDN) – Information Resource for the Release of Organisms (IRRO) http://panizzi.shef.ac.uk/msdn/

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

542. Article 20(3) requires Parties to make available to the BCH specific categories of information. Article 20(3)(a) refers to information required by Parties for the AIA procedure, some of which is expressly required to be submitted to the BCH, which includes:

- Notification of intended export from the Party of export or exporter (Article 8);
- Information required under Annex I (Article 8);
- Acknowledgement of the notification of intended export from the Party of import (Article 9);
- Decision by the Party of import on whether to approve, prohibit or restrict the import (Article 10(3)), and any relevant reasons for that decision (Article 10(4));
- Where relevant, information on the domestic regulatory framework governing the import of LMOs from the Party of import (Article 9 and 10);
- Additional information from the Party of export (Article 10(3)(c));
- Information on risk assessment (Articles 10(1) and 15 and Annex III);
- Information on review of decisions (Article 12); and
- Information on simplified procedures (Article 13).

543. In addition to the categories of information specifically mentioned in paragraphs (a) to (e) of Article 20(3), Parties are also required to submit to the BCH:

- Decisions by a Party regarding transit of specific LMOs through its territory (Article 6(1));
- Written notices of decisions approving, prohibiting or restricting the first intentional transboundary movement of LMOs for intentional introduction into the environment (Article 10(3));
- Final decisions regarding domestic use of LMO-FFPs (Article 11(1));
- Copies of national laws, regulations and guidelines applicable to the import of LMO-FFPs (Article 11(5));
- Declarations by developing country Parties or Parties with economies in transition concerning the basis of their decisions on the import of LMO-FFPs (Article 11(6));
- Notice of reviews of decisions regarding intentional transboundary movement (Article 12(1));
- Notice of simplified procedures regarding intentional transboundary movement and LMOs exempted from the AIA procedure (Article 13(1));
- Notice of bilateral, regional and multilateral agreements and arrangements with other Parties regarding intentional transboundary movements of LMOs (Article 14(2));

- Notice of application of domestic regulations affecting specific imports (Article 14(4));
- Notice of unintentional transboundary movement of LMOs (Article 17(1));
- Points of contact for notification of unintentional transboundary movement (Article 17(2)); and
- Information on illegal transboundary movements (Article 25(3)).

544. Information on national focal points and competent national authorities designated in accordance with Article 19 will also be made available through the BCH.

545. Under Article 20(3), Parties are to make information available to the BCH "without prejudice to the protection of confidential information". Protection of confidential information is addressed in Article 21. During the pilot phase of the BCH (see Article 20(4)), it was decided that the BCH should not contain information which is to be treated as confidential (for the procedure for determining whether specific information is to be treated as confidential, see commentary on Article 21).

546. While this approach may be helpful in maintaining open public access to the BCH, it may also create difficulties. In practice, certain detailed information regarding a LMO may not be available on the BCH due to confidentiality requirements. For example, under the AIA provisions of the Protocol, a Party of import should notify its decision on the first import of a LMO to the BCH (as well as to the notifier, see commentary on Article 10(3)). However, if certain detailed information about that LMO has to be kept confidential, then on the basis of information available through the BCH it may not be possible for a subsequent exporter to determine with certainty whether a LMO which has been authorized by a Party is the same LMO that it intends to export to that Party.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

547. Article 20(4) requires the COP/MOP to take a decision at its first meeting on the way the BCH will operate, and provides for ongoing review of the BCH. Given the role to be played by the BCH, it is important that a fully functioning BCH has been developed by the time the Protocol enters into force.[102] Work on the BCH began prior to ICCP1 (in accordance with ExCOP decision EM–I/3, paragraph 13) and was continued under a pilot phase. The pilot phase was launched in April 2001. A series of regional meetings were launched by the Secretariat to provide the special groups of countries identified in Article 20(1)(b) with an opportunity to discuss their needs and expectations with respect to the "pilot phase". Issues addressed during the pilot phase included:

- Relationship with the CBD's CHM;
- Identification of the types of information to be processed by the BCH;
- Special needs of developing country Parties and Parties with economies in transition, particularly access to electronic information systems, alternative non-electronic information systems, and resources and training to use the BCH;
- Information management issues: information requirements, common formats, data entry, common language, content validation and quality assurance, data-reporting;
- System architecture: whether the BCH will be a centralized mechanism administered by a single body or a decentralized

Box 37. Pilot phase of the Biosafety Clearing-House

The pilot phase of the Biosafety Clearing-House can be accessed at: http://bch.biodiv.org/Pilot/

The BCH website address may change with the entry into force of the Protocol, but will be accessible through the main CBD website at http://www.biodiv.org

[102] ICCP Recommendation 3/3, paragraph 6, UNEP/CBD/ICCP/3/10, Annex.

information network that coordinates national information systems; and

- Confidentiality considerations: methods for protecting confidential information.

548. Options for the structure and operation of the BCH, together with reports on the BCH "pilot phase", will be considered and decided upon by the first meeting of the COP/MOP. In addition, the BCH structure and operations must be reviewed by the COP/MOP on an ongoing basis after their first meeting.

549. As noted above, during the pilot phase of the BCH it was recognized that there were a series of challenges for its effective functioning. These include:

- Access to the BCH, including:
  - Who can access the BCH and how;
  - Ensuring regular and reliable access to the BCH, including issues of technical and financial capacity; and
  - Ensuring utility of the BCH, including for example the formats and languages in which information will need to be submitted by Parties and made available on the BCH.
- The authenticity and validation of information on the BCH.
- Coordination of the BCH with other databases.

Access

550. In relation to the format and language for information, in the pilot phase, the Secretariat developed common formats for the submission of information to the BCH on, for example, transboundary movements of LMOs, national laws and regulations, bilateral, regional and multilateral agreements, and risk assessment summaries. The pilot phase of the BCH was in English, but the BCH is being designed to accommodate all UN languages at a later stage. In terms of accessibility, work is also being undertaken to identify alternatives to internet-based information exchange – for examples through printed materials or CD-ROMs.

Validation of data

551. This is an issue which the COP/MOP will have to consider. The ICCP recommended that countries establish a national focal point for the BCH which would be responsible for validating data registered on the BCH for that country. Entry of data onto the BCH would be limited to certain registered entities.

Coordination and accessibility

552. Guidelines were being developed in the pilot phase for the interoperability of the BCH with other databases, and links to other information sources, such as the OECD Biotrack and UNIDO BINAS systems. Coordination and accessibility of information may be aided by unique identification systems for LMOs to facilitate searches for information on specific LMOs (see Box 34).

Article 21. Confidential information

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

553. *Article 21 addresses the treatment of certain information provided under procedures established under the Protocol. In practice, most of this information is likely to be submitted in the context of the Protocol's AIA procedure (or consistent domestic procedures). However, Article 21 is not explicitly limited to such information. In principle, it could also be relevant, for example, to information provided on unintentional transboundary movements of LMOs under Article 17, or on LMO-FFPs under Article 11. Nonetheless the language used in certain provisions of Article 21, such as "Party of import" and "notifier", suggest that the Article's primary relevance will be to information provided on a bilateral basis in the context of the AIA procedure.*

554. *A number of countries pressed for a provision on confidential information during the negotiations, on the basis that information provided to the Party of import during AIA, or other procedures, would be likely to include proprietary commercial information that required protection. Others argued that no such provision was necessary, since such requirements were already addressed in other international and national legal instruments (including intellectual property law), and that constraints on disclosure of information may hamper the ability of the Party of import to address emergency situations involving LMOs.*

555. *While Article 21 allows certain information to be treated as confidential, it does not*

require information concerning LMOs to be treated as confidential as a general rule. Rather, it is up to the provider of the information (the notifier) to specify the information which it considers should be treated as confidential and then to consult with the Party of import.

556. *The provisions of Article 21:*

- *specify the basic procedure for ensuring protection of confidential information provided under the procedures of the Protocol;*
- *address the situations where the Party of import and the notifier disagree as to whether particular information should be treated as confidential or not, and where the notifier decides to withdraw a notification;*
- *set out a general obligation to protect confidential information received under the Protocol; and*
- *specify categories of information which shall not be considered confidential.*

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

557. Article 21(1) requires the Party of import to allow information provided by the notifier to be identified and treated as "confidential" upon request by the notifier. This may include, for example, certain information provided in accordance with Annex I, or subsequently upon request by the Party of import during the AIA procedure. Where the Party of import so requests, the notifier must provide reasons or justification as to why the information should be treated as confidential. The implication of Article 21(1) is that a Party of import would not be able to make available to others, for example to the public, the information provided. On the contrary, it would be under an obligation (see commentary on Article 21(3)) to take steps to ensure that the confidentiality of the information in question is protected.

558. Article 21(1) does not specify what may be required in terms of justification for confidentiality. This is a matter for the Party of import to determine (although consultation with the notifier is required – see commentary on Article 21(2)).

559. The language used in Article 21(1) is general, allowing the notifier, in the first instance, to identify as confidential any of the information which it provides to the Party of import. In contrast, Article 21(5), in common with a number of other global and regional agreements,[103] refers to "confidentiality of commercial and industrial information". It is not clear in what circumstances a notifier might claim confidential treatment for information other than commercial and industrial information.

560. Existing examples of national biosafety frameworks often make reference to confidential information, setting out the circumstances in which confidential treatment may be claimed, a requirement for justification of a claim for confidential treatment, and categories of information which may not be treated as confidential (see commentary on Article 21(6)). Some examples are given in Box 38.

561. Other international agreements such as the Stockholm Convention on Persistent Organic Pollutants also address the issue of confidentiality. Article 9(5) of that Convention, on "the exchange of information" establishes that *information on health and safety of humans and the environment shall not be regarded as confidential*. However, this Article provides that Parties that exchange "other" information pursuant to the CBD must protect any confidential information "*as mutually agreed*". The 1998 Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Article 14(2)) also establishes that Parties that exchange information pursuant to that Convention must protect any confidential information "*as mutually agreed"*.

[103] For example Aarhus Convention, Article 4(4)(d). See also paragraph 561 below.

Box 38. National provisions on confidential information: examples

- In the European Union, according to Article 25 of Directive 2001/18/EC on the deliberate release into the environment of GMOs, "the Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the data received". The Directive further requires the notifier to give justification for the information that has been identified as requiring confidential treatment as its disclosure "might harm his competitive position".
- The Swiss Ordinance on the Release of Organisms into the Environment No. 814.911 states that authorities responsible for the enforcement of the ordinance will treat as confidential information for which there are grounds for confidentiality, and specifies as such the protection of business and production secrets.
- In Australia, under the 2000 Gene Technology Act, the declaration of confidentiality of commercial information is subject to proof that the information specified in the application is: a trade secret; or any other information that has a commercial or other value that could be destroyed or diminished if the information were disclosed; or other information that concerns the lawful financial and commercial affairs of a person, organization or undertaking, and that if it were disclosed it could reasonably affect that person, organization or undertaking. In spite of that the Regulator may refuse declaring the confidentiality of such information if it is satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person.
- In South Africa, under the Genetically Modified Organisms Act 1997, the Executive Council for Genetically Modified Organisms decides, after consultation with the applicant, which information will be kept confidential and shall inform the applicant of its decision.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

562. Where the notifier identifies information that should be treated as confidential, but the Party of import considers that the information in question does not qualify for such treatment, it must consult with the notifier. Thus the final decision on confidentiality rests with the Party of import. If the request by the notifier is considered unjustified, then the notifier must be informed before the information is disclosed. The decision refusing confidential treatment does not need to give reasons unless the notifier so requests.

563. Although the Party of import takes the final decision, it must allow for consultation with the notifier and also for internal review of its decisions refusing confidential treatment. Interestingly, this appears to be the only reference in the Protocol explicitly requiring the Party of import to provide for internal review of a decision (with the exception of Article 12).

564. The Party of import is not free immediately to disclose information which it has decided is not subject to confidentiality. The Party of import must notify its decision to the notifier before the information can be disclosed so that the notifier has an opportunity to consult and to have the decision reviewed ahead of any disclosure. If the consultation and review do not resolve the issue, the consequences of continued disagreement between the notifier and the Party of import as to whether particular information should be treated as confidential are addressed in Article 21(5).

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

565. Article 21(3) sets out a general obligation on Parties to protect confidential information received under the Protocol. Parties must protect confidential information in their national

legislation. Adequate procedures must be set up to this effect to prevent disclosure or the commercial use of confidential information.

566. This paragraph also requires "non-discrimination" between imported and domestically produced LMOs in relation to confidentiality, i.e. the same level of protection must be accorded to each.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

567. In the case of LMOs, confidential information is likely to be related to modern biotechnology techniques used in the production of the LMO and other relevant information of a commercially sensitive nature. While such information will need to be made available to the Party of import through the notification procedure (see commentary on Article 8, and Annex I), the Protocol forbids the commercial use of that information by the Party of import, unless written consent from the notifier has been obtained. It should be noted here that the notifier may not itself be the entity which has the legal right to permit commercial use of the information provided. As noted under Article 9, according to the Protocol's AIA procedure the notifier may be either the Party of export or the exporter. It may be that none of these is the entity which holds proprietary rights over the commercial use of information in question.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

568. Article 21(5) addresses the situation where a notifier decides to withdraw a notification made to a Party of import. This may occur because the proposed transboundary movement is not going ahead for a variety of reasons, including the possibility that the notifier and the Party of import have been unable to agree on which information should be treated as confidential. In such circumstances, the Party of import is not free to use or disclose the disputed information. It must respect the confidentiality of the information, even if it is of the view that confidential treatment has not been justified by the notifier. It is noteworthy that paragraph 5 refers specifically to "commercial and industrial information, including research and development information", as well as more generally to "information".

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

569. Article 21(6) lists four categories of information which are not to be treated as confidential. Debate on this provision during the negotiation focused on the categories of information that should be included here, and also on whether such information should never be treated as confidential or whether a weaker formulation should be used. The provision adopted suggests that the four categories of information cannot be identified by the notifier as confidential, and shall not in any circumstances be treated as confidential. The categories identified mirror those set out in corresponding provisions of some existing national biosafety frameworks. National legislation may also identify additional categories of information which the Party of import will not treat as confidential. For example, EU Directive 2001/18 on the deliberate release of GMOs into the environment provides that the purpose of the release, its location and intended uses may "in no

case" be kept confidential.[104] Colombia's Resolution 3492 regulating and establishing a procedure for the introduction, production, release and commercialization of GMOs, South Africa's Genetically Modified Organisms Act and Swiss Ordinance 814.911 on the Release of Organisms into the Environment have similar provisions listing information that will not be considered as confidential in nature. These norms then exclude as confidential the description of the GMOs; the contact details of the applicant (South African GMO Act 1997) or of those responsible for the release for experimental purposes or the placing on the market (Swiss Ordinance 814.911) or responsible for the project (Colombia Resolution 3494); the methods and plans for their monitoring and emergency measures in case of accident; and the evaluation of foreseeable impacts (South African GMO Act 1997). Australia's Gene Technology Act states that the Regulator must refuse to declare commercial information as confidential if such information relates to field trial locations, unless the Regulator is satisfied that disclosure would involve significant risks to health and safety.

[104] Article 25(4), Directive 2001/18 EC, OJ L 106, 17 April 2001.

Article 22. Capacity-building

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity- building in biosafety.

570. *It is widely recognized that, if the Protocol is to be effective, support is needed to build the capacity of developing countries and countries with economies in transition in the field of biosafety. Many such countries currently lack adequate human, technical and financial resources to implement the Protocol fully: for example to undertake risk assessment and risk management of LMOs, or to monitor LMOs once released into the environment.*

571. *Article 22 seeks to address these needs. It requires Parties to cooperate in building capacity for implementation of the Protocol in developing country Parties and Parties with economies in transition. It particularly recognizes the needs of least developed countries and small island developing States in this regard.*

572. *Article 22 of the Protocol is closely linked to Articles 16 and 18 of the CBD. Article 16 of the CBD requires Parties to the CBD to provide and facilitate access to and transfer of technologies that are "relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment". Access to and transfer of technology, if directed towards developing countries, are to be provided "under fair and most favourable terms." Article 18 of the CBD requires Parties to undertake technical and scientific cooperation, especially with respect to the development and strengthening of national capabilities in human resources development and institution building.*

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

573. Article 22(1) sets out the general obligation of cooperation in respect of capacity-building. The inclusion of a reference to "biotechnology" in Article 22(1) was initially

opposed by some countries in the negotiations. Some developing countries viewed it as an attempt by developed countries with strong biotechnology industries to promote trade in biotechnology products and services (including LMOs) rather than to promote biosafety. On the other hand, some developed countries proposed limiting the scope of the Article to issues relating to transboundary movements since making an unqualified reference to biotechnology and biosafety would make the scope of the Article extend beyond the Protocol, and may have obliged them to undertake more wide-ranging activities to build biotechnology capacity.

574. The text of Article 22(1) reflects the compromise solution agreed – i.e. capacity-building efforts should cover biotechnology "to the extent required for biosafety". Furthermore, the scope of Article 22(1) is further clarified by the statement that cooperation in capacity-building is "for the purpose of the effective implementation of this Protocol". The Executive Secretary to the CBD noted, in relation to the capacity-building provisions of the Protocol, that:

> The scope of capacity-building usually includes the assessment of needs, identification of options at the national (and possibly regional) level, the development and strengthening of relevant institutions, the development of skills and expertise in human resources, including through education and training, establishment of necessary scientific and information management facilities, and assessments for technology transfer. These and other areas of capacity-building are generally supported through the provision of external technical assistance and financial resources on a bilateral, multilateral or private basis.[105]

575. Under Article 22(1), Parties are expected to cooperate with each other to develop and strengthen the human resources and institutional capacities of developing countries and Parties with economies in transition in the field of biosafety. Such cooperation may be achieved in the framework of existing "global, regional, subregional and national institutions and organizations". Parties also have the option to promote the involvement of private sector actors in capacity-building activities under Article 22(1).

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity- building in biosafety.

576. The first sentence of Article 22(2) of the Protocol makes reference to the provisions of the CBD relating to the provision of financial resources and access to and transfer of technology (see commentary on Article 28). Under the provisions of Article 20(2) of the CBD, developed country Parties are required to provide "new and additional financial resources" to developing country Parties to enable them to meet the costs of implementing their obligations under the CBD. Under Article 20(4) of the CBD, the implementation by developing country Parties of their commitments will depend on the degree to which developed country Parties provide financial resources and technology transfer to the former. The precise implications of CBD provisions on technology transfer are not clear. Article 16(2) of the CBD requires that access to and transfer of technology to developing country Parties must be under "fair and most favourable terms". Such terms may include preferential or concessional terms – i.e. at or below market terms – if mutually agreed upon. Technology transfer may also be in accordance with, as necessary, the CBD's

[105] UNEP/CBD/ICCP/1/4 *Capacity Building (Article 22, Article 28): Indicative framework for capacity-building under the Cartagena Protocol on Biosafety – Note by the Executive Secretary*, paragraph 2.

provisions on financial resources and mechanism. Furthermore, such technology transfer must recognize intellectual property rights that may be attached to the technology.[106] Discussion on the implementation of Article 16 are ongoing in the CBD COP.

577. Article 22(2) of the Protocol also describes the general areas in which capacity-building cooperation is to be undertaken. These are:

- scientific and technical training in the proper and safe management of biotechnology;
- scientific and technical training in the use of risk assessment and risk management for biosafety; and
- the enhancement of technological and institutional capacities in biosafety.

578. Thus there are three "kinds" of capacity that need to be addressed for the effective implementation of the Protocol:

- legal, institutional, and administrative regulatory capacity with respect to biosafety;
- scientific and technical capacity with respect to risk assessment; and
- scientific and technical capacity with respect to risk management.

579. In providing for or developing these capacities, the Protocol recognizes that no single model will fit the situation of all countries, but that capacity-building should be tailored to fit the specific national context of the country whose capacity is being assisted and developed. Hence, cooperation in capacity-building is subject to and must take into account the different situations, capabilities and requirements of each Party.

580. Furthermore, cooperative capacity-building efforts by the Parties to the Protocol must be targeted at ensuring the effective implementation of Parties' obligations under the Protocol. The specific obligations in the Protocol most relevant for purposes of capacity-building are listed in the "tool kit" adopted by ICCP3.[107] This has been reproduced for ease of reference in the Supplementary Materials at the end of this Guide. It provides a useful checklist for reference for implementation of the Protocol.

Capacity-Building Action Plan

581. In October 2001, at its second meeting, the Intergovernmental Committee on the Cartagena Protocol endorsed the *Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety.* The objective of this Action Plan is to facilitate and support the development and strengthening of capacities for the ratification and effective implementation of the Protocol at the national, sub regional, regional and global levels in a timely manner. It recognizes that financial, technical and technological support to developing countries is essential, in particular the least developed and small island developing States among them, as well as countries with economies in transition, taking into account also countries that are centres of origin and centres of genetic diversity. To achieve its objective, the Action Plan aims at identifying country needs, priorities, and mechanisms of implementation, as well as sources of funding.[108] The ICCP recommended that the COP/MOP request the GEF and other donors (see commentary on Article 28) to take the Action Plan into account when providing assistance to developing country Parties and Parties with economies in transition towards ratification and effective implementation of the Protocol.

582. The ICCP identified the following key elements requiring action:

(a) Institutional capacity-building:

- Legislative and regulatory framework;
- Administrative framework;

[106] See, for example, discussion in Glowka *et al*. (1994) pp. 86-91. Chapter 34 (Transfer of Environmentally Sound Technology, Cooperation And Capacity-building) and Chapter 37 (National Mechanisms and International Cooperation for Capacity-building) of Agenda 21 also provide guidance on capacity-building efforts in environmental matters at the national level.

[107] ICCP Recommendation 3/5, UNEP/CBD/ICCP/3/10, Annex III; see Supplementary Materials.

[108] ICCP Recommendation 2/9, UNEP/CBD/ICCP/2/15, Annex.

- Technical, scientific and telecommunications infrastructures;
- Funding and resource management;
- Mechanisms for follow-up, monitoring and assessment;

(b) Human-resource development and training;

(c) Risk assessment and other scientific and technical expertise;

(d) Risk management;

(e) Awareness, participation and education at all levels, including for decision-makers, stakeholders and the general public;

(f) Information exchange and data management, including full participation in the Biosafety Clearing-House;

(g) Scientific, technical and institutional collaboration at sub-regional, regional and international levels;

(h) Technology transfer;

(i) Identification.

583. The analysis in Box 39, developed by the Secretariat of the CBD, identifies the required capacities for implementation of the Protocol obligations. This indicative list was incorporated into the Capacity-building Action Plan endorsed by the ICCP in its Recommendation 2/9.

Roster of experts

584. Discussions relevant to capacity-building have also taken place in relation to Article 10(7) of the Protocol, on procedures and mechanisms to facilitate decision-making by Parties of import. These mechanisms, and capacity-building under Article 22, are likely to draw upon the roster of experts established in Decision EM-I/3. Paragraph 14 of Decision EM-I/3 provides:

> *Decides* to establish a regionally balanced roster of experts nominated by Governments, in fields relevant to risk assessment and risk management related to the Protocol, to provide advice and other support, as appropriate and upon request, to developing country Parties and Parties with economies in transition, to conduct risk assessment, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movements of living modified organisms;

585. The ICCP also recommended that the COP/MOP adopt a Coordination Mechanism for the implementation of the Action Plan, to be administered by the Secretariat.[109] This would include a regionally balanced liaison group on capacity-building for biosafety to provide advice to the Secretariat and the COP/MOP, and a biosafety capacity-building projects database, as well as other mechanisms.

586. The Biosafety Clearing-House will provide a source of information on capacity-building initiatives in biosafety. This information is currently available in the Biosafety Clearing-House pilot phase at http://bch.biodiv.org/Pilot. In practice, relevant capacity-building initiatives are likely to be undertaken by a wide range of actors including governments, intergovernmental organizations, the private sector and non-governmental organizations.

[109] ICCP Recommendation 3/5, UNEP/CBD/ICCP/3/10.

Box 39. Indicative list of areas of advice and support for the roster of experts for implementation of the Cartagena Protocol

INSTITUTION BUILDING	RISK ASSESSMENT	RISK MANAGEMENT
Needs assessment and biosafety framework planning (a) Inventory of existing and anticipated biotechnology programmes and practices. (b) Capacity to develop present and future import/export data. (c) Accurate understanding of industry biotechnology practices in relevant sectors. (d) Capacity to compile and analyse existing legal and administrative biosafety regimes. (e) Multi-disciplinary strategic planning capacity. (f) Capacity to relate biosafety regime to other international obligations.	***General risk assessment capacities*** (a) Ability to coordinate multi-disciplinary analyses. (b) Enhancement of technological and institutional capacities for risk assessment. (c) Capacity to identify and access appropriate outside expertise. (d) Understanding of relevant bio-technology processes and applications.	***General risk management capacities*** Understanding of application of risk management tools to different biotechnology sectors.
Biosafety regime development (a) Develop/strengthen legal and regulatory structures. (b) Develop/strengthen administrative processes to manage risk assessment and risk management. (c) Develop domestic/regional risk assessment capacity. (d) Capacity to administer notification, acknowledgement and decision response process. (e) Capacity to make and report decision on LMO import in required time frames. (f) Emergency notification and planning and response capacity. (g) Enforcement capacity at borders.	***Science and socio-economic capacities*** (a) Analyse risks to conservation and sustainable use of biodiversity. (b) Undertake life-cycle analysis. (c) Analyse risks to human health of effects on biodiversity. (d) Analyse ecosystem effects of LMO introduction. (e) Assess food security issues arising from risks to biodiversity. (f) Value and roles of biodiversity to local and indigenous communities. (g) Other socio-economic considerations related to biodiversity. (h) Enhancement of related scientific, technical capacities.	***Decision-making capacities*** (a) Identification and quantification of risks, including through sound application of the precautionary approach. (b) Capacity to assess relative effectiveness of management options for import, handling and use, where appropriate. (c) Capacity to assess relative trade impacts of management options, where appropriate. (d) Impartial review of proposed management regime prior to decision-making.
Long-term regime-building/maintenance (a) Capacity to monitor, review and report on the effectiveness of risk management programme, including legal, regulatory and administrative mechanisms. (b) Capacity to monitor longer-term environmental impacts, if any (based on current baselines). (c) Establishment of environmental reporting systems.	***Note*** Specific types of scientific expertise required will vary from case to case, but broadly involve two areas; – evaluation of genetic modifications; – evaluation of interactions with the receiving environment.	***Implementation of decisions*** (a) Identification and handling of LMOs at point of import. (b) Monitoring of environmental impacts against expected impacts. (c) Capacity to monitor, enforce and report on compliance.

CROSS-CUTTING CAPACITIES

Data management and information-sharing

(a) Exchange of scientific, technical, environmental and legal information;
(b) Collection, storage and analysis of scientific, regulatory and administrative data;
(c) Communication to the Biosafety Clearing-House.

Human resources strengthening and development

(a) All aspects of regime development, evaluation and maintenance for risk assessment and risk management;
(b) Raise awareness of modern biotechnology and biosafety among scientists, government officials;
(c) Training and longer-term education;
(d) Procedures for safe handling, use and transfer of LMOs.

Public awareness and participation

(a) Administer and disseminate information on legal and administrative framework;
(b) Public awareness of/participation in scientific assessment process;
(c) Risks associated with handling and use.

Involvement of stakeholders e.g. non-governmental organizations, local communities, private sector

(a) Capacity to negotiate with and provide opportunity for private sector involvement;
(b) Processes for community, NGO consultation in development of risk assessment and management regimes;
(c) Processes for community, NGO consultation prior to decisions.

Regional capacity development

(a) Scientific assessment of risk;
(b) Harmonization of legal regimes;
(c) Training of human resources;
(d) Information sharing.

Source: ICCP Recommendation 2/9, UNEP/CBD/ICCP/2/15, Annex.

Article 23. Public awareness and participation

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

587. *Article 23 provides for a mix of mandatory and discretionary actions that Parties to the Protocol are expected to undertake relating to:*

- *the provision of information on LMOs to the public (Article 23(1));*
- *public participation in LMO-related decision-making processes (Article 23(2));*
- *provision of information to the public about access to the Biosafety Clearing-House (Article 23(3)).*

588. Article 23 is best understood in the context of Principle 10 of the 1992 Rio Declaration on Environment and Development (Box 40). Principle 10 articulates what are now known as the three "pillars" of public participation: (1) the right of citizens to information; (2) their right to participate in environmental decisions which affect them; and (3) their access to mechanisms of redress and justice when their rights are violated.

589. It should also be noted that Article 14(1)(a) of the CBD encourages public participation in:

> environmental impact assessment of proposed projects that are likely to have significant adverse effects on biological diversity.

Box 40. Principle 10 of the Rio Declaration

Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

590. Article 23(1) does not explicitly require Parties to make specific information available to the public. The obligation is somewhat softer. Parties are required to "promote and facilitate" public awareness, education and awareness regarding LMOs, and are to "endeavour" to ensure public awareness and education on LMOs that may be imported.

591. The phrase "promote and facilitate" would indicate that Parties intended to commit themselves to encourage and make easier the flow of information to the public concerning LMO transfers, handling and use, through the establishment of such mechanisms as may be deemed appropriate or necessary. Article 23(1)(a) indicates that such mechanisms should be focused on three main areas of public information:

- public awareness – e.g. through the use of media and other means of general information distribution to the public;
- public education – e.g. through general public information distribution mechanisms and specific public education programmes through the formal and non-formal educational system; and
- public participation – e.g. through the provision of appropriate mechanisms for public feedback and input into decision-making and regulatory processes relating to LMO transfers, handling and use.

592. Article 23(1)(b) expressly indicates that public awareness and education mechanisms should cover and provide access to information pertaining to LMOs "that may be imported". A significant omission from Article 23(1)(b), however, is a reference to "public participation". This would imply that Parties have not bound themselves to provide, or endeavour to provide, public participation mechanisms with respect to LMOs that may be imported. This gap, however, seems to be addressed in Article 23(2).

593. A major difference between subparagraphs (a) and (b) of Article 23(1) is the level of obligation to which Parties have agreed to be bound. Article 23(1)(a) requires Parties to "promote and facilitate" – i.e. encourage and make easier through the setting up of appropriate or necessary mechanisms – public awareness, education, and participation with respect to LMOs. The use of such a phrase clearly indicates that the establishment and implementation of such mechanisms for promotion and facilitation are mandatory. Article 23(1)(b), on the other hand, uses the word "endeavour" to refer to the obligation to ensure that public awareness and education mechanisms cover and include access to information on imported LMOs. The word "endeavour" suggests that the Parties must attempt or strive to ensure such inclusion of access to information on imported LMOs within the scope of public awareness and education mechanisms relating to LMO transfers, handling, and use.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

594. Article 23(2) of the Protocol lays down affirmative obligations on Parties to:

- consult the public in the decision-making process regarding LMOs; and
- make the results of such decisions available to the public.

The obligation to consult the public applies generally to all decision-making processes regarding LMOs, including the making of decisions on imports of LMOs.

595. The obligation to consult with the public, however, is qualified by two factors:
   - consultation with the public must be "in accordance with [the Party's] laws and regulations"; and
   - it must respect "confidential information in accordance with Article 21" of the Protocol.

596. This means that the scope, extent, and methodologies for public participation are subject to national laws and regulations governing public participation in each Party. Furthermore, the information to be provided to the public to enable them to effectively participate in LMO-related decision-making processes must not include information that has been identified as "confidential information" pursuant to Article 21 of the Protocol.

597. Article 23(2) does not provide specific guidance on the public consultation mechanisms to be adopted in decision-making processes and on how to make results of decisions on LMOs available to the public. This effectively leaves it up to the Parties to decide how this obligation should be implemented in their own national contexts. These issues are addressed in some other existing regional and international agreements (see Box 41). Possible elements may be grouped in three phases:

- *Notice* to all concerned stakeholders, in a language understood by them and through media to which they have access.
- *Public consultations,* as a way to secure wide input into the decisions that are to be made. These could include *public hearings* in certain cases, particularly where there is public concern about the proposed measures.
- *Consideration of public concerns* in the decision-making phase following consultation.

Box 41. Information and public participation in decision-making

The linkage between the provision of information to the public and public participation in decision-making relating to environmental matters has long been recognized as an essential element in ensuring environmentally-sustainable development. Aside from Principle 10 of the Rio Declaration, recent international environmental conventions that incorporate public participation provisions include:

- the 1991 UN/ECE Convention on Environmental Impact Assessment in a Transboundary Context – Article 2(2) and (6); Article 4(2);
- the 1992 UN Framework Convention on Climate Change – Article 6(a)(iii);
- the 1992 UN/ECE Convention on the Transboundary Effects of Industrial Accidents – Article 9(2);
- the 1994 UN Convention to Combat Desertification in those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa – Article 3(a); Article 4.2(e) and (f).

In addition, the most recent and comprehensive international agreement relating to public participation is the 1998 UN/ECE Convention on Access to Information, Public Participation in Decision-Making, and Access to Justice in Environmental Matters (the 'Aarhus Convention'). This treaty outlines and effectively provides guidance on how public participation should be realized in the context of environmental decision-making processes. Among the principles contained in its provisions on public participation are that public participation must be "timely, effective, adequate and formal, and contain information, notification, dialogue, consideration, response". It establishes obligations that Parties to the Aarhus Convention must comply with in providing for timely, adequate, and effective public participation. These include requirements concerning public notification, timing, provision of relevant information, provision of opportunities for public comment, responses to such comments, and communication.

Article 6(11) of the Aarhus Convention expressly makes applicable the provisions relating to public participation in Article 6 thereof to "decisions on whether to permit the deliberate release of genetically modified organisms into the environment". Implementation of this provision is to be done "within the framework of [the Party's] national law".

The public participation elements contained in Article 6 of the Aarhus Convention are outlined below:

- Parties are required to guarantee public participation in decision-making in matters that have a potentially significant environmental impact;
- Notification to the public about the decision-making to be done must be "adequate, timely, and effective" and lays out the minimum contents for such notification;
- Time frames for public participation procedures;

Cont.

Box 41. Information and public participation in decision-making (cont.)

- Public participation must take place early in the decision-making and must not be pro-forma;
- Public participation procedures must encourage exchanges of information between permit applicants and the public before the permit application is acted upon. Explanations regarding the permit application must be provided and dialogue among all stakeholders must be encouraged;
- Public authorities must provide the public concerned with access to all information relevant to the decision-making, free of charge and as soon as available, pursuant to the minimum contents laid down in this paragraph;
- Procedures for public participation should include mechanisms that allow public participation in writing or through public hearings, and which allow the submission of any comments, information, analyses or opinions. The public should be free to determine which particular piece of information is relevant for purposes of decision-making;
- Public opinion as gauged through the procedures for public participation must be taken into account in the decision. Public participation must not be pro-forma;
- The public must be informed of the final decision promptly, have access to the decision, and must be provided with the reasons and considerations resulting in the decision;
- Public authorities must ensure that public participation in accordance with paragraphs 2 to 9 above must be done in the event of any reconsideration or changes in the activities to which the decision applied;

Work is underway under the Aarhus Convention to elaborate the requirements of public participation in decisions concerning deliberate releases of LMOs into the environment. A double track approach is being followed: on one hand, draft guidelines have been adopted by the first Meeting of the Parties in October 2002 to elaborate public participation requirements; at the same time, a Working Group on GMOs has been established to examine possible legally binding options, including a draft amendment of the Convention to develop the application of the Convention in the field of GMOs.

(See: UNECE, *The Aarhus Convention: An Implementation Guide,* 87–122 (2000). For more information, see http://www.unece.org/env/pp/acig.htm).

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

598. Article 23(3) of the Protocol requires Parties to take steps to inform the public about the means of access to information contained in the Biosafety Clearing-House (Article 20).

Article 24. Non-Parties

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

599. *Article 24 addresses the obligations of Parties in relation to the transboundary movement of LMOs to and from non-Parties to the Protocol. As noted in relation to Article 17, as an international treaty, the Protocol cannot create binding obligations for non-Parties – if a State chooses not to become a Party to the Protocol it will not be bound by the Protocol rules (see Box 32 and Box 43). Non-Parties to the Protocol may include States which are not Parties to the CBD.*

600. *However, Article 24 of the Protocol does govern the conduct of Parties in relation to the transboundary movement of LMOs between Parties and non-Parties. Article 24 requires such transboundary movements to be consistent with the Protocol's objective but does not require that they be carried out in precise accordance with the Protocol's detailed provisions, such as the AIA procedures.*

601. *It should be noted that States which are not Parties to the Protocol, but which are Parties to the CBD, will remain bound by relevant CBD requirements including those contained in Article 8(g) and Article 19(4) of the CBD. These are discussed in the Introduction.*

602. The relationship between Parties and non-Parties is an important issue in international environmental agreements, especially those addressing trade in substances or products that are potentially harmful to the environment. In general terms, provisions on potential dealings between Parties and non-Parties to a treaty aim to :

- ensure that Parties to the treaty in question do not allow transboundary movements with non-Parties that would undermine the treaty, i.e. that omit protective measures prescribed by the treaty, or that adhere to environmental standards considerably lower than those of the treaty. If this were permissible, a Party could circumvent the treaty by simply sending potentially harmful substances to a country that is not a Party and does not adhere to the treaty's standards, or by receiving potentially hazardous materials from such a country;
- encourage non-Parties to join the treaty. Restricting trade between Parties and non-Parties provides an incentive for countries to join the treaty, discourages the development of a dual standard of environmental protection, and prevents non-Parties from developing a competitive trade advantage by remaining outside the treaty regime.

These two aims are reflected in Article 24 of the Protocol: Article 24(1) addresses the first aim, and Article 24(2) the second. As illustrated in Box 42, these aims have been addressed in different ways in different multilateral environmental agreements.

Box 42. Approaches to transboundary movements between Parties and non-Parties in selected multilateral environmental agreements

As this indicates, some multilateral environmental agreements addressing trade in potentially harmful substances allow Parties to trade with non-Parties only if a minimum standard of protection is applied. This can be achieved by:

- prohibiting trade with non-Parties unless it is undertaken in accordance with a separate agreement establishing, as a minimum, environmental standards that are equivalent to those set by the treaty (e.g. Basel Convention);
- by providing that trade may only be carried out with non-Parties that use standards equivalent to those established by the treaty (e.g. Montreal Protocol); or
- permitting transboundary movements with non-Parties and stating the conditions that must be met by such transboundary movements (e.g. CITES).

MEA (Issue)	Transactions with non-Parties	Conditions
Basel Convention (hazardous wastes) Article 4(5), Article 11	Prohibited in principle, permissible under specified conditions	Agreement with the non-Party, establishing standards equivalent to those of the Basel Convention.
Montreal Protocol (ozone-depleting substances) Article 4	Prohibited in principle, permissible under specified conditions	Meeting of Parties determines that the non-Party is in compliance with the requirements of the Montreal Protocol.
CITES (endangered species of plants /animals) Article 10	Permissible	Comparable documentation may be accepted instead of documentation required by CITES.
Cartagena Protocol (LMOs) Article 24	Permissible	Transboundary movement must be consistent with the objective of the Protocol. Separate agreement with non-Party possible but not required.
Rotterdam Convention (potentially hazardous chemicals)	Not addressed	Not addressed

603. The question whether or not the Protocol should permit transboundary movement of LMOs from or to non-Parties, and if so, to what extent its provisions should apply to such transboundary movements, was one of the more contentious issues in the Protocol negotiations. A proposal to prohibit transboundary movement of LMOs to or from non-Parties altogether met with considerable opposition and was eventually dropped. Some countries raised the concern that a prohibition on transboundary movements of LMOs between Parties and non-Parties could be challenged as an import or export ban under the WTO. The question as to whether transboundary movement from or to non-Parties should be consistent with the "objective" or with the "provisions" of the Protocol was also extensively discussed.

604. The resulting text of Article 24 allows Parties to engage in transboundary movements of LMOs with non-Parties, but only under certain conditions.

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

605. This provision addresses the aim of ensuring that Parties adhere to a standard of protection consistent with the Protocol in relation to their dealings with non-Parties. It requires that transboundary movement of LMOs between Parties and non-Parties must be "consistent with the objective of this Protocol".

606. Since the Protocol cannot create obligations for non-Parties, Article 24(1) makes it the

responsibility of any Party conducting transboundary movements with a non-Party to ensure consistency with the objective of the Protocol. In order to be consistent with the Protocol's objective, an Article 24 arrangement or agreement would need to be in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration, and contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs that may have adverse effects on biological diversity, taking also into account risks to human health. While the agreement or arrangement would not need to replicate the same procedures and techniques, such as the AIA provisions, contained in the Protocol it should provide for equivalent measures necessary to achieve an adequate level of protection. Thus, as a minimum, it should provide for a mechanism to ensure safe transfer, handling and use of LMOs, and for a method to provide the importing country with an opportunity and a basis for deciding whether or not to consent to the import of LMOs. (See also commentary on Article 9, paragraphs 302 and 303).

607. Parties may conclude separate agreements with non-Parties to govern transboundary movements of LMOs, but they are not obliged to do so. If such an agreement is concluded, its relationship with the Protocol will be governed by the applicable rules of international law as codified in the Vienna Convention on the Law of Treaties (see commentary on Article 14).

608. As noted in relation to Article 14, one question which arises in relation to Article 14 is whether the "additional" standard set in that Article for bilateral, regional and multilateral agreements and arrangements also applies to such agreements and arrangements between Parties and non-Parties under Article 24(1). Article 24(1) requires that transboundary movements of LMOs between Parties and non-Parties are "consistent with the objective of this Protocol". Article 14(1) requires that such agreements and arrangements must be "consistent with the objective of this Protocol" and also must "not result in a lower level of protection than that provided for by the Protocol. Two possible interpretations have been put forward:

- Article 14 addresses agreements and arrangements between Parties only; Article 24 addresses agreements and arrangements between Parties and non-Parties. This interpretation is supported partly by the negotiation history of the two provisions: i.e. by the fact that separate provisions are included in Article 24 addressing non-Parties, and that there is no explicit cross-reference in Article 24 to Article 14. It is also supported by the reference to "transboundary movement" in Article 14, taken together with the definition of that term in Article 3(k) which limits it to movements of LMOs *between Parties* except in relation to Articles 17 and 24. A narrow reading of Article 3(k) and Article 14 would imply that "transboundary movement" in Article 14 can only take place as between Parties.
- Article 14 addresses separate agreements and arrangements in general terms; Article 24 specifies that such agreements and arrangements may also be concluded with non-Parties. This interpretation is based on the following argument: Article 14 provides that Parties may enter into bilateral, regional and multilateral agreements and arrangements, but does not specify with whom such agreements or arrangements may be concluded. It could therefore reasonably be interpreted as referring to such agreements and arrangements in general terms, while Article 24, which also refers to "bilateral, regional and multilateral agreements and arrangements" specifically addresses dealings with non-Parties. In that case the requirements of Article 14 would also apply to agreements and arrangements entered into by Parties under Article 24.

609. Thus, there are arguments to support each interpretation, although the text of the Protocol would appear more strongly to support the first. In practice, however, the distinction may not be of major significance. As an international treaty, the Protocol is, of course, not binding upon non-Parties without their consent. However, one or more of the parties to the bilateral, regional or multilateral agreement or arrangement will be a Party to the Protocol. As such, it will remain bound by its obligations under the Protocol. These include, for example:

- the obligation to act in a manner consistent with the objective of the Protocol (Article 1; Article 24(1));
- the obligation to ensure that activities involving LMOs are undertaken in a manner that prevents or reduces the risks to

biological diversity, taking also into account risks to human health (Article 2(2));

- the obligation to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol associated with the use, handling and transboundary movement of LMOs (Article 16(1)).

610. As Parties to the Protocol will also be in every case Parties to the CBD, relevant obligations will also include those contained in Article 8(g) and Article 19(4) CBD. States which are not Parties to the Protocol, but which are Parties to the CBD will also remain bound by Article 8(g) and Article 19(4) CBD (see Introduction). In accordance with Article 2(4), and subject to agreement with the non-Party concerned, agreements and arrangements entered into under Article 24(1) could also establish a higher level of protection than that provided for by the Protocol.

611. Where a Party enters into such agreements and arrangements with non-Parties, it must provide information on those agreements and arrangements to the Biosafety Clearing-House under Article 20(3).

612. The application of Article 24 in practice may differ according to whether the Party to the Protocol is the Party of import or the Party of export of the LMO. The following considerations, for example, may be relevant:

- If the Party is the importing State, it may require the non-Party exporting State to comply with the AIA procedure of the Protocol, as implemented in its national regulations (or with its own consistent domestic regulatory framework). Alternatively, it may accept another form of prior notification, which must however ensure that the importing Party has a firm basis for undertaking risk assessment prior to the intended movement. In any event, the importing Party may not consent to the movement unless the exporting non-Party State agrees to use a procedure that fulfils the requirement of consistency with the objective of the Protocol. In deciding whether to allow the proposed import, the Party should undertake a risk assessment based on Article 15 and Annex III in order to assess potential impacts on biodiversity, taking also into account risks to human health, and to identify appropriate risk management measures.
- If the Party is the exporting State intending to transfer LMOs to a non-Party, it must notify the importing State either in accordance with Article 8, or in a manner that is otherwise consistent with the objective of the Protocol. One issue that may arise here is whether a Party of export can proceed with an export to a non-Party State if that State has no regulatory framework or other risk assessment and risk management framework in place. In this case, the Party of export would need to consider whether the export would be consistent with the objective of the Protocol and with its own other relevant obligations under the Protocol. However, it is not required, of course, that the measures in place in a non-Party State of import be the same as those required under the Protocol.
- As transit of LMOs is exempt from the AIA procedure in accordance with Article 6(1), the State of transit, whether or not it is a Party, does not have to be notified of, or to consent to, a transboundary movement of LMOs, unless its relevant domestic regulations so require.

In practice, for reasons of regulatory efficiency, one might expect Parties to the Protocol to deal with imports from and exports to Parties and non-Parties within the same regulatory framework.

Box 43. Responsibilities of the States involved in transboundary movement between Party and non-Party

State of export (SE)	State of import (SI)	Responsibilities
Party	Non-Party	SE must notify SI, using AIA or similar procedure. If SI agrees to movement, SE must ensure that this is carried out in a way consistent with the objective of the Protocol.
Non-Party	Party	SI may require SE to use AIA. It can also accept a procedure consistent with the objective of the Protocol, but may not consent to the movement without such a procedure.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

613. Parties must "encourage" non-Parties to adhere to the Protocol, i.e. to apply its principles or to become Parties. The way in which they do this is left open. It may include active encouragement, for example by pointing out the advantages of Party status or by providing technical, financial or institutional support for adherence to the Protocol.

614. Article 24(2) also encourages States that are not Parties to provide information to the Biosafety Clearing-House on transactions related to LMOs in which they have been involved. The aim is to gather as much relevant information as possible and make it available to all Parties, in accordance with the general function of the Biosafety Clearing-House (see commentary on Article 20).

Article 25. Illegal transboundary movements

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

615. *As explained in earlier sections of this Guide, the Protocol provides for the regulation of transboundary movements of certain categories of LMOs, primarily through the AIA procedure. Article 25 addresses the situation where transboundary movement of LMOs takes place in contravention of national regulations implementing the Protocol. In essence, Article 25:*

- *requires each Party to adopt domestic measures to prevent and (if appropriate) penalize transboundary movements of LMOs which contravene its national measures to implement the Protocol. Such transboundary movements are deemed illegal.*
- *allows a Party affected by an illegal transboundary movement of LMOs to request the Party of origin to dispose of the LMOs in question at its own expense.*
- *requires Parties to exchange information through the Biosafety Clearing-House on illegal transboundary movements of LMOs.*

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

616. Article 25(1) obliges Parties to adopt appropriate domestic measures aimed at preventing and penalizing transboundary movements carried out in contravention of domestic measures to implement the Protocol. The term "domestic measures" refers to the legal and institutional framework that a Party adopts to implement its obligations under the Protocol. The domestic measures must be designed so as to ensure that persons under the national jurisdiction of the Party act in accordance with the rules of the Protocol.

617. As the term "transboundary movement" means "the movement of a living modified organism from one Party to another Party" (and in certain circumstances between Parties and non-Parties), Article 25(1) would appear to cover imports and exports of LMOs carried out in contravention of relevant domestic measures. Article 25(1) specifies that a Party should adopt both measures to prevent persons under its jurisdiction from carrying out illegal transboundary movements, and measures to penalize infringement of the preventive measures, where it considers this appropriate.

618. Article 25(1) appears to cover all LMOs that are subject to the Protocol's provisions on transboundary movement, even if they are not subject to the Protocol's AIA procedure. Thus transboundary movements of LMOs destined for contained use in the Party of import, LMOs in transit and LMO-FFPs could be deemed illegal under Article 25(1) if they are carried out in contravention of domestic measures to implement the Protocol.

619. Article 25(1) sets out the definition of illegal transboundary movements. These are "transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol". It is notable that the illegal nature of a transboundary movement is judged by reference to a Party's domestic measures to implement the Protocol, rather than directly

by reference to the provisions of the Protocol itself. This appears to recognize the flexibility and discretion accorded to Parties in their implementation of the Protocol. However, what is the legal situation if a transboundary movement of LMOs is carried out under the jurisdiction of a Party, in direct contravention of the provisions of the Protocol (e.g. the AIA procedure), but the Party in question has *not* enacted domestic measures on this issue? This situation is not addressed by the Protocol.[110] The reference to domestic measures here means that the Protocol will not necessarily provide a universal standard of what is considered an illegal transboundary movement. The higher the standards set by the implementing legislation of a Party, the more types of behaviour will be classified as illegal transboundary movement. It is possible that the same conduct related to a movement of a LMO could be considered illegal in one Party but legal in another. Thus it is important to have regard to the specific national legislation of the Party of import and Party of export and any transit Party in relation to each transboundary movement of a LMO within the scope of the Protocol.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

620. Article 25(2) addresses the legal relationship between the Party from which the illegal transboundary movement originated, and the Party affected by the transboundary movement. The two States involved are termed "the Party of origin" and "the affected Party", without providing criteria to determine when a Party is considered "of origin" or "affected". Since illegal transboundary movements are defined in Article 25(1) as movements carried out in contravention of domestic measures to implement the Protocol, the "Party of origin" is presumably the Party where the movement has originated in contravention of that Party's domestic legislation or the relevant legislation of the Party of import. The "affected Party" is presumably any Party in which LMOs are present in contravention of the domestic legislation of that Party implementing the Protocol, regardless of whether it is the Party "of import", a transit Party, or a neighbouring Party that suffers damage through a spillage occurring near its border (see commentary on Article 17).

621. The affected Party may request the Party of origin to re-import, or otherwise dispose of the LMOs, at its own expense. This does not mean that the Party of origin will necessarily take the relevant measures itself. It may provide, either in its national legislation, or on a case-by-case basis, that they are to be taken by the person or entity responsible for the illegal transboundary movement, or it may require that person or entity to bear the costs of such measures.

622. Unlike the equivalent provisions of the Basel Convention, which clearly state that the Party responsible for an illegal transboundary movement "shall ensure" that the wastes are appropriately disposed of,[111] Article 24(2) of the Protocol is silent on whether the Party of origin must comply with the request of the affected Party to dispose of the LMO in question, or whether this will be subject to agreement between the Parties concerned, or even be at the discretion of the Party of origin.

623. Article 25 refers to "Parties" rather than to "States". Thus, the rights and obligations set out in Article 25 only apply to Parties to the Protocol. They are not applicable to a non-Party involved in an illegal transboundary movement. In the case of the State of origin, this has its basis in international treaty law: the Protocol cannot create obligations for States that are not Parties to it (see Boxes 32 and 43).[112] Where non-Parties are involved, their rights and obligations will be determined in accordance with customary international law or subject to a separate agreement in accordance with Article 24, if such an agreement exists between the States concerned. Rules of customary law that may be applicable in such situations include the rule reflected in Principle 21 of the 1972 Stockholm Declaration and Principle 2 of the

[110] This can be contrasted to the equivalent provision of the Basel Convention on hazardous wastes, which defines "illegal traffic" as movements carried out in contravention of the provisions of the Convention itself.

[111] Basel Convention, Article 9(2)–(4).

[112] Vienna Convention on the Law of Treaties, Articles 34–38.

1992 Rio Declaration. In accordance with this rule, a State has an obligation to ensure that activities carried out under its national jurisdiction do not cause damage to the environment of other States or to the global environment. Of course, in their dealings with non-Parties, Parties remain obliged to act in manner consistent with the objective of the Protocol and to comply with their own obligations under Article 1, 2(2) and 24 of the Protocol. In addition, in any event, persons, entities or States dealing in transboundary movements of LMOs will need to comply with any relevant national legislation of the States involved in such movements. Thus although Article 25 will not apply directly to transboundary movements involving non-Parties, it will still be important for a person, entity or State carrying out such transboundary movements to be aware of the requirements of relevant national regulations on LMOs and the possible consequences of non-compliance with such regulations.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

624. Article 25(3) obliges Parties to provide the Biosafety Clearing-House with information on illegal transboundary movements of LMOs. This is intended to promote transparency and to allow Parties to benefit from each other's experience. It could also facilitate cooperation between Parties to combat illegal transboundary movements.

Article 26. Socio-economic considerations

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

625. *In reaching decisions on imports under Article 10, Parties are required by the Protocol to take into account potential effects of the LMO concerned on the conservation and sustainable use of biological diversity, taking into account risks to human health. Where there is a lack of scientific certainty about the extent of such potential adverse effects, Article 10(6) allows Parties to take a precautionary approach. Article 26 addresses the extent to which Parties are entitled to take socio-economic considerations into account in reaching decisions on imports of LMOs.*

626. *Article 26 identifies the types of socio-economic considerations that Parties may take into account in reaching decisions on imports. It requires that such considerations be taken into account consistent with a Party's other international obligations (for example, under international agreements other than the Protocol). Finally, it encourages Parties to cooperate on research and information exchange on the potential socio-economic impacts of LMOs.*

627. *During the Protocol negotiations, the question of including references to socio-economic considerations in the text of the Protocol was one of the issues that divided along mostly developing and developed country lines. Most developing countries emphasized the importance of ensuring that socio-economic considerations arising from biotechnology and LMOs should be made part of the Protocol as one of the bases for the conduct of risk assessment, risk management, and making decisions on imports of LMOs under the Protocol. Most developed countries, on the other hand, argued that socio-economic considerations are issues of national domestic concern, are difficult to quantify for purposes of making decisions on imports of LMOs, and that such considerations should therefore not be within the scope of the Protocol. In the end, the concept of socio-economic considerations was accepted provided that its application was consistent with existing international obligations, in particular the trade obligations of the Parties. But because there was no extensive engagement between developing and developed countries on how to approach socio-economic considerations in practice, further work may well need to be undertaken on this issue by the COP/ MOP in the future.*

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

628. The range of socio-economic considerations contemplated in Article 26(1) of the Protocol covers only those "considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities". This wording clearly indicates that not all socio-economic considerations may be taken into account, but rather only those that arise from the impact of LMOs on biological diversity.

629. Article 26(1) can thus be interpreted so that there must, first, be an "impact … on the conservation and sustainable use of biological diversity" as a result of or "arising from" the transboundary movement, handling, and use of the LMO concerned. The "impact" referred to may include the potential effects of the LMO on biological diversity. Hence, where the introduction of LMOs under the Protocol affects biological diversity in such a way that social or economic conditions are or may be affected, a Party can use Article 26 to justify taking such impacts on its social or economic conditions into account for purposes of making decisions on imports of LMOs or in implementing domestic measures under the Protocol. Such social or economic impacts are generally referred to as secondary or higher order effects in technology assessment literature.

630. Article 26(1) of the Protocol identifies one particular socio-economic consideration that Parties may be expected to take into account. This consideration is the "value of biological diversity to indigenous and local communities". In the negotiating history of Article 26(1), this phrase replaced a reference to Article 8(j) of the CBD, which provides as follows:

> Each Contracting Party shall, as far as possible and as appropriate:
>
> (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

631. Article 8(j) imposes on Parties to the CBD three basic obligations with respect to the "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles":

(1) respect, preserve and maintain such knowledge, innovations and practices relevant for the conservation and sustainable use of biological diversity;

(2) promote the wider application of such knowledge, innovations and practices with the approval and involvement of their holders; and

(3) encourage the equitable sharing of the benefits arising from the utilization of such knowedge, innovations and practices.

632. Socio-economic considerations with respect to the value of biological diversity to indigenous and local communities, may also refer to the impact of introduction of LMOs on the ability of indigenous and local communities to make use of the biological diversity upon which their community's survival and traditional livelihood depends. These socio-economic considerations may include, *inter alia*, the impact that decisions on imports or other domestic LMO regulatory measures may have on:

- the continued existence and range of diversity of the biological resources in the areas inhabited or used by indigenous or local communities;
- the loss of access to genetic and other natural resources, previously available to indigenous or local communities in their territories; or
- the loss of cultural traditions, knowledge, and practices in a particular indigenous or local community as a result of the loss of biological diversity in their territory.

633. The phrase "consistent with their international obligations" was inserted into the text at the insistence of countries concerned that the use of socio-economic considerations for purposes of making decisions on import of LMOs may create trade barriers. This indicates that where a Party is a Member of the World Trade Organization, that Party is also expected to ensure that its obligations under the WTO Agreements are not violated as a result of any application of socio-economic considerations in making import decisions on LMOs. This issue is considered further in the Appendix.

634. Parties may take socio-economic considerations into account in two instances:

- when "reaching a decision on import" of LMOs; and
- under its domestic measures implementing the Protocol.

635. The broad language of Article 26(1) of the Protocol implies that, in making decisions on imports of LMOs, or under its domestic measures implementing the Protocol, Parties may take socio-economic considerations into

account when implementing a number of provisions of the Protocol. For example,

- Article 10 – Procedures for decisions on import;
- Article 11 – Procedure for LMOs intended for use as food or feed, or for processing (LMO-FFPs);
- Article 12 – Review of decisions on import;
- Article 13 – Simplified procedure for decisions on imports;
- Article 15 and Annex III – Risk assessment;
- Article 16 – Risk management;
- Article 17 – Unintentional transboundary movements and emergency measures;
- Article 18 – Measures relating to handling, transport, packaging and identification;
- Article 19 – The establishment of national focal points and designation of competent national authorities;
- Article 21 – Protection and disclosure of confidential information;
- Article 22 – Capacity-building;
- Article 23 – Public awareness and participation;
- Article 24 – Measures with respect to transboundary movements of LMOs with non-Parties;
- Article 25 – Illegal transboundary movements.

636. Article 26, however, does not give any guidance on exactly how socio-economic considerations can be "taken into account" with respect to the Protocol provisions above. At the very least, Parties that decide to use socio-economic considerations as the basis for their LMO import decisions or the domestic measures on LMOs can point to Article 26 as the treaty basis for such decision or measure.

637. Possible ways of taking socio-economic considerations "into account", especially with respect to indigenous and local communities, may include, for example:

- procedures for assessing and addressing socio-economic impacts in risk assessment and management; and/or
- subjecting decisions on import of LMOs to prior public consultation processes, especially with respect to communities that will be directly affected by the import decision – for example the local community in which the LMO is destined for field trial or use, or which may be affected by any potential adverse impacts of the LMO on biodiversity.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

638. Article 26(2) of the Protocol recalls Article 17(2) of the CBD, which provides that Parties are to exchange information that includes the "results of … socio-economic research, as well as information on … indigenous and traditional knowledge as such and in combination with" biotechnology. The focus of the obligation in Article 26(2) of the Protocol is on cooperation in research and information exchange with respect to the socio-economic impacts of LMOs. Both developed and developing country Parties to the Protocol are expected to work with each other in developing and sharing information and research relating to the impacts that LMOs may have on the social and economic conditions of countries and communities, especially indigenous and local communities.

Article 27. Liability and redress

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movement of living modified organisms, analyzing and taking due account of the ongoing process in international law on these matters, and shall endeavour to complete this process within four years.

639. *Article 27 concerns the issue of liability for damage that may result from the transboundary movement of LMOs. The kinds of questions generally addressed under the heading of liability and redress include:*

- *What types of remedy should be available for damage resulting from the transboundary movement of LMOs?*
- *What kinds of loss or damage should be compensated?*
- *Who should pay for such loss or damage?*
- *In what circumstances?*
- *Is a specific international regime required setting out rules on liability and redress for damage resulting from the transboundary movement of LMOs?*

640. *These issues are complex and could not be resolved during the negotiations. Article 27 therefore contains what is called an "enabling" provision. – i.e. it requires the first meeting of the COP/MOP to establish a process to consider this issue, and establishes a time-frame for this process.*

641. In international law, the term "liability" is associated with the obligation to provide for compensation for damage caused by activities which pose potential risks to persons, property and the environment. In relation to certain activities, States have tended to opt to conclude international treaties establishing civil liability regimes, which "channel" liability for damage to private parties and operators (see Box 44 below).

642. In any regulatory system, rules and procedures on liability and redress perform various functions. They play, among other things, preventive and reparative functions. Current trends in international environmental law focus on preventing rather than remedying damage.

643. During the negotiation of the Protocol, the issues of liability and redress gave rise to considerable debate and disagreement. At an early stage in the negotiations, the African Group put forward a proposal for strict liability of the Party of export for any damage caused by LMOs – i.e. the Party of export would have been held liable for any damage caused by LMOs exported from its jurisdiction even if it was not itself at fault. Many developing countries viewed existing private international law as an inadequate means for ensuring redress for any damage that may be caused by the transboundary movement of LMOs. They therefore sought to include more detailed provisions on liability and redress within the Protocol. Among developed countries there were different views on this matter. Some argued that there was no need for international rules on liability for damage caused by LMOs, since these matters were or could be addressed under national law, and within the context of private international law. Others took the view that there simply was not sufficient time during the Protocol negotiations to address such a complex issue.

644. As a consequence of these disagreements, Article 27 of the Protocol is a compromise which provides an enabling provision for a process to consider the issue of liability and redress, but leaves all substantive discussions on liability and redress to the COP/MOP of the Protocol.

645. The text of Article 27 has three main elements:

(i) The COP/MOP shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movement of LMOs,

(ii) analyzing and taking due account of the ongoing process in international law on these matters, and

(iii) shall endeavour to complete this process within four years.

646. The *first element* imposes an obligation on the COP/MOP to adopt a process at its first meeting for the appropriate elaboration of international rules and procedures in the field of liability and redress. The form and mandate of this process has to be decided by the COP/MOP. The preparation of this issue was part of the mandate of the ICCP (see further below).

647. The expression "appropriate elaboration of international rules and procedures in the field of liability and redress" could imply that the process will consider the elaboration of substantive rules and procedures under international law and could be interpreted to exclude the possibility of leaving the matter only to national law. However, the scope and nature of any rules and procedures developed under Article 27 is, of course, a matter for negotiation within the process to be established by the first meeting of the COP/MOP.

648. The *second element* of Article 27 requires the future process on liability and redress to analyze and take due account of the ongoing process in international law on these matters. This may imply that some sort of a comparative analysis of the relevant international legal frameworks is required. There are a number of international agreements and relevant processes that might provide useful examples for analysis in respect of the elaboration of rules and procedures on liability and redress (see Box 44 below).

Box 44. Other international conventions and processes relating to liability and redress: examples

State Liability

- 1972 Convention on International Liability for Damage Caused by Space Objects

Civil Liability

- 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy, and 1963 Brussels Supplementary Convention.
- 1963 Vienna Convention on Civil Liability for Nuclear Damage, amended by the 1997 Protocol, and 1997
- 1969 Convention on Civil Liability for Oil Pollution Damage and 1971 Convention on the Establishment of an International Fund for Compensation for Oil Pollution Damage, amended and replaced by the 1992 Protocols
- 1992 International Convention on Civil Liability for Oil Pollution Damage
- 1992 International Convention on the Establishment of an International Fund for Compensation for Oil Pollution Damage
- 1993 Lugano Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment (not in force).
- 1996 International Convention on Liability and Compensation in connection with the Carriage of Hazardous and Noxious Substances by Sea (not in force).
- 1999 Basel Protocol on Liability on Liability and Compensation for Damage resulting from the Transboundary Movements of Hazardous Wastes and their Disposal (not in force).
- 2001 International Convention on Civil Liability for Bunker Oil Pollution Damage (not in force).

Other relevant processes

- Examination by the Conference of the Parties of the CBD of the issue of damage to biological diversity in accordance with Article 14(2) of the CBD.
- Consideration of a liability regime under the 1991 Protocol on Environmental Protection to the Antarctic Treaty.
- International Law Commission Draft Articles on Prevention of Transboundary Harm from Hazardous Activities, 2001.
- International Law Commission Draft Articles on Responsibility of States for Internationally Wrongful Acts, 2001.

649. An additional process of potential relevance for the future negotiations under Article 27 is the examination of the question on liability for damage to biodiversity under Article 14(2) of the CBD. Article 14(2) of the CBD provides that:

> The Conference of the Parties shall examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter.

650. Thus Article 14(2) of the CBD addresses damage to biological diversity, however it is caused. By contrast, Article 27 of the Protocol addresses "damage resulting from the transboundary movement of LMOs". Only damage caused by LMOs is covered by Article 27, and while this may include damage to biological diversity, it may or may not be limited to such damage. This is, again, a matter for future negotiations under Article 27.

651. Work on Article 14(2) of the CBD has been initiated by the CBD COP, and it can be expected that there will be some linkages between this work and work undertaken in relation to Article 27. The ICCP has acknowledged in its recommendation to the COP/MOP[113] that while the process under Article 27 is distinct from the process under Article 14(2) of the CBD, there is a need to identify and promote synergies and cross-fertilization between the two processes. In its decision VI/11, the CBD COP decided to establish a group of legal and technical experts to begin to consider aspects of this issue, including clarifying basic concepts and developing definitions, such as the concept of damage to biological diversity.

652. The *third element* of Article 27 sets out a time-frame of four years in which the "process" established shall endeavour to complete its work. While the word "endeavour" does not in itself establish an absolute deadline for completion of this work, it does at least oblige Parties to strive in good faith to finalise the process within this time-frame.

653. Article 27 is silent in relation to the final form of the product of this entire process. The nature and final content of any future liability and redress regime will be decided and resolved by the COP/MOP.

Consideration of Article 27 by the Intergovernmental Committee for the Cartagena Protocol

654. The ICCP adopted a recommendation for a draft decision of the first meeting of the COP/MOP of the Protocol regarding the process to be adopted under Article 27, and requested certain additional measures to prepare for the COP/MOP's consideration of Article 27.[114] The ICCP recommended the establishment of an open-ended ad hoc group of legal and technical experts to carry out the process under Article 27 (i.e. a working group open to all Parties to the Protocol as well as to observers). If the COP/MOP decides that such a working group should be established, it will also have to determine the working group's terms of reference at its first meeting. The ICCP requested views from Parties and governments to be submitted to the Executive Secretary of the CBD on elements of the terms of reference for the working group. The ICCP also recommended that the CBD Secretariat continue to gather and disseminate information on national, regional and international measures and agreements in the field of liability and redress for damage resulting from the transboundary movement of LMOs. Box 45 highlights some of the issues that have been addressed in other international regimes on liability and redress. Of course, whether and how these issues are addressed in relation to Article 27 of the Protocol remains a matter for the COP/MOP to determine. Further information on approaches to some of these issues in existing international and national liability regimes is contained in the Secretariat documentation on liability and redress prepared for the meetings of the ICCP.[115]

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[113] ICCP Recommendation 2/1, UNEP/CBD/ICCP/2/15.

[114] ICCP Recommendation 2/1,UNEP/CBD/ICCP/2/15; ICCP Recommendation 3/1, UNEP/CBD/ICCP/3/10.

[115] See UNEP/CBD/ICCP/2/3, *Liability and redress for damage resulting from the transboundary movements of living modified organisms. Review of existing relevant instruments and identification of elements*. See also UNEP/CBD/COP/6/INF/5, *Report of the Workshop on Liability and Redress in the context of the Convention on Biological Diversity*.

Box 45. Core issues commonly addressed in liability and redress regimes

If the COP/MOP decides to adopt international rules and procedures for liability for damage resulting from the transboundary movement of LMOs under Article 27, the following issues may be amongst those to be considered. Similar issues may also need to be considered by a Party if it were to decide to adopt a liability and redress regime at the national level:

- *Scope of the rules and procedures*
  - Activities – what activities and organisms would be covered?
  - Geographical scope
  - Temporal scope – would the rules and procedures only apply to damage arising after the entry into effect of the regime
- *"Channelling" liability*
  Who would be liable for damage? Possibilities to be considered here may include: the Party of export; the Party of import; the exporter; the importer; the notifier; or the operator (i.e. the person with operational control of the LMOs at the time the incident causing damage occurs). Other proposals may also be put forward.
- *Access and standing*
  Who would be entitled to bring claims?
- *Ancillary sources of compensation*
  For example if the person or entity that is liable for the damage is not in a position to meet all costs of damage incurred (or if there is a ceiling on the level of liability – see below), where should additional compensation come from? – Other international liability regimes have created compensation funds for this purpose and/or imposed some residual liability on States.
- *Defining Damage*
  What kind of damage would be compensated? – Possible categories of damage that may be considered here may include harm to biological diversity, harm to human life or health, damage to property, harm to the environment, and socio-economic damage.
- *Standard of Care*
  Would liability be strict or fault based?
  - Strict liability imposes an obligation of result – i.e. a person/entity would be liable if damage occurs as a result of the transboundary movement of a LMO, regardless of fault.
  - Fault-based liability imposes an obligation of conduct – i.e. a person/entity must act with due diligence to prevent damage from occurring as a result of the transboundary movement of a LMO, and would not be held liable unless fault is proved.
- *Exoneration/defences*
  In what circumstances would a person/entity be exonerated from liability where harm has occurred? Examples to be considered may include:
  - Force majeure;
  - Where an act of a third party has caused the damage in question;
  - State of the art or regulatory compliance defences.
- *Causation*
  What evidence would be required to demonstrate a causal link between the damage and a specific LMO or LMOs?
- *Time limits for bringing claims*
  What would be the appropriate limitation period after which claims for damage could not be brought?
- *Limitations on the amount of liability*
  Would it be appropriate to impose a ceiling on the amount of liability of a person/entity under the rules and procedures?
- *Financial guarantees*
  Should exporters/importers/users/operators of LMOs take insurance or other financial guarantees against possible damage?
- *Competent tribunals for hearing claims*
  If damage results from the transboundary movement of LMOs, where should claims be brought – for example in the Party of import or the Party of export?
- *Mutual recognition and enforcement of judgements*
  What provision, if any, should be made for judgments of courts of one country to be recognized and enforced in other countries?

General introduction to Articles 28–31

655. Articles 28–31 establish the financial and institutional infrastructure of the Protocol, i.e. the bodies that constitute the "machinery" which operates the Protocol. These bodies manage the provision of financial assistance to developing and transition countries, govern the Protocol's future development, review its implementation and deal with its administration.

656. The financial mechanism (Article 28): The Global Environment Facility (GEF) is an international entity that has been established to generate and provide financing for environmental activities. It is not part of the Protocol's internal institutional infrastructure, but has been designated in Article 28 to serve as its financial mechanism. The GEF fulfils this same function for a number of other multilateral environmental agreements as well. Article 28 also addresses financial assistance outside of the GEF, and contains provisions regarding the relationship between the COP/MOP and the GEF.

657. The institutional infrastructure of the Protocol as set out in Articles 29 to 31 closely resembles the institutional framework of most other modern multilateral environmental agreements. It consists of three types of institution:

- The Conference of the Parties serving as the meeting of the Parties to the Protocol (COP/MOP) (Article 29): This is the "supreme" governing body of the Protocol. Article 29 sets out its functions and describes its relationship with the Conference of the Parties to the CBD. It also regulates participation in the meetings of the COP/MOP by States and organizations.
- Subsidiary bodies (Article 30): These are bodies established to undertake specific tasks, for example to provide advice to the COP/MOP.
- The Secretariat (Article 31): This is the body which serves to administer the Protocol.

658. Essentially, the Protocol will be served by the institutions established under the CBD. Special provisions are incorporated into the Protocol regarding the membership and costs of these institutions when they are serving the Protocol.

Article 28. Financial mechanism and resources

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

659. *Article 28 provides for financial assistance to be provided to developing country Parties, and to some extent to Parties with economies in transition. The underlying rationale of this provision is that Parties with limited capacity need assistance if they are to comply with their obligations under the Protocol. That they should be able to comply is not only in the interest of the Parties concerned, but also of the community of Parties to the Protocol as a whole. In order to make the Protocol effective, all Parties need to be in a position to implement it at the national level.*

660. *Article 28 addresses two basic issues:*

- *The provision of financial assistance through a multilateral financial mechanism established under the CBD; and*
- *The provision of financial assistance by developed countries through other bilateral, regional and multilateral channels.*

661. *Under Article 28, the financial mechanism established under the CBD will also be the financial mechanism for the Protocol – i.e. financial assistance in relation to the Protocol will be available through the Global Environment Facility (GEF).*

662. *Under the provisions of Article 28, for both sources of financial assistance, the developed country Parties to the Protocol assume the role of donors, and the developing country Parties are designated as recipients. Parties with economies in transition have a somewhat ambiguous role: they can be recipients of bilateral assistance, but they are not mentioned as beneficiaries of the financial mechanism, although they do in practice receive assistance from the GEF. They can also assume the role of donors on a voluntary basis, both through the financial mechanism and on a bilateral basis.*

663. *The category of "developed countries" has been defined for the purposes of financial resources and mechanism in the context of the CBD – and, by implication, its protocols – through a list adopted by the CBD COP at its first meeting.*[116] *There is no corresponding list of "developing countries".*

664. *Article 28 of the Protocol is closely linked to the corresponding provisions of the CBD, namely Articles 20 (Financial Resources) and 21 (Financial Mechanism). Article 28 must therefore be read in conjunction with these CBD provisions. Paragraphs 1 and 4 of Article 28 refer to Article 20 of the CBD, and paragraphs 2, 3 and 5 refer to Article 21. Paragraph 6 restates and refines the concept of Article 20 paragraph 3 of the CBD.*[117]

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

665. Article 28(1) provides that the Parties shall "take into account" the provisions of Article 20 of the CBD in "considering" financial resources for the implementation of the Protocol. This means that Article 20 of the CBD does not directly apply to the provision of financial resources under the Protocol, but is merely to be "taken into account" in this context, for example if a specific issue is not addressed by Article 28. This wording is the result of a compromise between those countries that wanted to include a strong obligation to provide financial resources, and those that were reluctant to include a provision of this type. The wording softens the obligation of potential donor countries in two respects. First, they are not obliged to provide financial resources, but merely to consider the issue of financial resources, and second, the provisions of Article 20 of the CBD are not declared to be directly applicable to the Protocol, but to be taken into account.

666. Article 28(1) refers to all aspects of Article 20 of the CBD. In seven paragraphs, Article 20 CBD sets out a wide range of obligations and guidelines, covering national financing activities, the provision of new and additional resources by developed country Parties to developing countries; the provision of funds through bilateral or multilateral channels; the interlinkage between developing countries' implementation of the CBD and the funding received for this purpose; consideration of the special dependence of developing countries on biological diversity; and the special consideration to be given to the situation of developing countries. The open wording of Article 28(1) also takes into account the fact that all provisions of Article 20 of the CBD are not equally relevant to the issue of biosafety, but that they should be considered to the extent that they do have a bearing on this issue.

667. As a result of the general reference to Article 20 of the CBD, there is certain duplication with the concepts set out in Article 28 of the Protocol. Thus Article 28(6) corresponds to Article 20(3) of the CBD, and Article 28(4) corresponds to Article 20(5) CBD, although the provisions of the Protocol are more detailed.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

668. Article 28(2) refers to Article 21 of the CBD, which regulates the establishment and function of the financial mechanism under the CBD. It designates the financial mechanism of the CBD as the financial mechanism of the Protocol, through the institutional structure entrusted with its operation. The institutional structure referred to is the Global Environment Facility (GEF), which was designated as the financial mechanism of the CBD on an interim basis, in accordance with Article 39 of the CBD and relevant decisions of the Conference of the Parties.[118]

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[116] Decision I/2, UNEP/CBD/COP/1/17, Annex II.

[117] See Glowka *et al.,* pp. 100–108 for an in-depth analysis of Articles 20 and 21 CBD.

[118] Nairobi Diplomatic Conference (May 1992), Resolution 1 on Interim Financial Arrangements; CBD COP Decisions I/2, II/6, III/7, III/8, IV/11, IV/12, V/11 and V/12.

Box 46. The Global Environment Facility (GEF)

The Global Environment Facility (GEF) was established in 1991. After the pilot phase from 1991 to 1994, it was restructured in order to respond to criticism of its organizational and structural shortcomings, with the acceptance by 73 States of the Instrument for the Establishment of the Restructured Global Environment Facility ("the Instrument"). The Instrument lays down the fundamental principles of the operation of the GEF.

The objective of the restructured GEF is to serve as a mechanism for international cooperation for the purpose of providing new and additional grants and concessional funding to meet the agreed global environmental needs in the four following focal areas: (1) global warming, (2) pollution of international waters, (3) loss of biological diversity, and (4) depletion of the stratospheric ozone layer. The GEF supports activities in the above areas through projects on a grant or concessional basis. The GEF has adopted a specific programme on biosafety and set aside around US$ 50 million for its implementation.

The GEF is jointly operated by the World Bank, the United Nations Development Programme (UNDP) and the United Nations Environment Programme (UNEP). Its principal mechanism is the GEF Trust Fund. Any member State of the UN or of any of its specialized agencies may become a participant in the GEF by depositing an instrument of participation in accordance with the Instrument. As of October 2002, there were 173 participants. The governing bodies of the GEF are the Assembly and the Council. The Assembly, in which all participating States are represented, reviews the general policies of the GEF, and evaluates its operation on the basis of reports submitted by the Council. The Council is the main governing body, responsible for developing, adopting and evaluating the operational policies and programmes for GEF-financed activities. It is composed of 32 members (16 from developing countries, 14 from developed countries, and two from Central and Eastern European countries).

In accordance with the Instrument, beneficiaries of the GEF are the countries eligible to borrow from the World Bank, or eligible for technical assistance from UNDP, i.e. countries with a per capita income of less than 4000 US$ per year. The following principal criteria for project selection (grants) are applied: (1) the project must benefit the global environment, and (2) it must be innovative. Any country (developed, developing, and transitional) can pledge contributions to the GEF in accordance with the criteria laid down in the Instrument. Contributions by developed countries are roughly in line with a formula based on their shares in the World Bank's International Development Association. For the 2nd replenishment, 28 countries announced pledges to the GEF Trust Fund, including 10 developing countries.

In accordance with Article I(6) of the Instrument and the relevant treaty provisions, the GEF operates the multilateral financial mechanisms of several environmental conventions. It operates the financial mechanism of the CBD on an interim basis. In accordance with Article 28 of the Protocol, it will also operate the financial mechanism of the Protocol.

The negotiations for the third replenishment of the GEF were concluded in August 2002. Thirty-two donor countries agreed on a US$2.92 billion replenishment to fund the GEF's operations in the four year period 2002–2006.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

669. Articles 28(3)–(6) clarify or restate some of the relevant principles contained in Articles 20 and 21 of the CBD. As paragraphs 1 and 2 of Article 28 also contain references to Article 20 and 21 respectively, this means a certain duplication. However, paragraphs 3 to 6 do not restate the principles in exactly the same way, but adjust them to the Protocol. Not all provisions of the CBD are taken up in the Protocol. For example, the Protocol does not contain a provision equivalent to Article 20(4) of the CBD, which links implementation of the CBD by developing countries to the financial assistance they receive for this purpose.

670. Article 28(3) relates to the financial mechanism of the Protocol. It refers to Article 21 of the CBD under which the CBD COP is assigned the authority of determining the policy of the financial mechanism. Under the Protocol, the COP/MOP(see commentary on Article 29) will provide guidance with respect to the financial mechanism as it relates to the Protocol, for consideration by the CBD

COP. Hence the ultimate authority to determine the guidance to the financial mechanism, with respect to the Protocol as well as with respect to the CBD, rests with the CBD COP. This provision is reinforced by the Instrument for the Establishment of the Restructured GEF (paragraphs 6 and 26), which states that the Conferences of the Parties of the CBD for which the GEF acts as financial mechanism shall provide relevant guidance to the GEF.[119] This is a key area of the Protocol in which the CBD COP retains competence.

671. Article 28(3) also establishes a link between the financial mechanism and the provisions on capacity-building set out in Article 22 of the Protocol. It specifies that in setting out the guidelines for the role of the financial mechanism, as it relates to the Protocol, the CBD COP, on the recommendation of the COP/MOP, shall take account of the needs regarding capacity-building as set out in Article 22. In carrying out its role, the GEF shall thus aim to meet the specific capacity-building needs that are enumerated in Article 22(2). As specified in Article 22, the different situations in potential recipient countries must be taken into account. This is important given the great diversity of situations and needs in the different categories of countries that are potential recipients of assistance from the financial mechanism.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

672. Article 28(4) recognizes that certain groups of Parties may have specific needs in capacity-building that need to be reflected in the provision of financial resources for implementation of the Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.

673. This provision refers to the provision of guidance by the CBD COP to the financial mechanism. It is based on Article 21(2) and (3) of the CBD.

674. Article 21(2) CBD stipulates that the CBD COP, at its first meeting, "shall determine the policy, strategy and programme priorities, as well as detailed criteria and guidelines for eligibility for access to and utilization of the financial resources" of the mechanism. In accordance with Article 21(3) CBD, these criteria and guidelines are reviewed periodically.

675. At each of the six meetings of the CBD COP held since the entry into force of the CBD, a decision has been adopted addressing this issue.[120] Thus there already exists a body of guidance to the financial mechanism from the CBD before the adoption of the Protocol. Some of this guidance specifically relates to capacity-building for biosafety.

676. The application of the guidance "*mutatis mutandis*" means that the differences between the CBD and the Protocol that are relevant to the issue must be taken into consideration when applying the guidance to the financial mechanism. In concrete terms, the guidance may be modified in applying it to the Protocol, to the extent necessary to adapt it to the specificities of the Protocol.

677. Future guidance to be developed under Article 28(3) of the Protocol for consideration by the CBD COP will also apply. Article 28(5) ensures a strong link between the policy of the CBD COP with respect to the GEF in relation to the CBD and in relation to the new requirements of the Protocol.

[119] See UNEP/CBD/ICCP/1/INF/2.

[120] CBD COP Decisions I/2, II/6, III/5, IV/13, V/13, VI/17.

Box 47. Financial assistance for biosafety: example

The UNEP-GEF Project on the development of National Biosafety Frameworks

The UNEP-GEF global project on the development of National Biosafety Frameworks is a three year project which started in June 2001. The UNEP/GEF Biosafety Project is part of the GEF "Initial Strategy for assisting countries to prepare for the entry into force of the Protocol on Biosafety"(GEF/C.16/4). The global project is designed to help countries comply with the Protocol, and takes into account the lessons learned from the UNEP-GEF Pilot Project on Development of National Biosafety Frameworks.

The UNEP-GEF Biosafety Capacity Building Project is intended to:

- Assist up to 100 eligible countries to prepare their National Biosafety Frameworks. Using a country-driven process, the global project will help each participating country to set up a framework for management of LMOs at the national level, allowing them to meet the requirements of the Protocol.
- Promote regional and sub-regional collaboration and exchange of experience on issues of relevance to the National Biosafety Frameworks. This will help to make efficient use of financial and human resources, establish regional and sub-regional networks, and promote harmonization of risk assessment procedures and regulatory instruments.
- Provide advice and support to countries throughout the development of their National Biosafety Frameworks.

The total cost of the UNEP-GEF Biosafety Project is $38.4 million. This is funded by a contribution of $26.1 million from the Global Environment Facility (GEF), with co-financing of $12.3 million from UNEP and participating countries. These countries will contribute one third of the costs of their national projects, in cash and/or in kind.

To join the project, countries need to meet the GEF eligibility requirements:

- They must sign or ratify the Protocol on Biosafety;
- They must be eligible for GEF funding;
- They must not have received assistance previously from the UNEP-GEF Pilot Project on Biosafety;
- Their national GEF Focal Point must have formally expressed the country's interest in participating in the Project.

As of 6 October 2002 there were 106 countries participating in the project distributed in the following regions: 31 from Africa, 33 from Asia-Pacific, 16 from Central and Eastern Europe and 26 from Latin America and the Caribbean.

Source: UNEP-GEF project website: www.unep.ch/biosafety

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

678. Article 28(6) re-states the substance of Article 20(3) CBD, according to which financial and technological assistance may be available to developing country Parties and Parties with economies in transition from developed country Parties on a bilateral basis, for example through overseas development assistance. Such assistance may also be available through regional or multilateral channels – such as regional development banks or the World Bank. Some examples of existing bilateral initiatives are given in Box 48.

Box 48. Bilateral assistance for capacity-building in biosafety: examples

A number of countries have initiated bilateral schemes to promote capacity-building in biosafety. For example:

The project to implement the CBD (BIODIV) managed by the GTZ (German Agency for Technical Co-operation – Deutsche Gesellschaft für Technische Zusammenarbeit GmbH) on behalf of the German Ministry for Development and Economic Co-operation (BMZ) is also assisting developing countries with the implementation of the Protocol.

Within this project the current priorities for action are the following:

- policy advice;
- institution building;
  - public administration
  - Biosafety Clearing-House Mechanism
  - monitoring/evaluation/inspection services
- basic and further training of decision makers and experts;
- public awareness raising, education and promotion of public participation.

Support can be given for activities that, *inter alia*, aim at:

- strengthening existing capacities in the field of environmental and health protection, establishing new capacities where needed, assessing the presented risk assessment documents and, if necessary, performing or commissioning independent risk assessment;
- establishing decision mechanisms and structures responsible for the AIA-procedures concerning LMOs and LMO-FFPs that are independent from those public and private institutions which promote and apply modern biotechnology to avoid conflicts of interest and to lay the basis for public confidence in governmental decisions;
- basing governmental decisions regarding the import of LMOs and LMO-FFPs on the precautionary approach as laid down in the Protocol, if necessary;
- facilitating public participation in the establishment of biosafety frameworks and regulations, in the AIA procedure and in the decision procedure;
- including socio-economic considerations into the decision procedure.

Source: GTZ BIODIV website at www.gtz.de/biodiv

Following a request from pre-accession countries in Central and Eastern Europe (CEE), the Dutch Government initiated in 1999 the 3-year project "Implementation of national biosafety frameworks in pre-accession countries of Central and Eastern Europe". The project started in November 1999 and ended in November 2002. The project was funded by the "Matra" programme of the Dutch Ministry of Foreign Affairs and implemented by the Dutch Ministry for the Environment. The aim of this project was to support pre-accession countries in CEE in establishing, workable and transparent national biosafety frameworks in conformity with the relevant EC directives and other international obligations such as the Protocol.

The primary objective of the project was to assist the participating countries in establishing:

- a regulatory framework, consistent with international obligations;
- a system to provide information to stakeholders about the national biosafety framework;
- a mechanism to handle requests for permits for certain activities, such as releases of GMOs into the environment; and
- a mechanism for follow up and feed back, including monitoring and inspections for compliance.

The main mechanism of the project was the transfer of information and experience in tailor-made *training workshops*, created in consultation with the participating countries.

In addition to these training activities on the national level, the project also included *regional activities*, aimed at ensuring sustainability of the results of the project through establishing mechanisms for regional collaboration. On top of these national and regional activities, the project included "*outreach activities*", aimed at broadening the impacts of the project.

Source: http://biosafety-cee.org

A database of biosafety capacity-building initiatives is incorporated in the Biosafety Clearing-House at http://bch.biosafety.org/Pilot

Article 29. Conference of the Parties serving as the meeting of the Parties to this Protocol

1. **The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.**

2. **Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.**

3. **When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.**

4. **The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:**

   (a) **Make recommendations on any matters necessary for the implementation of this Protocol;**

   (b) **Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;**

   (c) **Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non- governmental bodies;**

   (d) **Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;**

   (e) **Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and**

   (f) **Exercise such other functions as may be required for the implementation of this Protocol.**

5. **The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.**

6. **The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol**

shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

679. *Multilateral environmental agreements generally establish a governing body known as the "Conference of the Parties" or "Meeting of the Parties" to steer and supervise the entire process of implementing and further developing the treaty. These bodies are comprised of representatives of all States that are party to the agreement in question, and meet on a periodic basis.*

680. *The legal link between the Protocol and its parent convention, the CBD, means that there is a relationship between the governing body of a Protocol and that of the CBD. In this case, the Conference of the Parties to the CBD (CBD COP) will also serve as the meetng of the Parties to the Protocol. This gives rise to the use of the convoluted term "Conference of the Parties serving as the meeting of the Parties to this Protocol" used in Article 29 and other provisions of the Protocol. This term is generally abbreviated to "COP/MOP". The COP/MOP is the governing body of the Protocol.*

681. *When drawing up Article 29, as well as the other institutional provisions (see commentary on Articles 30 and 31), the approach of the negotiators of the Protocol was to assign the functions to be carried out under the Protocol to the existing bodies of the CBD in order to achieve greater coherence and efficiency between the two instruments, while ensuring the necessary independence of the work under the Protocol. This approach was considered to have several advantages, including avoiding the proliferation of new institutions, and minimizing operational costs. At the same time, the negotiators recognized the need for a certain flexibility to take into account the distinct nature of the Protocol.*[121] *Thus the COP/MOP is considered a distinct and independent body for all practical purposes, save for two issues: the guidance to the financial mechanism, and the costs of Secretariat services to the extent that they cannot be split up between the CBD and the Protocol (see commentary on Articles 28 and 31 respectively).*

682. *Since the Protocol is a separate legal instrument, the functions of the COP/MOP differ to some extent from those of the CBD COP. In addition, the membership of the two bodies is not entirely the same: not all Parties to the CBD (who are represented in the CBD COP) may necessarily opt to become Parties to the Protocol, and those that do not will not be entitled to participate in the decision-making of the COP/MOP.*

[121] See Note by the Executive Secretary of CBD on Rules of Procedure for Meetings of the COP/MOP, UNEP/CBD/ ICCP/2/6, 31 July 2001.

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

683. Article 29(1) establishes the principle that the CBD COP shall serve as the meeting of the Parties to the Protocol (MOP). Article 29(2)-(8) put this into practice by laying down the mode of operation of the COP/MOP.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

684. Article 29(2) addresses who is entitled to participate in the COP/MOP. In meetings held by the COP in its capacity as COP/MOP, States that are Parties to the CBD but not to the Protocol may participate as observers. Observer status is governed by Rules 6 and 7 of the Rules of Procedure of the CBD COP:[122] it means participation without the right to vote. Only Parties to the Protocol may vote and thus take part in the adoption of the decisions of the COP/MOP, which relate to the Protocol.[123] This is a restatement of the principle set out in Article 32(2) of the CBD. Although not entitled to vote, observers may participate in the discussions, make interventions and submit proposals. In practice, some observers play a very active role in the discussions. Observer status for States that are not Parties to the CBD is addressed by Article 29(8).

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

685. Article 29(3) refers to the bureau of the COP/MOP. The "bureau" performs functions relating to the meetings of the COP/MOP, for example: providing guidance to the Secretariat for the preparation and conduct of the meetings of the COP/MOP;[124] organizing the work of the meetings; and chairing informal negotiations during meetings of the COP/MOP. Since the CBD COP serves as the meeting of the Parties to the Protocol, it follows that the bureau of the COP serves as the bureau of the COP/MOP. This means that as a general rule, the bureau of the COP/MOP will have the same composition as the bureau of the COP, as laid down in the Rules of Procedure of the CBD. The bureau of the COP is composed of 11 members: the President; and 10 Vice-Presidents (one of whom also acts as Rapporteur) representing the five UN regions.[125] The bureau is elected at the beginning of each ordinary meeting of the COP. The President then serves from the beginning of that meeting until the beginning of the next ordinary meeting, while the Vice-Presidents serve from the closure of that meeting to the closure of the next meeting. The bureau also serves at any extraordinary meeting of the COP held during its term of office. No bureau member may serve for more than two consecutive terms.[126]

686. In accordance with the overall aim to streamline the institutions and procedures of the CBD and the Protocol while ensuring the necessary independence of the Protocol, Article 29(3) provides that if the bureau of the

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[122] Rules of Procedure for the Meetings of the Conference of the Parties to the CBD, Annex to COP Decision I/1, as amended by Decision V/20.

[123] It should be noted that the rules of procedure of the CBD COP do not presently contain a voting rule for making decisions on matters of substance. The Parties to the CBD have been unable to agree such a rule. Decisions on matters of substance are therefore taken by consensus.

[124] Rule 21 of the Rules of Procedure.

[125] The five UN Regions are Africa, Asia, Eastern Europe, Latin America, and Western Europe and others. Their representation is laid down in Rule 21 of the Rules of Procedure, as amended by CBD COP Decision V/20.

[126] Rule 21 of the Rules of Procedure, as amended by CBD COP Decision V/20.

COP includes one or more members representing States that are not Parties to the Protocol, those members shall be replaced with representatives of Parties to the Protocol when the COP meets as COP/MOP. In keeping with the Rules of Procedure, which apply *mutatis mutandis*[127] to the Protocol, the representation of the five UN regions must be maintained if a replacement is made in accordance with Article 29(3).

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non- governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

687. This provision sets out the functions of the COP/MOP. It corresponds to Article 23(4) of the CBD, which sets out the function of the CBD COP,[128] and is structured in the same way. An introductory provision states the general function of the COP/MOP, and is followed by a list of specific functions. The introductory provision requires the COP/MOP to keep under regular review the implementation of the Protocol and make the necessary decisions to promote the implementation of the Protocol. It goes on to specify that the COP/MOP shall perform the specific functions assigned to it in other Articles of the Protocol as well as the functions listed in Article 29(4) (a)–(e). In addition, subparagraph (f) gives the COP/ MOP the authority to "exercise such other functions as may be required for the implementation of this Protocol". Taken together, this provision and the introductory provision to Article 29(4) ensure that any present and future function needed for the implementation of the Protocol may by carried out by the COP/MOP, even where this is not specifically listed in Article 29(4) (a)–(e).

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

688. The Rules of Procedure and Financial Rules of the CBD[129] were adopted by the CBD COP in accordance with Article 23 CBD. The Rules of Procedure govern, for example, the timing and preparation of the COP, and the conduct of COP meetings. They cover important issues such as decision-making procedures in the COP. The Financial Rules

[127] For an explanation of this term, see commentary on article 29(5).

[128] For a discussion of Article 23 of the CBD see Glowka *et al.*, p.112.

[129] CBD COP Decision I/6, as amended by Decision III/1.

govern the Trust Fund which is used for financing the administration of the CBD, including the functions of the Secretariat.

689. The application of the Rules of Procedure and the Financial Rules "*mutatis mutandis*" means that while the same rules are applied, the differences between the CBD and the Protocol that are relevant to a given issue must be taken into consideration when applying the Rules to that issue. In concrete terms, the rules may be modified in applying them to the Protocol, to the extent necessary to adapt them to the specificities of the Protocol. In addition, the COP/MOP may, by consensus, decide against the application of the rules in particular instances. In a number of instances, the Protocol itself establishes provisions regarding issues addressed by the Rules of Procedure. To the extent that such provisions differ from the Rules of Procedure, they take precedence. Within Article 29, for example, such provisions address the members of the bureau (Article 29(3)); ordinary and extraordinary meetings of the COP/MOP (Article 29(6) and (7)); and observers (Article 29(2) and (8)). In summary, it can be said that the Rules of Procedure and the Financial Rules are applicable to the Protocol, with modifications if necessary, unless the COP/MOP by consensus decides otherwise or if the Protocol itself establishes a different provision.[130]

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

690. Article 29(6) and (7) address the meeting arrangements for the COP/MOP, building on Rule 4 of the Rules of Procedure and taking into account the special relationship with the CBD COP. They are largely self-explanatory. They adhere to the concept of utilizing the existing rules and bodies of the CBD as far as possible while retaining sufficient independence for the Protocol. Article 29(6) harmonizes the schedule for the meetings of the COP/MOP with those of the COP, while Article 29(7) provides that extraordinary meetings of the COP/MOP may be held outside this schedule. Article 29(6) also reiterates that the COP/MOP by consensus may decide on a differing schedule for its ordinary meetings.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present

[130] See Note by the Executive Secretary of the CBD on the rules of procedure for the COP/MOP, UNEP/CBD/ICCP/ 2/6, and ICCP Recommendation 2/5, UNEP/CBD/ICCP/2/15.

object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

691. The provision grants observer status to the UN, its specialized agencies, and the International Atomic Energy Agency, as well as to member and observer States of these organizations that are not Parties to the CBD. Thus, States that are not Parties to the CBD may be represented as observers at meetings of the COP/MOP. As discussed above, States that are Parties to the CBD but not to the Protocol are accorded observer status under Article 29(2). The implications of such observer status are discussed under Article 29(2).

692. Any governmental or non-governmental body or agency may also apply to the Secretariat for observer status. This is granted if the body in question is qualified in matters covered by the Protocol, and unless one-third of the Parties present at a particular meeting object. The mention of Parties "present" indicates that at each meeting of the COP/MOP, an objection can only be made by Parties attending that meeting and thus only with respect to the presence of a non-governmental body or agency at that meeting. The acceptance or rejection of a body or agency is therefore only valid for that particular meeting. At the next meeting, it is possible that a different decision could be taken with respect to the same body or agency, depending on which Parties are present.

693. Applications for observer status are made to the Secretariat. In practice, a large number of organizations attend the open-ended meetings held under the auspices of the CBD. Judging from observer participation at the meetings of the BSWG that negotiated the Protocol, as well as subsequent meetings of the ICCP, the number of observers is also likely to be high at the meetings of the COP/MOP once the Protocol has entered into force. The terms used in Article 29(8) have been broadly construed in the CBD – non-governmental agencies or bodies may include environment, consumer or development organizations, indigenous peoples' groups, academic or research institutions, industry associations or individual companies.

Article 30. Subsidiary bodies

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the Bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

694. *Article 30 addresses:*

- *The performance of functions by subsidiary bodies of the CBD in relation to the Protocol;*
- *Which States are entitled to participate in the proceedings of subsidiary bodies when they are performing functions in relation to the Protocol; and*
- *Who is entitled to act as an officer (or "bureau member") of a subsidiary body when it is performing functions in relation to the Protocol.*

695. *At present there is only one standing subsidiary body established by the CBD: the Subsidiary Body on Scientific, Technical and Technological Advice, established under Article 25 CBD. Under Article 30 of the Protocol, this body could be asked to provide scientific, technical or technological advice to the COP/MOP of the Protocol.*

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

696. Under Article 30(1), the COP/MOP may assign functions related to the Protocol to the subsidiary bodies of the CBD, specifying the functions that the body shall exercise in the context of the Protocol. At present, the body that would appear to be primarily affected by this provision is the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), established in accordance with Article 25 of the CBD. The role of the financial mechanism of the CBD in the context of the Protocol is addressed in a separate provision (see commentary on Article 28).

697. Article 30(1) does not require the consent of the CBD COP to the assignment of functions to the SBSTTA or to any future CBD subsidiary bodies under the Protocol. The CBD COP has adopted a *modus operandi* for SBSTTA[131] which does not specifically envisage it playing a role in relation to the Protocol or responding to requests for advice from the COP/MOP. The question was not specifically raised in the negotiations. It would however become relevant if additional tasks assigned to the SBSTTA under the Protocol significantly add to the workload or costs of SBSTTA. It could be argued that the COP to the CBD may exercise its right to "consider and take any additional action that may be required for the achievement of the purposes of this Convention" (Article 23(4)(i) CBD) to intervene in this event.

[131] Decision IV/16, UNEP/CBD/COP/4/27, Annex 1.

Box 49. Functions of SBSTTA under Article 25 CBD

…

2. Under the authority of and in accordance with guidelines laid down by the Conference of the Parties, and upon its request, this body shall:
   (a) Provide scientific and technical assessments of the status of biological diversity;
   (b) Prepare scientific and technical assessments of the effects of types of measures taken in accordance with the provisions of this Convention;
   (c) Identify innovative, efficient and state-of-the-art technologies and know-how relating to the conservation and sustainable use of biological diversity and advise on the ways and means of promoting development and/or transferring such technologies;
   (d) Provide advice on scientific programmes and international cooperation in research and development related to conservation and sustainable use of biological diversity; and
   (e) Respond to scientific, technical, technological and methodological questions that the Conference of the Parties and its subsidiary bodies may put to the body.
3. The functions, terms of reference, organization and operation of this body may be further elaborated by the Conference of the Parties.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

698. Under Article 30(2), when a subsidiary body of the CBD exercises functions in relation to the Protocol, only Parties to the Protocol may take part in the adoption of any decision the subsidiary body reaches. This follows the approach taken in relation to participation in meetings of the COP/MOP under Article 29. Parties to the CBD which are not Parties to the Protocol may nonetheless participate on observers.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the Bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

699. The Rules of Procedure of the CBD COP also apply, as appropriate, to its subsidiary bodies. The composition and functions of the CBD COP and COP/MOP bureau have been described under Article 29(3). As with the meetings of the COP/MOP, when a subsidiary body of the CBD carries out functions under the Protocol, any member of the bureau who does not represent a Party to the Protocol must be replaced by a representative of a Party to the Protocol.

Article 31. Secretariat

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

700. *This Article makes provision for the Secretariat of the Protocol. The Secretariat's functions are referred to in Article 31(2). One of the main functions of the Secretariat is to administer the Protocol and to act as day-to-day contact point for the Protocol for Parties, international organizations and others. The Secretariat also prepares documentation for meetings of the governing and subsidiary bodies of the Protocol, and is in charge of organizing and servicing the meetings. It is also likely to play an important role in the functioning of the Biosafety Clearing-House (Article 20). Once the Protocol is in force, the COP/MOP may assign additional specific functions and tasks to the Secretariat.*

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

701. Article 31(1) provides that the CBD Secretariat shall serve as the Secretariat to the Protocol. The CBD Secretariat is established under Article 24 CBD. In accordance with a decision by the CBD COP, the Secretariat is provided by the UN Environment Programme.[132] Its offices are in Montreal, Canada.[133] Rules 27 and 28 of the Rules of Procedure of the CBD COP, which lay down practical arrangements for the CBD Secretariat, will also apply to the Protocol Secretariat.

702. Under Article 31(2), the functions of the Secretariat shall be the same as under the CBD. The words "*mutatis mutandis*" mean that the Secretariat functions may be modified when applied to the Protocol, to the extent necessary to adapt them to the specificities of the Protocol (see also Article 29(5)).

703. The Secretariat's functions set out in Article 24 of the CBD are as follows:

(a) To arrange for and service meetings of the Conference of the Parties provided for in Article 23 [of the CBD];

(b) To perform the functions assigned to it by any protocol;

(c) To prepare reports on the execution of its functions under this Convention and present them to the Conference of the Parties;

(d) To coordinate with other relevant international bodies and, in particular to enter into such administrative and contractual arrangements as may be required for the effective discharge of its functions; and

(e) To perform such other functions as may be determined by the Conference of the Parties.

[132] CBD COP Decision I/4, UNEP/CBD/COP/1/17 Annex II.

[133] CBD COP Decision II/19, UNEP/CBD/COP/2/19, Annex II.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

704. Article 31(3) specifies that the costs of Secretariat services for the Protocol shall be met by the Parties to the Protocol *only*, rather than through the overall budget of the CBD (to which all Parties to the CBD contribute). It mandates the COP/MOP to decide on necessary budgetary arrangements at its first meeting.

705. Whereas there was widespread agreement on the principle of separate budgets during the Protocol negotiations, the question of the practicability of this arrangement was raised. In view of the potential overlap of services, tasks and projects to be carried out by the Secretariat in relation to the CBD and the Protocol, it is not likely to be easy to make a clear distinction.

706. Article 31(3) also leaves open the question of who is responsible for making the distinction between costs of secretariat services for the Protocol from those for the CBD. In practice, the Secretariat itself will probably propose a division of costs as far as it considers this possible, and submit this to both the CBD COP and the Protocol's COP/MOP. It is likely that a solution based on practicability considerations will need to be found once the Protocol is in force. The wording of the first sentence of Article 31(3) suggests, in any case, that to the extent that the costs are not distinct or cannot be distinguished, they will be met by the Parties to the CBD rather than only by the Parties of the Protocol.

707. The separation of costs may have practical impacts on the ratification of the Protocol by developing countries. If the Secretariat costs for the Protocol are to be borne by the Protocol Parties only, and if developing countries join the Protocol faster than developed countries (which seems likely to be the case), the costs will be divided among the developing countries that are already Protocol Parties. This may constitute a significant financial burden for the countries in question.

Article 32. Relationship with the CBD

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

708. As explained in the Introduction to this Guide, the CBD is the "parent" Convention of the Protocol. As such, the two instruments are closely linked. The CBD contains a number of provisions which relate not only to the CBD itself, but also to any protocols adopted under it. These are:

- Article 27: Settlement of disputes
- Article 28(2): Adoption of protocols
- Article 29: Amendments to protocols
- Article 30: Adoption and amendments of Annexes
- Article 31: Right to vote
- Article 32(1): Parties to protocols
- Article 34: Ratification, acceptance or approval
- Article 35: Accession
- Article 36: Entry into force
- Article 38: Withdrawal
- Article 41: Depositary

709. Articles 28(2), 32(1) and 38 are fundamental, in particular the fact that, in accordance with Article 32(1) of the CBD, only States and regional economic integration organizations (see Article 3(j)) that are Parties to the CBD may become Parties to any protocol adopted under the CBD.

710. The other provisions are "optional" in that when negotiating protocols to the CBD, Parties to the CBD are free in each case to agree upon different arrangements and to incorporate those into the provisions of the protocol concerned. If they choose to do this, then the special provisions of that protocol will apply. However, if they do not incorporate special rules then the relevant provisions of the CBD on its protocols (above) will apply.

711. In the case of the Protocol, there are a number of issues on which the Protocol does not contain special provisions. Therefore, relevant provisions of the CBD which apply are:

- Article 27: Settlement of Disputes
- Article 29: Amendment to the Convention or Protocols
- Article 30: Adoption and Amendment of Annexes
- Article 31: Right to Vote (but see also Article 29 of the Protocol)
- Article 34: Ratification, Acceptance or Approval
- Article 35: Accession
- Article 41: Depositary

In addition, as noted elsewhere in this Guide, the Protocol creates several additional "links" to the CBD through use of the same institutional arrangements (see commentary on Articles 28–31).

Article 33. Monitoring and reporting

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

712. *This Article imposes two obligations on Parties:*

- *to monitor their implementation of the Protocol, and*
- *to report on measures taken to implement the Protocol.*

713. The obligation to monitor implementation of the Protocol is a logical consequence of the duty of States to implement international obligations which they have accepted by becoming Party to the Protocol. Monitoring is perhaps particularly required in cases, such as this Protocol, where most of the obligations are not self-executing, and thus require national measures, of a legislative, regulatory and institutional character, to enable their implementation.

714. The obligation to prepare reports on implementation for consideration by the governing body of a treaty has become a standard feature of multilateral environmental agreements. The formula used in describing the subject of these reports varies from treaty to treaty. Here the obligation is to provide information on measures to implement the Protocol. The reports will be submitted to the COP/MOP. In practice, they will be submitted through the Secretariat.

715. The intervals at which reports are to be submitted will be determined by the COP/MOP. Many other conventions require such reports to be provided at each meeting of their governing body.

716. The COP/MOP will also give guidance to Parties to the Protocol on the format and content of the reports. This will help to ensure that information is provided in a comparable format.

717. While the obligations of monitoring and reporting are separate, in practice they reinforce one another: Monitoring will provide information needed for the reporting, and, in turn, the requirement to provide reports may provide useful feedback on the way monitoring has operated, and may be improved in the future.

718. For the Parties to implement these obligations, it will be important to have access to, or set up, reliable mechanisms of information gathering and data management at national level.

719. The ICCP adopted two recommendations on monitoring and reporting.[134] The Secretariat prepared a draft general format for reporting for consideration by the ICCP, and the ICCP invited governments to provide comments on the draft format in advance of the first meeting of the COP/MOP. The first meeting of the COP/MOP will consider the format for reporting. The ICCP recognized the need for clear and simple reporting requirements.

[134] ICCP Recommendation 2/2, UNEP/CBD/ICCP/2/15, and ICCP Recommendation 3/7, UNEP/CBD/ICCP/3/10.

Article 34. Compliance

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

720. *Article 34 addresses the need to develop a mechanism to promote compliance of Parties with their obligations under the Protocol. It provides that procedures and mechanisms to promote compliance will be approved at the first meeting of the COP/MOP after the Protocol enters into force. In order to prepare for this, discussions on the nature and functioning of the compliance mechanisms were undertaken by the ICCP.*

721. The focus of the compliance mechanism foreseen in Article 34 is on the compliance of individual Parties with their obligations under the Protocol. This kind of mechanism supplements the review of the collective implementation of the Protocol by its Parties, which is to be carried out by the COP/MOP (see Articles 29(4), 33 and 35). In principle, such a mechanism may identify instances where Parties have not complied with their obligations. The consequence of a finding of non-compliance will depend upon the type of compliance mechanism that is adopted.

722. Article 34 of the Protocol takes the form of a so-called "enabling provision". It does not actually establish a compliance mechanism, but provides a basis and framework for its establishment by the COP/MOP. This is a common way of approaching the issue of compliance in recent multilateral environmental agreements.[135]

723. Although the precise nature of the compliance mechanism to be adopted under the Protocol must await the decision of the COP/MOP, it may be noted at this stage that the core of a compliance mechanism is often a body to which questions and problems regarding individual compliance can be referred. In general, a Party can refer to the body problems it is facing in trying to comply with its own obligations; Parties may also be able to refer matters pertaining to another Party's compliance; and the Secretariat may refer to the body problems identified in reviewing the reports submitted by Parties. The body considers the matter and issues a recommendation for resolving the problem. Access to the body is generally restricted to Parties to the treaty concerned. See Box 50 below.

Box 50. Core elements and characteristics of existing and emerging compliance mechanisms in multilateral environment agreements[136]

Compliance procedures and mechanisms adopted, or under development, under other multilateral environment agreements to date tend to include a number of common core elements and characteristics. These include:

- **Objective**: To promote compliance, to address cases of non-compliance, and to provide advice or assistance to Parties to help them comply
- **Nature**: facilitative, non-confrontational and cooperative
- **Structure**: A small standing committee composed of experts in the relevant subject area, to be nominated and elected by the Parties in accordance with the criteria for composition defined by the parties to the

Cont.

[135] A similar approach was taken in the Montreal Protocol (Article 8), the Climate Change Convention (Article 13), the Kyoto Protocol (Article 18), the Rotterdam Convention (Article 17), and the Stockholm Convention (Article 17).

[136] There are existing or emerging compliance regimes under the following multilateral environmental agreements: Montreal Protocol, Climate Change Convention, Kyoto Protocol, Basel Convention and Rotterdam Convention, as well as a number of environmental agreements adopted within the UN/ECE Region, including the Aarhus Convention.

Box 50. Core elements and characteristics of existing and emerging compliance mechanisms in multilateral environment agreements (cont.)

agreement (e.g. regional representation). One aspect of this issue is whether members of the committee serve in a personal capacity or as representatives of their respective governments.

- **Referral of a compliance problem to the mechanism**: This may be done by a Party with regard to itself; and in some cases by a Party with regard to another Party, or by the Secretariat or other body of the agreement.
- **Functions**: To examine cases of possible non-compliance, with a view to proposing a solution, and to make recommendations for concrete responses to the Parties concerned or to the Conference of the Parties to the agreement.
- **Outcome**: The Conference of the Parties to the agreement generally decides how to implement the recommendations of the compliance mechanism. In some instances, the Parties concerned have to report back on measures taken in accordance with the recommendations.

The mechanisms adopted under the various other multilateral environment agreements adopt different approaches to some of these elements. After considering the recommendation of the ICCP, the COP/MOP to the Protocol will decide on the approach to be taken in the Protocol's compliance procedures and mechanisms.

724. By requiring that the COP/MOP consider and approve mechanisms and procedures to promote compliance and address cases of non-compliance at its first meeting, Article 34 provides both a definite mandate to the COP/MOP and a time frame. This makes it one of the more progressive enabling provisions found in recently negotiated multilateral environmental agreements. Article 34 expressly requires that these procedures and mechanisms shall include provisions on advice and assistance. It also expressly states that future compliance provisions should be separate from the dispute settlement procedure established under Article 27 of the CBD (see Box 51), which also applies to the Protocol (see commentary on Article 32). Beyond that, the elements of the mechanism remain open pending its elaboration by the COP/MOP. The ICCP considered the procedures and mechanisms for compliance at its second and third meetings. It prepared a draft text for consideration at the first meeting of the COP/ MOP, although the text included a number of unresolved issues.[137]

Box 51. Dispute settlement provisions of the CBD

Article 27. Settlement of Disputes

1. In the event of a dispute between Contracting Parties concerning the interpretation or application of this Convention, the parties concerned shall seek solution by negotiation.
2. If the parties concerned cannot reach agreement by negotiation, they may jointly seek the good offices of, or request mediation by, a third party.
3. When ratifying, accepting, approving or acceding to this Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that for a dispute not resolved in accordance with paragraph 1 or paragraph 2 above, it accepts one or both of the following means of dispute settlement as compulsory:
   (a) Arbitration in accordance with the procedure laid down in Part 1 of Annex II;
   (b) Submission of the dispute to the International Court of Justice.
4. If the parties to the dispute have not, in accordance with paragraph 3 above, accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II unless the parties otherwise agree.
5. The provisions of this Article shall apply with respect to any protocol except as otherwise provided in the protocol concerned.

[137] ICCP Recommendation 3/2, UNEP/CBD/ICCP/3/10, Annex.

725. National reports submitted in accordance with Article 33, and the self-monitoring to be carried out by each Party in accordance with that provision, are likely to provide an important basis for the work of a future compliance mechanism.

726. Unlike a dispute settlement procedure, a compliance mechanism is basically a multilateral and non-confrontational instrument. By contrast, a dispute settlement procedure constitutes a legal and institutional framework for solving conflicts or disagreements between two or more Parties. A compliance mechanism can be used as an alternative to, or concurrently with, a dispute settlement procedure. As it is a "softer" mechanism, it is possible that Parties would choose to submit their problem to a compliance mechanism before resorting to dispute settlement under the Protocol/CBD, or to any other relevant dispute settlement procedure. In this sense, a compliance mechanism might help to prevent disputes and thus the need for dispute settlement. It is worth noting that while most multilateral environmental agreements, like the CBD, provide procedures for dispute settlement, these tend to be optional and have not, in practice, been used.

Box 52. Compliance mechanisms under other multilateral environmental agreements

Among the MEAs that are in force, the most mature compliance mechanism is that of the Montreal Protocol on Substances that Deplete the Ozone Layer. It has been operational for several years.

The compliance mechanism of the Montreal Protocol on Substances that Deplete the Ozone Layer

The compliance mechanism was developed on the basis of Article 8 of the Montreal Protocol. It operates independently of, and without prejudice to, the dispute settlement procedure as laid down in Article 11 of the parent treaty to the Protocol, the Vienna Convention for the Protection of the Ozone Layer.

The core of the mechanism is the Implementation Committee, consisting of representatives of 10 Parties, which are elected by the Meeting of the Parties based on equitable geographical distribution. The term of office is two years, with a possibility of serving for two consecutive terms. The Committee meets twice a year. Any Party may, through the Secretariat, bring to the attention of the Committee any reservations regarding another Party's implementation of its obligations under the Protocol, as well as any problems it experiences regarding its own implementation. In addition, the Secretariat may bring to the attention of the Committee cases of possible non-compliance it becomes aware of, in the event that it has not received a satisfactory explanation from the Party concerned.

The Implementation Committee considers the matters submitted to it. It identifies possible causes of the non-compliance. The Party or Parties concerned are entitled to participate in the deliberations of the Committee. Upon the invitation of the Party concerned, the Committee may gather further information on the matter. Based on its considerations, the Committee makes recommendations for the amicable solution of the problem. It submits a report to the Meeting of the Parties, outlining the recommendations made. The report is made publicly available, except where it contains confidential information submitted by a Party. The Party or Parties concerned may not participate in the adoption of the recommendations or in the formulation of the report.

The Party or Parties concerned must subsequently inform the Meeting of the Parties of any measures adopted to improve the situation, in accordance with the recommendations.

The compliance mechanism of the Kyoto Protocol to the United Nations Framework Convention on Climate Change

After several years of work, a compliance mechanism was adopted for the Kyoto Protocol at the 7th meeting of the Conference of the Parties to the Convention in 2001.[138] It is the strongest compliance mechanism in any MEA to date, and atypical in incorporating an "enforcement branch". There is no provision for appeal, except on grounds of procedure.

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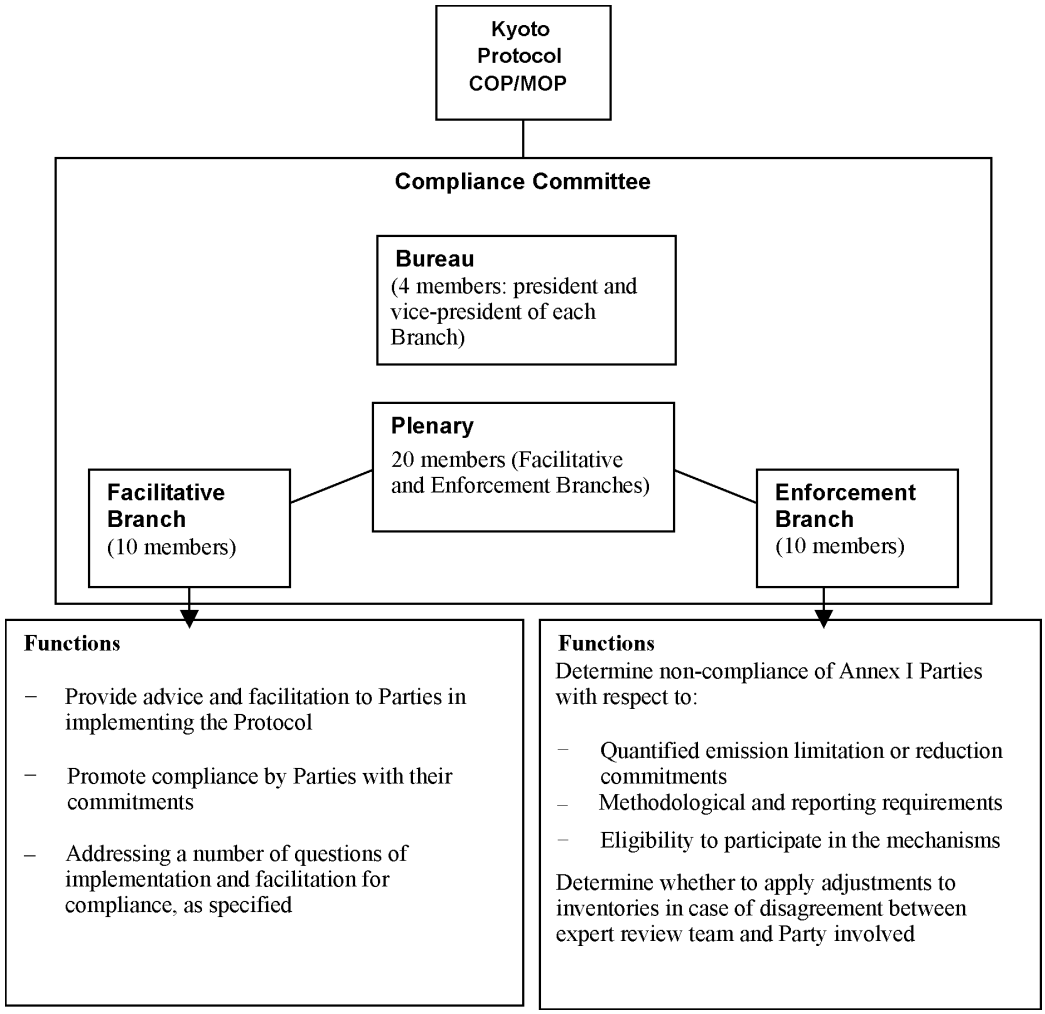
[138] See Decision 24/CP7, Procedures and Mechanisms Relating to Compliance under the Kyoto Protocol, FCCC/ CP/2001/13/ Add.3, 21 January 2002. At the time of writing, the compliance mechanism was not yet in effect.

Box 52. Compliance mechanisms under other multilateral environmental agreements (cont.s)



Article 35. Assessment and review

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

727. Together with Articles 29(4) and 33, this Article provides a basis for institutional supervision of the implementation of the Protocol on a collective basis, and for the monitoring of its effectiveness. This will be undertaken by the COP/MOP.

728. The assessment and review may also provide an important addition to the work of a future compliance mechanism (see commentary on Article 34). In contrast to compliance monitoring under Article 34, the evaluation under Article 35 is undertaken by the COP/MOP not with respect to individual Parties, but looking at implementation of the Protocol as a whole. This could give rise to changes in the procedures or other aspects of the Protocol (for example, through amendment, adoption of additional annexes of other decisions of the COP/MOP) if the evaluation shows that this is necessary to improve the effectiveness of the Protocol.

729. Article 29(4) requires the COP/MOP to review the implementation of the Protocol, and to take the decisions necessary to promote implementation. In addition, Article 35 requires the COP/MOP to undertake evaluations of the Protocol's effectiveness at five- year intervals. The first such review will therefore take place five years after the Protocol enters into force. Both these review processes are likely to be based in part on the information provided by Parties in their national reports on implementation of the Protocol under Article 33. Other sources of information may also play a role in the evaluation. The mechanism and modalities for undertaking the evaluation required under Article 35 will be decided by the COP/MOP.

Article 36. Signature

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

730. Article 36 specifies which entities may sign the Protocol, and the arrangements for signature.

731. The term "regional economic integration organization" is defined in Article 3(j).

732. As of June 5, 2001, 102 States and the European Community had signed the Protocol.

733. By signing the Protocol, States indicate that they intend to become bound by the obligations contained in it. However, signing a treaty does not normally of itself have a binding effect on the State concerned if that instrument requires ratification, as is the case for this Protocol. The Protocol becomes binding in accordance with its provisions on entry into force (see commentary on Article 37). However, after signature, the State concerned is obliged to refrain from acts which could defeat the object and purpose of the instrument.[139] In the case of this Protocol, the objective is set out in Article 1.

734. Article 36 allows "States" to sign the Protocol, while only "Parties to the CBD" may actually become Parties. No State that is not Party to the CBD, however, signed the Protocol before the close of the signature period.

[139] Vienna Convention on the Law of Treaties, Article 18.

Article 37. Entry into force

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

735. *This Article establishes the formal requirements for the entry into force of the Protocol – i.e. when the Protocol will become binding on States or regional economic integration organizations (REIOs). Procedures for ratification, accession, acceptance or approval of the Protocol will vary according to the domestic requirements of the State concerned. However, in each case, in order to become bound by the Protocol, a State or REIO will need to deposit an instrument of ratification, accession, acceptance or approval with the Depositary of the Protocol: the United Nations Secretary General.*

736. Two separate issues are addressed in Article 37:

- when the Protocol itself enters into force as a binding legal instrument (Article 37(1)); and
- when the Protocol enters into force, or becomes binding, on individual States (Article 37(2)).

737. Article 37(1) determines the date of entry into force of the Protocol itself. This is 90 days after 50 Parties to the CBD have deposited their instrument of ratification or acceptance, approval or accession with the Depositary. In accordance with Article 41 CBD, the Secretary General of the United Nations (UN) is the Depositary of the Protocol. In practice, instruments of ratification, accession, acceptance or approval will be lodged with the Treaty Division of the UN Office of Legal Affairs at UN Headquarters in New York, USA.

738. For the first 50 States that have ratified, approved or acceded to the Protocol, the Protocol will enter into force in accordance with Article 37(1).

739. Under Article 37(2), the date of entry into force for States depositing their instruments of ratification, accession or approval after the Protocol itself has entered into force will vary, according to the specific situation of that State, as follows:

- If the State is already a Party to the CBD, the Protocol will enter into force 90 days after the deposit of its instrument of ratification, acceptance, approval or accession to the Protocol. This is also the case if a State becomes a Party to the CBD during this period.
- If the State is not already a Party to the CBD, then even if it deposits the required instrument of ratification, etc. under the Protocol, the Protocol will only enter into force for it on the date that it becomes bound by the CBD – i.e. in order to become a Party to the Protocol, the CBD must also be in force for that State This follows from the CBD requirement that only a Party to the CBD may become a Party to its Protocols (Article 32(1)CBD).

740. Once the Protocol has entered into force for a particular State or REIO, then that State or REIO is described as a Party to the Protocol.

Article 38. Reservations

No reservations may be made to this Protocol.

741. A reservation is a formal declaration by a State, at the time it initiates action needed to become a Party to an international treaty, whereby it announces that it does not consider itself bound by one or more of that treaty's provisions. Reservations must be clearly enunciated and cannot be made at a later date. They may, however, be withdrawn.

742. The text of any international treaty may restrict the right to make reservations, and the Protocol has done this by excluding reservations altogether – as is the case for the CBD (see Article 37 CBD). States that become Parties to the Protocol must therefore accept all its provisions as binding.

Article 39. Withdrawal

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

743. A Party to an international treaty may withdraw from it as prescribed by the treaty itself. The Protocol provisions concerning withdrawal are similar to those prescribed by the CBD (see Article 38 CBD).

744. In addition, under Article 38 of the CBD, withdrawal from the CBD itself automatically triggers withdrawal from any Protocol to which the State concerned is also a Party. This follows from the requirement under Article 32 of the CBD that only Parties to the CBD may be Parties to the Protocol.

Article 40. Authentic texts

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

745. All authentic texts of an international instrument are equally authoritative. The terms of the instrument are presumed to have the same meaning in each authentic text.

746. Cases of discrepancies between authentic language versions may, however, sometimes occur. These may be resolved by negotiation, and amendment of one or more versions.

747. The Protocol was negotiated and adopted in the six official languages of the United Nations and of the CBD.

Annex I. Information required in notifications under Articles 8, 10 and 13

748. *Annex I sets out the minimum information that notifications under Articles 8 (Notification), 10 (Decision Procedure) and 13 (Simplified Procedure) of the Protocol must contain. Under Article 8, the Party of export is responsible for providing, or for requiring the exporter to provide, this information to the competent national authority of the Party of import. Under Article 10(3)(c), the Party of import may request additional information to be provided by the notifier in accordance with Annex I.*

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

749. The name and address of the exporter and importer are to be specified; these will generally be "corporate entities" rather than individuals. The exporter and importer are defined in Article 3 (d) and (f).

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

750. A formal identification of the LMO is required. There may be many varieties of a particular organism on the market, each possibly distinct, uniform and stable. It must be possible to identify the specific LMO in question. A formal identification of the LMO could include any unique identification of the living modified organism that may have been ascribed to it, under any system that may be developed for this purpose (see Box 34).

751. Some States define a system of "biosafety levels" according to which some LMOs may be classified, according to various factors. Each biosafety level prescribes general levels of risk, and may also prescribe general requirements for handling.

752. An example of a classification of biosafety levels is given in EC Directive 90/219, as amended by Directive 98/81/EC, on contained use where risk and containment levels for genetically modified organisms are described as follows:

Class 1: activities of no or negligible risk, that is to say activities for which level 1 containment is appropriate to protect human health as well as the environment;

Class 2: activities of low risk, that is to say activities for which level 2 containment is appropriate to protect human health as well as the environment;

Class 3: activities of moderate risk, that is to say activities for which level 3 containment is appropriate to protect human health as well as the environment;

Class 4: activities of high risk, that is to say activities for which level 4 containment is appropriate to protect human health as well as the environment.

753. It would be possible to designate similar levels for organisms introduced into the environment ranging from those unlikely to impact upon either the environment or human health to those that might be expected to have serious adverse effects on the environment or human health.

754. Where a Party of export applies a system of biosafety levels, the domestic classification of the LMO should be provided as part of the information required under Annex I. It is unclear why the Protocol uses the term "State of export" here rather than "Party of export.

(d) Intended date or dates of the transboundary movement, if known.

755. The information given here will provide countries of import with an indication of the date or dates, if known, on which the notifier would like the transboundary movement to take place, subject to approval being granted by the Party of import. This information is provided to assist Parties of import in monitoring imports of LMOs, including LMOs that are subject to the simplified procedure set out in Article 13.

756. On the exporter's side, there may be constraints on the timing due to, for example, a growing season and the need to begin the use of the LMO at a particular time of the year, or delay for up to one year. The latest date on which the exporter would like to have the LMO in place may, therefore, be of significance.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

757. Paragraphs (e)–(g) require provision of the basic data concerning identification of the organisms that are recipients of any transferred genetic material, and/or of parental organisms, and of those that are used as donors of genetic material. Parental organisms include, first, those that are involved in any crosses that incorporate LMO traits, including any non-LMOs which may be involved in such crosses; and secondly, those organisms which are involved in cell fusion. Donor organisms include all organisms from which genetic material is used to form a gene construct (see Box 16).

Taxonomic status

758. Taxonomic status refers to the biological classification of the organism, using the internationally agreed conventions of biological nomenclature. Organisms are classified into families, genera within those families, and species within each genus. Species may be further classified into sub- species, varieties, cultivars, strains, or other sub-categories. The classification reflects evolutionary relationships: species within a genus are more closely related to each other than to species in other genera, and species and genera within a family are more closely related to each other than to those in other families. The scientific or Latin names of organisms are formally accompanied by abbreviated lists of "authorities" which identify the taxonomists who have made the classification: this provides information that shows if changes may have been made to the classification as a result of new information concerning evolutionary relationships.

Common name

759. Common name refers to the names by which organisms are commonly known, other than their biological or Latin names. Common names for the same organism may vary from area to area: for example, *Zea mays* (Family: Graminea) is known commonly as maize in Europe, but as corn in North America; *Brassica napus* sub-species *oleifera* (Family: Brassicaceae) is known commonly as oil seed rape in Europe, but as canola in North America.

Point of collection or acquisition

760. Article 15 of the CBD requires that access to genetic resources shall be subject to the prior informed consent of the Party providing such resources. This provision within the Protocol to provide information on the point of collection or acquisition, makes it possible to ensure that such consent has been provided.

Characteristics … related to biosafety

761. Characteristics related to biosafety would suggest that the information to be provided may be expected to cover any characteristics already identified by the Party of export and/or the exporter that may be related to possible adverse effects identified in a risk assessment, or as a result of observations subsequent to a risk assessment, and any other known characteristics which may represent risk of possible adverse effects in the potential receiving environment.

Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate

762. A centre of origin is the term used to describe the area where a particular organism was first domesticated and brought into use by humans. The centre of origin for sheep is in the Middle East; the centre of origin for potatoes is in the Andes. Centres of origin may still retain a very high diversity of the genetic resource base and related wild relatives from which the organism concerned was domesticated.

763. A centre of genetic diversity is the term used to describe an area where there is a high diversity present amongst a particular group of related species – either within a family, genus, or of sub-species, varieties, cultivars, strains, or other sub-categories within a species. Mexico, for example, is recognized as a centre of genetic diversity for maize.

764. Because of the importance of the genetic diversity in centres of origin or of diversity, efforts may be in place to conserve and protect them and the genetic resources which they contain. Many such centres are found in developing countries. During the negotiation of the Protocol countries which host such centres stressed the importance of the genetic resources which they contain for their domestic agriculture, and for the world as a whole, and called for the specific biosafety issues in relation to such centres to be referenced in the Protocol. The level of diversity amongst closely related species may lead to a higher likelihood of gene transfer from a LMO of a similar species to naturally- occurring, wild or cultivated relatives which may be present with a higher frequency in centres of genetic diversity or origin than elsewhere. Therefore the introduction of a LMO of a similar species to naturally-occurring, wild, or cultivated relatives in centres of origin or genetic diversity, and any possible adverse effects in the context of such centres, may need to be given particular attention in a risk assessment.

A description of the habitats where the organisms may persist or proliferate

765. Organisms generally tend to grow and reproduce better in some habitats than in others. This depends on a variety of ecological factors, including climatic conditions, the presence or absence of predators, disturbance or particular stress factors. If a LMO is introduced into habitats where the recipient organism and/or the parental organisms may persist or proliferate, then it may be expected that the LMO may also have the potential to persist or proliferate in such habitats. The provision of information on such habitats may help in identification of possible adverse effects that may need to be given particular attention in a risk assessment.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

Description of the nucleic acid … introduced

766. It is important that a description of the nucleic acid introduced into the recipient organism be available. It provides information about all the genes including control elements that have actually been introduced, for example, through the use of a gene construct (see Box 16). In general, if there is introduced nucleic acid, then it will contain a number of elements with functions important to the production of a gene product; to the amount of gene product produced and the organelles or tissues in which the genes are expressed; to the selection of the modified organisms from amongst those that have not been successfully modified; and other

control elements which are part of genes. These are important in considering how the introduced genetic information may be expressed in the modified organism.

767. It should be noted that in most cases, although the complete sequence of the introduced nucleic acid or gene construct is known, the sequence of the genome into which it is placed is not known. In general more than one copy of the introduced nucleic acid may occur in the new organism. Multiple copies may affect the introduced genes, either reducing or increasing their activity, and therefore further affect the characteristics of the modified organisms.

768. The information to be provided is a description of the nucleic acid introduced into the recipient organism in order to modify that organism to create a LMO – this relates to the use of *in vitro* nucleic acid techniques. How the description is to be made is not specified, but it may be assumed that the description would include details of the genetic material introduced, such as the sequence of nucleotides along with details of the origin of the various parts of the sequence from donor organisms, or from chemical synthesis or modification, and the functions of those parts. In some cases, rather than simply extracting a gene from one organism and then introducing it into a recipient, laboratory modifications may be made artificially to attempt to improve the manner in which that gene is expressed in the recipient organism.

Description of … the modification introduced

769. Introduction of nucleic acid into the recipient organism is intended to produce modifications to that recipient resulting in a LMO. Information is to be provided on the modification that is introduced in the LMO. Introduction of the same nucleic acid sequence to cells of the same recipient can result in a range of different effects for reasons that are not fully understood, but which may in part be related to the way in which the introduced nucleic acid becomes associated with the genome of different recipient cells.

770. Where cell fusion is used to introduce modifications to produce a LMO, it is unlikely that detailed information will be available on the sequences of the nucleic acids involved in the modifications that result, since the technique results in exchange and possible recombination and segregation of genes and chromosomes. In such cases, information may only be available concerning the modifications introduced.

The technique used

771. As defined in the Protocol, modern biotechnology refers to application of *in vitro* nucleic acid techniques, or of techniques for fusion of cells beyond the taxonomic family. Within these categories there are many variants and different types of techniques: the particular technique used in producing a LMO may affect the nature of the modification introduced, its stability, or other aspects of the modification. Annex I(h) requires information on the technique used to introduce the nucleic acid and/or modification to be provided.

The resulting characteristics of the living modified organism

772. This refers to the characteristics that result from the nucleic acid and/or the modification introduced to produce a LMO. The resulting characteristics refer to the actual characteristics that result from the introduction of the nucleic acid or modification, which may differ in degree and detail from the characteristics that it was intended to introduce. For example, in the modification of trout, through *in vitro* nucleic acid techniques, to create genetically modified trout that express high levels of growth hormone, considerable variation can be found between the growth of the different recipient individuals and their offspring. The resulting characteristics of the introduced modification include expression of growth hormone at a particular level, a particular growth rate, any effects that may have resulted concerning maturation, reproduction, etc. in the trout, and the spread or variability in the way these characteristics are manifest in different individuals.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

773. Information is required on the intended use(s) of the living modified organism, or the products of the LMO. The information concerning products of LMOs is only required in relation to products that contain detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology. This reflects concern that the genetic material in products might, under some circumstances, be transferred in a viable state to other organisms, resulting in their transformation by that novel genetic material. If genetic material is present, it may be capable of being replicated under some circumstances (e.g. if it is taken up by an organism and enters its cells) if introduced into another organism.

774. Depending on processing, nucleic acids may be removed from purified products during the processing steps. If nucleic acids containing the novel combination of genetic material are not present in a product, there can be no risk of transfer of a genetic modification to another organism. Therefore information concerning a processed product that does not contain detectable novel combinations of replicable genetic material is not required. Products vary in their nucleic acid content. For example, refined sugar is highly purified and does not contain nucleic acids under normal conditions; flour obtained by milling of grain will contain nucleic acids; oils obtained by various methods of extraction may generally contain some nucleic acids, often as short sequences of nucleotides (less than 50 nucleotides in length), but under some conditions as longer sequences that may be equivalent to the length of some genes.

(j) Quantity or volume of the living modified organism to be transferred.

775. The quantity, volume or amount of a LMO that it is intended to transfer, may affect the level and exposure of the potential receiving environment to the LMO. The way in which this information is provided may vary according to the type of LMO concerned – examples of the type of information that might be provided could include: 5000ml of a 10^7 bacteria per ml suspension; 5 tonnes of seed; 20 individuals (e.g. fish).

776. Any differences in level and exposure to the LMO concerned need to be taken into account in the risk assessment.

(k) A previous and existing risk assessment report consistent with Annex III.

777. The availability of any existing or previous risk assessments provides the Party of import with a point of reference for their own risk assessment. Existing or previous risk assessments, while containing information relevant to release of the LMO concerned, may not provide a complete picture as the receiving environment into which the release is to occur, and the biodiversity it contains, may be very different from those for which previous risk assessments have been performed elsewhere.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

778. If an organism has been used elsewhere, conditions for its handling etc. may have been specified following a previous risk assessment and would provide information that could be of assistance on these issues to the Party of import. Information is required on suggested methods for safe handling, storage, transport and use, including any requirements that may be necessary according to specific circumstances in the Party of import and/or the intended use of the LMO in the Party of import.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

779. The purpose of paragraphs (m) and (n) is the sharing of information on action taken in the Party of export, and in other States, in relation to the LMO concerned. It is, for instance, important that Parties of import are aware of any restrictions that any other countries may have imposed on the use of these organisms within their territories and their reasons for this, so that similar considerations may be assessed by the Party of import in its risk assessment and/or in the decision procedure.

(o) A declaration that the above-mentioned information is factually correct.

780. This declaration must be supplied by the notifier, which will be either the Party of export or the exporter as set out in Article 8(1). It should be recalled that, if the Party of export requires the information to be provided by the exporter, then Article 8(2) requires the Party of export to ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Annex II. Information required concerning living modified organisms intended for direct use as food or feed, or for processing under Article 11

781. *Annex II sets out the information required in relation to Article 11 (Procedure for LMO-FFPs). It is similar to that set out in Annex I, and is designed to serve the same purpose, except that the information in this case is to be provided to all Parties generally through the Biosafety Clearing-House. Most of the comments provided relating to the provisions of Annex I apply similarly to the equivalent provisions of Annex II, except that it is recognized that LMOs intended for direct use as food or feed, or for processing, are not intended for release into the environment, and that, therefore, it is only where they are inadvertently or accidentally released that they might pose a problem to the environment.*

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

782. The "applicant" here is the person or entity that submits an application relating to the domestic use of a LMO-FFP in the Party that makes a final decision on such use under Article 11. The "authority" in paragraph (b) is the relevant authority of that Party.

(c) Name and identity of the living modified organism.

783. See commentary on Annex I(c). Annex II(c) differs from Annex I(c) in that it does not include a specific requirement for the domestic classification, if any, of the biosafety level of the LMO in the country where the decision is made. However, any information on this may be required and provided as part of information provided under Annex II(i), (j) and/or (k) below.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

784. See commentary on Annex I(h). Annex II(d) differs from Annex I(h) in its reference to the "gene modification", rather than to the "nucleic acid or the modification introduced". However, since genes are lengths of nucleic acid, the difference in wording between Annex II(d) and Annex I(h) is not significant, and the same information is to be provided in relation to both of the provisions.

(e) Any unique identification of the living modified organism.

785. Work is underway to develop an international system of unique identifiers that would apply to each individual modification. The unique identifier system is similar in concept, for example, to the ISBN system for book publishing. The unique identifier would take the form of a code that would then provide a link to a database which would include full information about the specific modification to which the unique identifier referred. Guidance on an unique identifier for transgenic plants has been developed by an OECD working group (see Box 34).[140] Further information on progress on development of a unique identifier system for the Protocol can be found through the Biosafety Clearing-House website.

[140] OECD (2002). OECD Guidance for the design of a unique identifier for transgenic plants, *Series on Harmonization of Regulatory Oversight in Biotechnology* No. 23, OECD, Paris.

786. Under the unique identifier system, an identifier would be given to each modification event. For example, modification of a plant by introduction of the Bt toxin gene into two different individuals of the same species would represent two separate modification events, each of which, if commercialized as LMO-FFPs, would be allocated a unique identifier. If, for example, a cross were to be made between a LMO containing a Bt toxin gene modification and a LMO containing a herbicide resistance gene modification, the resultant LMO progeny from that cross would contain two separate modifications, which would therefore be indicated by the use of the two relevant unique identifiers. Alternatively, a further unique identifier could be allocated for the particular combination of modifications created by such a cross.

787. The system for unique identifiers, when it is developed and implemented, will assist the identification and monitoring of LMO-FFPs that have been approved by one or more national authorities, and will also assist the flow of information between Parties and their competent authorities, and with the public.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

788. See commentary on Annex I(e).

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

789. See commentary on Annex I(f).

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

790. See commentary on Annex I(g).

(i) Approved uses of the living modified organism.

791. Information on approved uses of the LMO may also be expected to include information on any restrictions or conditions that the authority responsible for the decision (as described under Annex II(b)) may have set in giving approval for particular uses of the LMO. (See also commentary on Annex I(m)).

(j) A risk assessment report consistent with Annex III.

792. See commentary on Annex I(k).

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

793. See commentary on Annex I(l).

Annex III. Risk assessment

794. *This Annex provides details on the risk assessment required under Article 15 of the Protocol, in particular regarding:*

- *objective of risk assessment;*
- *use of risk assessment;*
- *general principles for risk assessment; and*
- *methodology for risk assessment.*

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

795. Assessment of risk is intended to identify and evaluate potential adverse effects of LMOs on the conservation and sustainable use of biological diversity taking also into account risks to human health.

796. Risk assessment is linked to the likely potential receiving environment. It will often be necessary to assess risks of potential adverse effects of LMOs at various stages of their development and use, in relation to the potential receiving environment e.g. at the field test stage, and again before permitting the widespread release or marketing of LMOs.

797. Risk assessments will need to take into account new developments in applications of modern biotechnology – for example, some LMOs are designed to produce pharmacologically active compounds and industrial feedstocks, and in the future LMOs may be designed to produce a range of other compounds. Risk assessments will need to consider the possible impact on biological diversity and on human health in these circumstances, and identify the measures needed to avoid or minimize risk.

Use of risk assessment

2. Risk assessment is, *inter alia*, used by competent authorities to make informed decisions regarding living modified organisms.

798. The main purpose of risk assessment undertaken in accordance with this Annex and Article 15 is to provide information to be taken into account in the decision procedure under Article 10, and to provide a basis for risk management mechanisms, measures and strategies under Article 16 on risk management.

799. Thus, the risk assessment is to be used by Parties in order to make informed decisions as to whether or not to approve an import of the LMO concerned, and whether or not to attach any conditions, including requirements for risk management measures, to any approval. It is also to be used in relation to Article 11 on LMO-FFPs. In relation to Article 11, Annex II calls for a risk assessment report consistent with Annex III to be made available; and under Article 11(6) a Party without a domestic regulatory framework for LMO-FFPs may make a decision on import of a LMO-FFP on the basis of a risk assessment undertaken in accordance with Annex III.

800. Parties which lack adequate human, technical or other capacity relevant to risk assessment may utilize assistance through the roster of experts established under COP decision EM-I/3.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

801. The points covered in this provision are discussed in the commentary on Article 15, which includes consideration of the relevant scientific expertise that may be needed in carrying out a risk assessment. (See commentary on Article 15(1)).

802. The statement that risk assessment should be carried out in a "scientifically sound and transparent manner" suggests that risk assessment is to be undertaken in a systematic way, and that each risk assessment should provide sufficient information to enable others to repeat the stages of the risk assessment independently.

803. Annex III(3) refers to the possibility that expert advice of and guidelines developed by international organizations may be relevant and be taken into account in the course of risk assessment. Examples of such advice and guidance would include the UNEP Technical Guidelines on Biosafety, and the work of the OECD in relation to biosafety. Existing or future work of other international or regional organizations may also be relevant.

804. Parties may also call on the Protocol's roster of experts for advice and guidance to assist them in undertaking risk assessments.

4. 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.

805. This is a reflection of the precautionary approach in relation to risk assessment. With regard to biosafety, it may be that there are gaps in the information available in relation to some aspects of risk assessment. For example, where ecological issues are being considered, and/or where the number of variables may be such as to make prediction difficult or virtually impossible. In some circumstances, data needed may be absent or even unobtainable (see commentary on Article 15(1)). The risk assessment might result in the identification of areas that need further research, or may indicate that even where further research is identified, the risk assessment may remain equivocal.

806. Such circumstances are addressed in Article 10(6) and 11(8), which allow a Party of import to take a decision in these circumstances, in order to avoid or minimize potential adverse effects.

807. Annex III(4) also recognizes that where there may be a lack of scientific knowledge or consensus on relevant issues, different countries may legitimately decide to make different choices in relation to the acceptability of any given level or type of risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

808. This provides a point of reference for risk assessment. To assess the behaviour of a LMO in any environment requires extensive observation and testing. It may assist in the assessment of the possible adverse effects and associated risks of LMOs, if it is possible to consider the risks posed by the similar, non-modified varieties of the same organism, or the parental organisms, for example, through an understanding of the habitats where those organisms may persist or proliferate.

809. Annex III(5) includes a requirement for consideration of the risks posed by processed materials that are not themselves LMOs but which still contain "detectable novel combinations of replicable genetic material". Processed materials that as a result of processing do not contain genetic material, even though they contain the LMO product, are not required to be considered. For example, flour made from seeds of an LMO will still contain genes that might in some circumstances be replicable, and would therefore need to be considered in the risk assessment; refined sugar, however, would not normally contain genetic material, and would therefore not need to be considered by the risk assessment.

810. Processed LMO materials contain LMO products, even where the nucleic acid is not present itself – for example, if the oil content and composition of an oilseed has been modified through genetic modification, then the extracted oil will exhibit the new characteristics whether or not the nucleic acid is present in the final product. If this is for food or feed, then allergenic properties of the LMO product(s) may be important. If a modified

organism has been modified to produce pharmacologically active compounds, then the presence of those compounds rather than only the nucleic acid alone will be important to any risk assessment. (See also commentary on "products thereof" under Annex I (i)).

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

811. The case-by-case basis is fundamental to risk assessment of LMOs. A case-by-case approach is one where each release of a LMO is considered relative to the environment in which the release is to occur, and/or to the intended use of the LMO in question. A risk assessment performed for a particular LMO intended to be introduced to one environment may not be sufficient when assessing the possible adverse effects that may arise if that LMO is to be released under different environmental conditions, or into different receiving environments. A risk assessment performed for a particular use of a particular LMO may not be sufficient when assessing the possible adverse effects that may arise if that LMO is to be used in different ways. Because of this, it is important for each case to be addressed separately, taking into account specific information on the LMO concerned, its intended use, and its potential receiving environment.

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

812. As each risk assessment proceeds, it may become apparent that further information is needed on certain subjects, while information that may be available concerning other subjects may not be relevant in certain cases. One example of where further information may be needed is where a risk assessment carried out in relation to one receiving environment is used as a point of reference for a risk assessment relating to release of the same LMO into a different receiving environment. Differences between the receiving environments may mean that the profile of risks to be considered, and their likelihood and consequences, are also different. Further information may therefore be required in order to assess risks in relation to the potential receiving environment. This information might be obtained through various means, including through the undertaking of more research, monitoring, or assistance from experts.

Methodology

813. This section of Annex III sets out the methodology for risk assessment to be used in the context of the Protocol. Some general comments on risk assessment are made in the commentary on Article 15.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health

814. The risk assessment entails identification of each adverse effect that may arise from modification of the genotypic and/or phenotypic characteristics of the LMO and its introduction to a potential receiving environment, taking into account risks to human health.

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism

815. Once the possible adverse effects have been identified, the likelihood of each of these being realized is to be evaluated.

(c) An evaluation of the consequences should these adverse effects be realized

816. The evaluation of the consequences of possible adverse effects, should they occur, is undertaken separately from the evaluation of the likelihood of those adverse effects occurring. The consequences of adverse effects, should they occur, may take many forms, including damage to biodiversity, damage to genetic resources, damage to livelihoods, damage to agriculture, etc., and also include the magnitude of any damage. The consequences may arise either directly as a result of the adverse effect occurring, or indirectly through a chain of events as a result of the occurrence of the adverse effect. Adverse effects may arise in the short-term, or may only become apparent on a longer time-scale.

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized

817. Estimation of the overall risk brings together both the evaluation of the likelihood that a possible adverse effect may occur, and consequences of the identified adverse effect should it occur. Risk may be expressed qualitatively or quantitatively in risk assessments. Estimation of overall risk will also need to take into account the precautionary approach that is embodied in the Protocol's objective, and to highlight areas of uncertainty, for example where there is a lack of knowledge concerning aspects of key risk.

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks

818. Annex III(8)(e) requires a recommendation, made by those undertaking the risk assessment, as to whether or not the risks of potential adverse effects that have been identified in the risk assessment are acceptable, or manageable – and if so how. The recommendation will be considered by the decision makers in reaching their decision on import.

819. No definition of, or methods for assessing, acceptability or manageability are provided in the Protocol.

820. Considering the acceptability of a given risk is complex, and may involve many factors. A potential adverse effect which has a low likelihood of occurrence, but which would have serious consequences in the (unlikely) event that it should occur, may be less acceptable than a potential adverse effect which has a high likelihood of occurrence, but which would have only small consequences in the (likely) event that it should occur, even if the overall estimate of risk in both instances were similar. It is therefore important to consider acceptability in the context of both nature of the risk, and the nature of the consequences. Furthermore a level of risk which might not be acceptable in one Party or region, may be acceptable in others elsewhere. (See also Appendix, paragraphs 905–908).

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment

821. Paragraph (f) suggests that it may be possible to address uncertainties concerning a particular level of risk by obtaining further information – to seek to resolve the uncertainty – or by implementing appropriate risk management strategies.

822. It may also be possible to address uncertainty by monitoring the LMO in the receiving environment. This would provide further information on the LMO, and should any adverse effects be detected, would enable additional appropriate risk management measures to be

instituted. In many cases, monitoring of the LMO may be required in any case for regulatory purposes once approval has been given for its use and environmental release.

823. It may be relevant to consider these possibilities in formulating recommendations under Annex III(8)(e). This provision may be taken into consideration along with other provisions – such as that of Annex III(6) – that set out the need that may arise for further information to be obtained in order to complete the risk assessment, and does not obviate the importance of obtaining such information prior to a decision being made under the decision procedure in Article 10.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

824. Annex III(9) sets out a range of factors that may need to be considered in a risk assessment, depending on the particular case. Not all points will necessarily be relevant to every case. Other subjects may also need to be considered depending on the specific case. Technical and scientific information relevant to the case being considered is required, including information supplied in the notification under Annex I.

825. Where a need for further information is identified during the risk assessment, obtaining this information may, as appropriate, require further research, testing, field trials, expert advice or other activities, in order to provide sufficient technical and scientific details regarding the characteristics of the subjects listed in paragraphs 9(a)–(h). (See also commentary on Annex III (6)).

(a) *Recipient organism or parental organisms*. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate

826. The wording of this paragraph is similar to that of Annex I(e) and (f).

827. There is one significant difference in the reference here to "biological characteristics", and "characteristics … related to biosafety" referred to in Annex I(e). Biological characteristics may be assumed to refer to any biological characteristics, and the wording here would seem to allow for all such characteristics to be taken into account in risk assessment, rather than only the information on characteristics of LMOs related to biosafety that is to be supplied under Annex I(e).

828. On the "description of the habitat where the organisms may persist or proliferate", see commentary on Annex I(f).

(b) *Donor organism or organisms*. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms

829. The wording of this clause is similar to that of Annex I(g).

(c) *Vector*. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range

830. A vector is an organism or object used to transfer genetic material from a donor organism to a recipient organism (see also Box 16).[141] Paragraph (c) notes the need to take into account in risk assessment, the characteristics of the vector, its identity, its source or origin, and its host range. The characteristics of the vector could include its nucleic acid sequence, as well as any characteristics concerning the way it interacts with its hosts, or the way it is used to transfer genetic material. The identity of the vector will be given by a standard code or name given to the vector. The source or origin of the vector refers to the original source from which the vector was isolated, and may include the

[141] *UNEP Technical Guidelines for Safety in Biotechology* (1995) Annex 2, paragraph 23.

laboratory or facility where it was first isolated. The host range describes the range of organisms (species, or sub-species, etc.) with which the vector is capable of interacting.

(d) *Insert or inserts and/or characteristics of modification*. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced

831. A similar provision is included in Annex I(h) (see commentary on Annex I(h)).

832. "Insert" refers to the nucleic acid introduced into an organism through the application of *in vitro* nucleic acid techniques. "Modification" refers to modifications to the genetic material introduced by the application of modern biotechnology – covering *in vitro* nucleic acid techniques, and cell fusion techniques.

833. Information concerning the nucleic acid introduced and the function that it specifies is to be considered. The characteristics of the modification introduced are also to be considered, referring to the modifications that are actually obtained, and not just to what it may have been intended to obtain, bearing in mind that introduction of novel genetic material into an organism may result in a variety of effects being manifest.

(e) *Living modified organism*. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms

834. Information on the differences between the biological characteristics of the LMO and those of the recipient organism or parental organisms, may help in considering how a LMO may behave in relation to the recipient organism or parental organisms. Differences in biological characteristics could cover both the direct effects of the modification introduced to the LMO that may include biochemical changes, behavioural changes and physical or growth changes; and indirect effects, for example, effects on other organisms that may feed on or be associated with the recipient or parental organisms. Such differences may affect its behaviour, including its ability to persist and propagate, in the potential receiving environment.

(f) *Detection and identification of the living modified organism*. Suggested detection and identification methods and their specificity, sensitivity and reliability

835. It is important for regulatory authorities to be able to detect and identify each LMO, and the product(s) of each LMO, in order to monitor their transboundary movement, handling and use. It is generally not possible by visual inspection to distinguish between LMOs and non-LMOs of the same species or sub-species. A range of tests that enable LMOs to be detected, are available, and are based on detection of the novel genetic material introduced into a LMO, or on the gene-products that are produced as a result of incorporation of that genetic material. Tests to detect LMOs are continually being developed, and are increasing in their specificity, sensitivity and reliability.

836. In the absence of specific, sensitive and reliable detection and identification methods, it may be difficult to implement risk management measures and/or monitoring, effectively.

(g) *Information relating to the intended use*. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms

837. Information on the intended use of the LMO needs to be taken into account in the risk assessment. However, unlike Annex I(i), which refers to intended uses of LMOs or their products, Annex III(g) does not mention products of LMOs. However, products may be regarded as an aspect of an intended use, and since Annex I specifies that information on products of LMOs is to be provided by the notifier, it would seem that there is an intent for such information to be taken into account in risk assessment and in the decision procedure. Paragraph (5) of Annex III also refers to consideration of risks associated with products of LMOs.

838. Paragraph (g) notes that new or changed use compared to the recipient organism or parental organisms may need to be taken into account. An example of such a new or changed use is where an organism normally used for one purpose is modified to be used for a significantly different purpose, as is the case with the modification of oil seed rape (canola) to produce high concentrations of biochemicals for specific use as feedstocks for industrial processes, rather than its normal use to produce oil for food or feed purposes. Similar considerations apply where organisms are modified so as to produce pharmaceutically active compounds.

(h) *Receiving environment*. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment

839. A potential receiving environment is an ecosystem or habitat, including humans and animals, which is likely to come in contact with a released organism.[142]

840. The potential adverse effects that may result from introduction of a LMO into a particular receiving environment, depend on the interaction between the LMO, the physical conditions of the environment, and the other organisms present in that environment.

841. Relevant information might include:[143]

- the geographical location of the site, the identity and any special features of the receiving environments that expose them to damage;
- the proximity of the site to humans and to significant biota;
- any flora, fauna and ecosystems that could be affected by the release, including keystone, rare, endangered or endemic species, potential competitive species and non-target organisms; and
- the potential of any organism in the potential receiving environment to receive genes from the released organism.

842. The climatic and ecological characteristics of the receiving environment, including relevant information on biological diversity and centres of origin (see commentary on Annex I(f)) are to be considered when undertaking the risk assessment.

843. The characteristics of the receiving environment may affect the way a LMO might behave in that environment. They may also indicate particular sensitivities in the receiving environment and the organisms its contains, which need to be taken into account.

[142] *UNEP Technical Guidelines for Safety in Biotechology* (1995) Annex 2, paragraph 18.

[143] *UNEP Technical Guidelines for Safety in Biotechology* (1995) Annex 3.

Appendix. The Cartagena Protocol and the World Trade Organization

The purpose of this Appendix

844. The purpose of this Appendix is to describe the potential interaction between the Protocol and the rules and institutions of the World Trade Organization (WTO). It is not the intention of this Guide, by highlighting the relationship between the Protocol and the WTO, to suggest that this interaction will lead to conflicts or to formal legal disputes. Instead, this analysis recognizes that Parties to the Protocol that are also WTO Members will need to take into account aspects of both regimes when regulating the intentional transboundary movement of LMOs. Not all Parties to the Protocol may be WTO Members, and WTO rules will not apply to those Parties. There may be WTO Members that are not Parties to the Protocol. Such countries may view WTO rules as being the only rules that apply to their trade in LMOs with Parties to the Protocol. If Parties to the Protocol are aware of the potential interactions between the Protocol and the WTO they can more effectively endeavour to ensure that their obligations under both regimes are implemented in a "mutually supportive" manner.

845. This analysis also recognizes, however, that there are instances where Protocol provisions either require, authorize, or could provide a justification for, measures that may slow or stop the flow of trade in LMOs between WTO Members. The basic objectives of the two regimes, one to protect biological diversity, taking also into account risks to human health, the other to promote free trade, are not inherently incompatible, but are also not identical. Thus, although there is no immediately identifiable conflict between what each regime requires of countries, the fact that both deal with the same area of activity, raises a possibility that individual countries could arrive at different interpretations in the context of a specific application of their rights and obligations.

846. This Appendix is structured to respond to a series of issues and frequently asked questions that have arisen while the Guide was prepared. These include:

- What is the WTO?
- Do the Protocol and the WTO overlap?
- What kinds of trade-related measures are required, authorized or justified under the Protocol?
  - Notification and identification requirements.
  - Risk assessment procedures.
  - Import bans or other trade restrictive measures.
- Is it relevant whether a trade-related measure taken under the Protocol is required or authorized by the Protocol?
- Which WTO Agreement would apply to a trade-related measure taken under the Protocol?
- How will the WTO system take into account the Protocol?
- How might Protocol-based measures be tested under WTO rules?
  - Rules against trade bans: GATT Article XI.
  - Rules against country-based discrimination.
  - Rules against indirect discrimination.
  - Exceptions to GATT rules for measures that protect the environment and human, animal and plant health.
  - Ensuring that measures are "no more trade restrictive than necessary" under the Agreement on Technical Barriers to Trade and Agreement on Sanitary and Phytosanitary Measures.
- Which WTO rules are relevant to risk assessment under the Protocol?
  - Precaution and risk assessment.
  - Socio-economic considerations in risk assessment.
  - Carrying out and funding risk assessment.
- Which WTO rules are relevant to risk management under the Protocol?
- Which WTO rules are relevant to transparency and timing of decision-making under the Protocol?
- How might a Protocol-related dispute arise at the WTO?

- Could a non-Party to the Protocol challenge a Protocol-based measure under the WTO?

What is the WTO?

847. The World Trade Organization is an intergovernmental organization that is the institutional successor to the General Agreement on Tariffs and Trade (GATT). The WTO was established in 1995 and has a Membership of 144 countries and customs territories, including the European Communities. The WTO is responsible for administering the WTO Agreements – multilateral trade agreements that regulate the international trade in goods and services and the protection of intellectual property rights. The WTO's institutions also provide a forum for the negotiation of new trade rules, for reviewing the Members' trade policies and for the settlement of disputes among its Members.

848. The WTO's essential purpose is to liberalize markets, by removing unnecessary, discriminatory and protectionist barriers to free trade. The three main WTO Agreements of potential relevance to the Protocol are the General Agreement on Tariffs and Trade 1994 (GATT), the Agreement on Technical Barriers to Trade (TBT Agreement), and the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement). At the most basic level, all three agreements share the common purpose of ensuring that measures that affect the trade in products do not discriminate on the basis of a product's country of origin in a manner that harms imports, and that these measures are no more trade restrictive than is necessary to achieve the purpose for which they were designed.[144] Each WTO Agreement has detailed rules, and a growing body of practice that further develops these rules, including the reports and recommendations of the WTO dispute settlement system.

849. The WTO Agreements are backed by a compulsory and binding dispute settlement system that can authorize bilateral trade sanctions. Any Member that feels that benefits it expected to derive from the WTO Agreements have been undermined by a trade-related measure put in place by another Member can challenge the validity of that measure through the WTO dispute settlement procedures. If the Members are unable to settle their differences by diplomatic means, a Panel of trade experts will be established to resolve the dispute. The report of the Panel can be appealed to the Appellate Body, composed of seven trade law specialists appointed by the WTO Membership. The WTO Dispute Settlement Body, a committee of all the WTO Members, formally reviews all the (unappealed) Panel reports and the reports of the Appellate Body. This Dispute Settlement Body can only reverse the conclusions of these reports by consensus. This means that the adoption of Appellate Body and of any unappealed Panel reports is effectively automatic. The main objective of the WTO dispute settlement system is to ensure that any trade-related measure that is found to be inconsistent with WTO rules either is removed or is amended to be made WTO consistent. If a Member fails to correct the offending measure, it can agree, on a temporary basis, to compensate the affected Member, or it may be subject to trade sanctions imposed by the affected Member at a level equivalent to the continuing harm done by the offending measure.

Do the Protocol and the WTO overlap?

850. The Protocol and the WTO Agreements overlap, as they both contain rules that govern the international trade in LMOs. The CBD Parties negotiating the Protocol, most of which were also WTO Members, were aware of this overlap and appear to have sought to design the Protocol in a way that would avoid conflicts with Parties' existing commitments under the WTO. As has been discussed in the analysis of the Protocol's preamble, Parties to the Protocol that are also WTO Members are encouraged to implement and interpret their rights and obligations under the Protocol in a manner that is "mutually supportive" of their rights and obligations under trade agreements, and vice versa.

[144] WTO Agreement on Technical Barriers to Trade, Articles 2.1, 2.2; WTO Agreement on the Application of Sanitary and Phytosanitary Measures, Articles 2.2, 2.3; General Agreement on Tariffs and Trade, Articles I, III, and XX.

851. In 2001, the WTO Ministerial Conference agreed, with a view to enhancing the mutual supportiveness of trade and environment, "to negotiations, without prejudging their outcome, on:

> …the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs). The negotiations shall be limited in scope to the applicability of such existing WTO rules as among parties to the MEA in question. The negotiations shall not prejudice the WTO rights of any Member that is not a party to the MEA in question."[145]

It is not yet clear what the implications of these negotiations, if any, will be for Parties to the Protocol. The negotiations are supposed to conclude on 1 January 2005 with report on progress due at the fifth session of the Ministerial Conference of the WTO in September 2003. Discussions on this issue are taking place in the WTO Committee on Trade and Environment.

852. Although the Protocol and the WTO overlap, the design of the Protocol has the effect of limiting its impact on international trade. Protocol provisions that have the greatest potential impact on trade are limited to the narrowest category of products. The Protocol's AIA and risk assessment procedures, which may provide the basis for trade restrictions, apply only to the first intentional transboundary movement of LMOs for intentional introduction to the environment. At present, this category of LMOs likely represents only a small proportion of overall international trade in LMOs. By contrast, the category of LMOs that likely represents the largest proportion of international trade, LMO-FFPs, is subject to less stringent measures under the Protocol, though transboundary movements of such LMOs may still be subject to similar domestic regulations of the Party of import.

853. It should also be noted that the Protocol governs some transboundary movements of LMOs that are unrelated to international trade and would thus fall outside the scope of the WTO. For example, the non-commercial transboundary movement of laboratory specimens (e.g. some LMOs destined for contained use), which is within the scope of the Protocol, but not within the scope of the AIA procedure (see commentary on Article 6). Measures regulating such transboundary movements would probably not be covered by the WTO, because they are unlikely to affect international trade. The unintentional transboundary movement of LMOs through, for example, the spread of pollen, is covered by the Protocol but would not be covered by the WTO. It is, however, possible that a trade-related measure could be used as a means of preventing the unintentional transboundary movement of LMOs. Such a measure would be covered by the WTO.

What kinds of trade-related measures are required, authorized or justified under the Protocol?

854. WTO rules will apply only to those measures taken by a Party under the Protocol that affect international trade. The Protocol provides for a number of trade-related measures. These measures vary depending, among other things, on whether the product at issue is a LMO or a LMO-FFP, and on the intended use to which the LMO is being put. Some of the trade-related measures can be described as obligations that are clearly identified and could be said to be *required* by the Protocol. Other trade-related measures can be said to be *authorized under* (but not required by) the Protocol. It is also possible that a Protocol Party could seek to use the Protocol to justify a trade-related measure related to LMOs that is not specifically required or authorized by the Protocol.

[145] Ministerial Declaration of the fourth session of the Ministerial Conference of the World Trade Organization, Doha, 9–14 November 2001, WT/MIN(01)/DEC/1, 20 November 2001, para 31.

Box 53. Examples of trade-related measures under the Protocol

Article	Trade-related measure	Measure taken by	Product	Timing	Character
8.1	Notification of Party of Import prior to export	Party of Export	LMOs	Prior to first intentional transboundary movement	Required
10.3(a)	Conditions attached to the import that affect internal sale	Party of Import	LMOs	Prior to first intentional transboundary movement	Authorized
10.3(b)	Import ban	Party of Import	LMOs	Prior to first intentional transboundary movement	Authorized
10.3(c)	Request for additional information prior to import	Party of Import	LMOs	Prior to first intentional transboundary movement	Authorized
10.3(a), 4	Unconditional approval of import	Party of Import	LMOs	Prior to first intentional transboundary movement	Authorized
12.4	Risk assessment	Party of Import	LMOs	Subsequent to first intentional introduction	Authorized
15	Risk assessment	Party of Import	LMOs	Prior to first intentional transboundary movement	Required
18.2(a)	Identification as "may contain" LMOs	Party of Export	LMO-FFPs	Prior to any intentional transboundary movement	Required
18.2(b)	Identification as LMOs	Party of Export	LMOs destined for contained use	Prior to any intentional transboundary movement	Required
18(c)	Identification as LMOs	Party of Export	LMOs destined for introduction into the environment	Prior to any intentional transboundary movement	Required

855. There are thus three main categories of trade-related measures that the Protocol either requires or authorizes its Parties to take:

■ Notification and identification requirements

856. Prior to the first intentional transboundary movement of a LMO into a Party of import the Party of export has an obligation to notify or to ensure the notification of the proposed movement to the Party of import, and to await the consent of that Party (see Article 8(1)). The importing Party has a right to demand such a notification and, presumably, the authority to deny import licences to any exporter that has failed to meet the notification requirements in Annex I of the Protocol.

857. Article 18 of the Protocol requires all Parties, prior to export, to identify through accompanying documentation any LMO-FFPs that "may contain" LMOs, and to identify any LMOs intended for intentional introduction into the environment or destined for contained use as such. The Protocol authorizes both exporting and importing Parties, to take measures to ensure this identification takes place. This requirement is a trade restrictive obligation willingly being undertaken by the Party of export, but that also may be enforced, through the use of additional trade-related measures, by the importing Party.

■ Risk assessment procedures

858. The risk assessment procedures under the Protocol are trade-related measures because they can delay the approval of the import of a covered product, and because they can provide the basis for a decision to ban or restrict imports under Article 10. Since, as will be discussed, the risk assessment procedures under the Protocol are not identical to those

under the WTO Agreements, disputes may arise that call for a Party to show the provisions of both regimes are being applied compatibly.

■ Import bans or other trade restrictive measures

859. The Protocol's core regulatory procedure, a system of advance informed agreement (AIA), provides that the Party of import has the discretion to agree or not agree to the import of a particular LMO. The Party of import may also place conditions, such as restrictions on use, packaging or labelling requirements, on the import that could affect the product's sale or competitiveness. Prohibiting the import of a LMO, or subjecting its import to one or more trade restrictive conditions, are two of the possible responses that the Protocol anticipates could be the result of a Party of import's "decision procedure" under Article 10.

860. An import ban or other trade restriction might also be justified under the Protocol in response to:

- The failure by a Party of export to ensure compliance with various provisions in the Protocol, or
- A determination by the Party of import, on the basis of a risk assessment, that a LMO presents an unacceptable risk to the conservation and sustainable use of biological diversity, taking also into account risks to human health.

861. Import bans are strictly regulated by the WTO. The GATT, the SPS Agreement and the TBT Agreement would require a Party of import to demonstrate that any import bans:

- have a rational basis,
- are in support of a legitimate policy objective,
- are no more trade restrictive than necessary to achieve that objective, and
- are not being applied in an arbitrary or discriminatory manner.

862. Specific aspects of these general disciplines are discussed below on an agreement by agreement basis.

Is it relevant whether a trade-related measure taken under the Protocol is required or authorized by the Protocol?

863. If a trade-related measure (TREM) taken under the Protocol were challenged under the WTO, it may be relevant whether that measure was specifically required by the Protocol, directly authorized under the Protocol, or was being justified only as promoting the Protocol's objectives. Some would argue that the existence of the Protocol would be relevant to the defence of a WTO challenge only if the trade-related measure at issue were specifically required by the Protocol. Others would argue that the Protocol gives its Parties considerable discretion in how they choose to meet its objectives, and that trade restrictive measures other than those specifically set out in the Protocol should be seen as compatible with both the Protocol and the WTO. Trade restrictive measures that are specifically required or authorized under the Protocol are likely to be less vulnerable under a potential WTO challenge. It should be noted that the issue of the relationship between MEA-based TREMs and WTO rules, including the relevance of the specificity and legal character of those TREMs, will be the subject of negotiations between WTO Members under the Doha Development Agenda (see paragraph 851 above).

Which WTO Agreement would apply to a trade-related measure taken under the Protocol?

864. Trade-related measures taken under the Protocol could fall within the scope of the GATT, the TBT Agreement or the SPS Agreement, and a Party would need to examine the compatibility of its measures under each Agreement. The GATT applies to all measures affecting any product in international trade, including LMOs. The TBT and the SPS Agreements were adopted to "further the objectives"[146] and to "elaborate rules for the application of the provisions"[147] of the GATT.

[146] TBT Agreement, preamble, 2nd recital.

[147] SPS Agreement, preamble, 8th recital.

865. The TBT expressly provides that it will not apply to sanitary and phytosanitary measures as defined in the SPS Agreement, while the SPS Agreement clarifies that it will not affect the rights of Members under the TBT Agreement with respect to non-SPS measures.[148] The SPS Agreement also provides that any measure found to be in conformity with its provisions will be presumed to be in accordance with Members' obligations under the relevant provisions of the GATT.[149]

866. The relationship between the GATT, the SPS Agreement and the TBT Agreement has yet to be fully clarified by the WTO dispute settlement system. It appears that the three Agreements were designed to work in a hierarchy which gives priority to the most specific Agreement applicable to any given measure. In practice, the GATT has provided a kind of catchall agreement that Members use as a basis of their claims in addition to the SPS Agreement or the TBT Agreement.[150]

867. The most specific of the three Agreements is the SPS Agreement. This Agreement, in simplest terms, governs all measures which may directly or indirectly affect international trade in any products, and that are applied with the policy objective of protecting animal or plant life or health within the territory of the Member from risks arising, *inter alia*, from pests, diseases or contaminants.[151]

868. If a trade-related measure does not fall within the scope of the SPS Agreement, it could be covered by the TBT Agreement. Indeed, a single law or regulation could contain some provisions that are disciplined by the SPS Agreement and others that fall under the TBT Agreement. The TBT Agreement applies to all measures affecting the trade in any products that are technical regulations or technical standards, as long as those measures do not fall under the SPS Agreement. Technical regulations are documents that lay down product characteristics that are mandatory in character (such as trade restrictions on products *containing* certain substances), and technical standards are those that are non-mandatory in character (such as voluntary labelling schemes).[152]

869. For example, a mandatory LMO-FFP identification scheme, because it would require a trade-related measure based on product characteristics, would be a technical regulation and fall under the TBT Agreement. However, if this identification scheme were being applied for one or more of the health and food safety-related objectives set out in the SPS Agreement, it would then fall exclusively within the scope of the SPS Agreement. Thus, which Agreement will apply to a measure will depend, in part, on the specific risks the measure has been designed to regulate. Finally, the GATT will continue to apply to any trade-related measure, regardless of its policy objective, that directly or indirectly affects the trade in products.

870. An analysis of the relationship between the WTO Agreements and any trade-related measure taken under the Protocol must, therefore, begin with an understanding of the policy objective behind the measure. What, in other words, is the risk that the measure is designed to protect against? The Protocol's scope and objective indicate that any trade-related

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[148] TBT Agreement, Article 1.5; SPS Agreement, Article 1.4.

[149] SPS Agreement, Article 2.4.

[150] The relationship between the GATT and the SPS Agreement was raised in *EC Measures Concerning Meat and Meat Products (Hormones)* Complaint by the US, Report of the Panel WT/DS26/R/USA, in which the Panel found that both the GATT and the SPS Agreement were applicable to the dispute, but that as the SPS Agreement contained commitments additional to the GATT, it was appropriate to analyse the case under the SPS Agreement first. Having found a violation of the SPS Agreement, the Panel then found that an analysis under the GATT was unnecessary. The applicability of the GATT to the dispute was not raised on appeal. The relationship between the GATT and the TBT Agreement was raised in the US Reformulated Gasoline and in the EC-Asbestos cases. Under the first dispute, the Panel chose to apply the GATT rather than the TBT Agreement, and upon finding a violation of the GATT did not find it necessary to proceed to a TBT analysis. *United States - Standards for Reformulated and Conventional Gasoline*, AB-1996-1,WT/DS2/9, adopted 20 May 1996 [the Panel and Appellate Body reports are published jointly and are referred to hereinafter as *US-Gasoline* and *US-Gasoline* Report of the Panel]. Under the EC-Asbestos dispute, the Panel found that the TBT Agreement did not apply to an absolute ban on a product, and applied the GATT. The Appellate Body reversed, finding that the TBT Agreement would apply to an import ban if it, in effect, applied to the characteristics of a product (e.g. a product *containing* asbestos). Because the Panel had not analyzed the facts of the case under the TBT Agreement, the Appellate Body was unable to carry out a legal analysis under that Agreement, and limited its opinion to an application of the GATT. *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R [hereinafter *EC-Asbestos* Report of the Appellate Body] adopted 5 April 2001.

[151] SPS Agreement, Article 1(1), Annex A, Article 1.

[152] TBT Agreement, Article 1(2), Annex 1(1). See also *EC-Asbestos* Report of the Appellate Body, paras 63–72.

measure taken under the Protocol would seek to ensure an adequate level of protection that would prevent "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". This poses a number of interpretative challenges that will be relevant to an analysis under WTO rules.

871. First, the specific risks that LMOs may pose to biological diversity, and to human health, are not identified in the Protocol. These risks will, however, be identified, on a case-by-case basis, in the course of the risk assessment procedures set out in Article 15 and Annex III of the Protocol. Without knowing the nature of the risk in advance, or the kind of trade-related measure that has been chosen to regulate that risk, it is not possible to determine in advance, which WTO Agreement will apply to a trade-related measure taken under the Protocol.

872. Second, the intended territorial scope of the Protocol is unclear. The Protocol's Articles on Scope (Article 4) and Objective (Article 1) indicate a specific focus on transboundary movements. This suggests that measures taken in accordance with the Protocol are primarily concerned with the impact of LMOs on the biodiversity, and/or human health, in the Party of import, i.e., the "likely potential receiving environment". But the Protocol's objective does not focus exclusively on transboundary movements. The Protocol's provisions related to safe handling, use and transport of LMOs suggest that the Protocol could perhaps be used to justify trade-related measures with the aim of discouraging the production of LMOs in the country of export where that production poses a threat to biodiversity. Such measures, for example, would not fall within the scope of the SPS Agreement, which applies exclusively to measures designed to protect the environment of the importing State. Either the TBT or the GATT could, however, continue to apply to such a measure.

How will the WTO system take into account the Protocol?

873. As discussed earlier in this Guide, the Protocol's preamble and other related provisions seek to ensure that Parties take into account the WTO and other international agreements when implementing the Protocol. But how will the WTO Agreements take into account the Protocol? Like the Protocol and the CBD, the WTO Agreements reflect the need to take into account other existing international agreements and other relevant State practice.

874. The Protocol contains potentially widely accepted international standards of treatment for LMOs in international trade. Both the SPS Agreement and the TBT Agreement make reference to international standards developed by competent international organizations that are not part of the WTO itself. Under the SPS Agreement, a WTO Member is required (unless it can justify the need for a higher standard) to base its SPS measures on international standards, guidelines or recommendations adopted by international agencies as identified in the SPS Agreement, or that might later be agreed by the WTO Membership.[153] SPS measures that are in conformity with these international standards are rebuttably presumed to be consistent with the SPS Agreement.[154] In the context of a dispute, a rebuttable presumption would require the Member challenging the measure to meet a higher burden of proof than would otherwise be the case. However, neither the CBD nor the Protocol is currently recognized as a standard setting body

[153] These include agencies which are conducting work of relevance to LMOs, such as the *Codex Alimentarius* and the International Plant Protection Convention (see Introduction and Box 12). SPS Agreement, Article 3.1; Annex A, Article 3. International standards, guidelines and recommendations are defined as:
"(a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
(b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
(d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the [SPS] Committee."

[154] SPS Agreement, Article 3.3, *EC-Beef Hormones*, Report of the Appellate Body, para 170.

under the SPS Agreement. The SPS Agreement does not preclude Members from setting standards that are higher than international standards, as long as these standards meet the Agreement's other requirements.

875. Under the TBT Agreement, a Member is also required (unless it can justify the need for a higher standard) to use international standards for the basis of its technical regulation.[155] A technical regulation that is put in place for an identified "legitimate objective" (which includes the protection of human heath or safety, animal or plant life or health, or the environment) and is in accordance with "relevant international standards" is rebuttably presumed to be TBT compatible.[156] Unlike the SPS Agreement, the TBT Agreement does not identify specific international standardizing bodies whose standards would by definition qualify for a rebuttable presumption of consistency with the TBT Agreement. Although this issue has never been tested, the CBD and the Protocol might meet the TBT Agreement's general definition of an "international body or system whose membership is open to the relevant bodies of at least all of the Members".

876. The GATT does not make reference to international standards or standard-setting bodies. However, when clarifying relevant provisions of the GATT, in the context of a specific dispute, the WTO Appellate Body has signalled its willingness to take into account existing international agreements and State practice outside the WTO. Indeed, the Appellate Body made reference to the CBD when, in the process of clarifying the meaning of "exhaustible natural resources" under GATT Article XX (General Exceptions), it reviewed State practice for evidence of the "contemporary concerns of the community of nations about the protection and conservation of the environment".[157] In that case, the CBD was one of many existing international agreements the Appellate Body referred to in concluding that the sea turtles at issue were an exhaustible natural resource.[158]

How might Protocol-based measures be tested under WTO rules?

877. In an effort to ensure that trade-related measures taken to implement the Protocol are mutually supportive of its existing commitments under the WTO Agreements, a Party may wish to consider specific aspects of the WTO Agreements that have been used to test trade-related environmental measures in past GATT/WTO disputes. The following set of bullet points identifies disciplines from the GATT, the SPS and the TBT Agreements that may be relevant to the implementation of the Protocol.

■ Rules against trade bans: GATT Article XI

878. GATT disciplines govern all products traded between WTO Members, including all LMOs. GATT Article XI forbids WTO Members from instituting or maintaining prohibitions or quantitative restrictions on the importation of products from another WTO Member (through quotas, import licences or other measures). Import bans under Article 10 of the Protocol would appear to be *prima facie* violations of GATT 1994. Thus any trade ban put in place to implement the Protocol could be challenged under Article XI, and a Party may be called upon to justify the measure under one of the GATT's exceptions, discussed in Box 55 below.

■ Rules against country-based discrimination

879. The WTO's anti-discrimination rules prohibit measures that directly or indirectly discriminate between "like products" on the basis of their country of origin in a manner

[155] TBT Agreement, Article 2.4.

[156] TBT Agreement, Articles 2.2 and 2.5.

[157] *United States – Import Prohibitions of Certain Shrimp and Shrimp Products*, WT/DS58/R, WT/DS58/AB/R, [hereinafter *US-Shrimp/Turtle*] reports adopted 8 November 1998, paras 129, 130.

[158] *US-Shrimp/Turtle* Report of the Appellate Body, para 134.

that modifies the conditions of competition in the relevant market to the detriment of imported products.[159] Under the GATT and under the TBT Agreement, a WTO Member must accord treatment to imported products that is no less favourable than treatment accorded to "like products" of national origin. This is the so-called "National Treatment" principle. Furthermore, a WTO Member may not provide any advantage, favour, privilege or immunity offered to any product originating in or destined for any other country without immediately and unconditionally extending the same to the like product originating in or destined for the territories of all other Members (Most Favoured Nation or MFN treatment). At a minimum, these rules require Members to apply the same or equivalent regulations to domestic LMOs that they are applying to like imported LMOs, and to treat all imported like LMOs in a similar manner that allows those LMOs an equal opportunity for market access.

■ Rules against indirect discrimination

880. Under both the GATT and the TBT Agreement, a trade-related measure that is on its face neutral as to country of origin could still be challenged as *indirectly* discriminatory, if the exporting country feels that the importing country is treating its product less favourably than a "like" domestic product or a "like" product imported from another country. A WTO Panel assessing such a claim would conduct a case-by-case examination of the relevant products, applying what has become known as the "like product test"(see Box 54).

881. The Protocol applies to "*LMOs . . . that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health*" (Article 4). Within that category, the Protocol distinguishes between various categories of LMO, primarily on the basis of the LMO's intended use (human pharmaceuticals, LMO-FFPs, LMOs destined for contained use, LMOs destined for intentional introduction into the environment). Each of these categories is subject to different treatment under the Protocol. This difference in treatment with regard to distinct categories of LMOs, should provide a sufficient basis, as between Parties to the Protocol, for concluding that LMOs are not, for WTO purposes "like" their non-LMO counterparts. As the Protocol gains wide acceptance internationally, it may also provide a basis for concluding that LMOs, or certain LMOs, are not "like" their non-LMO counterparts as between Parties and non-Parties to the Protocol.

882. The Protocol anticipates that Parties may make further distinctions in treatment with regard to categories of LMOs on the basis of risk assessments carried out under Articles 10 and 15 and Annex III.

883. Further arguments for distinguishing between LMO and non-LMO products, and for distinguishing among LMOs, can be derived from the GATT's own like product test, including differences in the products' physical characteristics, their end uses and in consumer preferences.

884. The WTO's rules against indirect discrimination can also be read to require a degree of consistency of treatment within a particular category of LMO. The failure to treat LMOs that carry "like" risks in a similar manner could provide the basis of a claim of indirect discrimination.

[159] *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS169/AB/R, 11 December 2000, para 137.

Box 54. The "like product" test

In the context of a dispute arising from a claim of indirect discrimination under the GATT, or under the TBT Agreement, a WTO Panel will apply the "like product test." To date there has been no determination by the WTO as to whether a particular LMO or LMO-FFP and its non-GM equivalent are "like products". If a Panel finds that the two products in question are different, then the importing country is under no obligation to treat the two products in the same way. If the products are found to be "like", then any difference in treatment that undermines the ability of the imported product to compete, would violate the WTO's rules against discriminatory treatment. Under the GATT, the "like product" test calls for a case-by-case determination in which a WTO Panel would assess and compare:

- the physical properties of the products;
- the extent to which the products are capable of serving the same or similar end-uses;
- the extent to which consumers perceive and treat the products as alternative means of performing particular functions in order to satisfy a particular want or demand; and
- the international classification of the products for tariff purposes.[160]

The Appellate Body has also found that "that evidence relating to the health risks associated with a product may be pertinent in an examination of 'likeness."[161]

■ Exceptions to GATT rules for Measures that Protect the Environment and Human, Animal and Plant Health

885. Measures that are found to violate GATT rules against trade bans, or against discrimination, may nonetheless qualify for an exception under GATT Article XX. The Member defending the measure bears the burden of provisionally justifying it under one of the policy objectives enumerated in subparagraphs of Article XX, including as being *necessary* to the protection of "human, animal or plant life or health" (Article XX(b)) and, under certain conditions, related to the conservation of natural resources (Article XX(g)). If a Party succeeds with its provisional justification, it must then demonstrate that the measure is not being *applied* in an arbitrary or unjustifiable manner, and is not as a disguised restriction on trade.

886. Measures taken under the Protocol to regulate LMOs that "may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health." would appear, as a general matter, to be necessary or related to the objectives of the protection of human, animal or plant life or health or of conservation of natural resources. GATT disciplines that would govern how these measures should be applied are described in Box 55.

Box 55. General exceptions under the GATT

WTO dispute settlement Panels have developed detailed analysis of the two GATT exceptions that are most relevant to the Protocol: Article XX, subparagraphs (b) and (g). These exceptions can be used by a WTO Member to defend a measure that has been found to violate one of the GATT's primary obligations, such as its prohibition on import bans, or on the discriminatory treatment of a "like" product. Because the terms and the concepts used in these exceptions also appear in the SPS and the TBT Agreements, Panel interpretations of these exceptions can guide Parties on how to design WTO-compatible measures under the Protocol. As with other aspects of the WTO Agreements, the analysis must begin with an understanding of the policy objective behind the measure.

Cont.

[160] *EC-Asbestos* Report of the Appellate Body, para 101.
[161] *EC-Asbestos* Report of the Appellate Body, para 113.

Box 55. General exceptions under the GATT (cont.)

Protection of Human, Animal and Plant Life or Health (GATT Art XX(b))

Article XX(b) of the GATT can be used to defend a measure if the following two criteria are met:

- the policy objective behind the measure must fall within the range of policies designed to protect human, animal or plant life or health; and
- the measure must be "necessary" to fulfil the policy objective.[162]

According to the Appellate Body, a measure would not be considered necessary if an alternative measure, which the Member could reasonably be expected to employ and which is not inconsistent with other GATT provisions, is available to that Member. "By the same token, in cases where a measure consistent with other GATT provisions is not reasonably available, a Member is bound to use, among the measures reasonably available to it, that which entails the least degree of inconsistency with other GATT provisions."[163] Whether a particular measure meets this "least degree of inconsistency" test, will require a case-by-case analysis.

The Appellate Body has held that when determining whether a less trade restrictive measure was "reasonably available," it will assess the extent to which the measure "contributes to the realization of the end pursued".[164] "The more vital or important [the] common interests or values" pursued by the measure, the easier it would be to accept as "necessary" measures designed to achieve those ends.[165] The international recognition, by the Protocol, of the special character of LMOs and of the need to protect biological diversity, may provide relevant evidence of "common interests and values".

Conservation of Exhaustible Natural Resources (GATT Art XX(g))

The following criteria need to be met for the application of Article XX(g):

- the policy objective behind the measure must fall within the range of policies related to the conservation of exhaustible natural resources;
- the measure must be "related to" the conservation of exhaustible natural resources; and
- the measure must be "made effective in conjunction with restrictions on domestic production or consumption."[166]

A measure is considered to be "related to" the conservation of natural resources, if there is a "substantial relationship" between the general structure and design of the measure at stake and the policy objective it purports to serve. The second criterion is met if "the means are, in principle, reasonably related to the ends".[167] The third criterion, concerning the restrictions on domestic production or consumption, requires the demonstration of an "even-handedness" in the imposition of the trade restrictions.[168] Restrictions on the production or consumption of imported LMOs must be in the context of similar restrictions on domestically produced LMOs.

The "Chapeau Test"

If a Member defending a challenged measure is able to justify that measure under one of these two subparagraphs of Article XX, it would then need to show that the measure also conforms to the requirements of Article XX's introductory paragraph or "chapeau." Article XX's chapeau is intended to prevent the abuse of the "limited and conditional"[169] exceptions in Article XX. It lays down three standards. The Member would need to demonstrate that the application of its measure did not constitute:

- arbitrary discrimination between countries where the same conditions prevail;
- unjustifiable discrimination between countries where the same conditions prevail; or
- a disguised restriction on international trade.

Cont.

[162] *US-Gasoline* Report of the Panel, para 6.20.

[163] *United States – Section 337 of the Tariff Act of 1930*, BISD 36S/345, para 5.26 (adopted on 7 November 1989). A similar reasoning was followed in *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes*, BISD 37S/200, para 75 (adopted on 7 November 1990). Both cases are quoted in para 6.24 of *US-Gasoline* Panel. The Panel's interpretation of Article XX(b) of the GATT was not appealed, and was thus not reviewed by the Appellate Body.

[164] *EC-Asbestos* Report of the Appellate Body, para 172.

[165] *EC-Asbestos* Report of the Appellate Body, para 172.

[166] *US-Gasoline* Report of the Panel, para 6.35.

[167] *US-Shrimp/Turtle* Report of the Appellate Body, para 136–142.

[168] *US-Shrimp/Turtle* Report of the Appellate Body, para 143.

[169] *US-Shrimp/Turtle* Report of the Appellate Body, para 157.

Box 55. General exceptions under the GATT (cont.)

According to the Appellate Body, the application of these criteria must strike a balance "between the right of a Member to invoke an exception under Article XX and the rights of the other Members under varying [GATT] substantive provisions." "[N]either of the competing rights will cancel out the other and thereby distort and nullify or impair the balance of rights and obligations" under the GATT.[170] The Appellate Body acknowledges that this balance can be assessed only on a case-by-case basis.[171]

Measures that have failed to meet the Chapeau test in the past have included those that have been applied in a unilateral manner, that did not offer a sufficient and equal opportunity for affected trading partners to agree a common solution; and in an inflexible manner, that did not allow other Members sufficient latitude to demonstrate compliance with the measure. A measure that is required or authorized under the Protocol, a multilaterally agreed instrument, open for signature to all WTO Members, may be more likely to pass these tests.[172]

■ Ensuring that Measures are "no more trade restrictive than necessary" under the TBT and SPS Agreements

887. The TBT and the SPS Agreements draw upon GATT Article XX (b) by requiring Members to ensure that measures falling under these agreements are no more trade restrictive than necessary to achieve their objectives.

888. Article 2.2 of the TBT Agreement requires that Members ensure "that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfillment would create". The TBT Agreement identifies as legitimate objectives "protection of human health or safety, animal or plant life or health, or the environment". In assessing the risks to life, health, safety and the environment, the relevant elements of consideration include: available scientific and technical information, related processing technology or intended end-uses of products. This suggests that a Party that has put in place a trade-related measure to implement the Protocol, may need to demonstrate that it has balanced the trade restrictiveness of that measure against the need to prevent the risks associated with the LMO.

889. As has been noted, the wide acceptance of the Protocol by the international community will be relevant to defending a LMO-related trade-related measure against a WTO challenge. In accordance with Article 2.5 of the TBT Agreement, any technical regulation that is "prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in [Article 2.2] and is in accordance with relevant international standards ... shall be rebuttably presumed not to create an unnecessary obstacle to international trade".[173] In other words a WTO Member challenging a measure that is in accordance with the Protocol, would carry a heavier burden of proof than would otherwise be the case.[174]

890. Article 2 of the SPS Agreement also contains a "necessity" test. Members are required to ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, and that these measures are applied in a manner which would constitute a disguised restriction on international trade. In practice, it has been the SPS Agreement's disciplines on risk assessment and risk management that are used to test the necessity of SPS measures.

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[170] *US-Shrimp/Turtle* Report of the Appellate Body, para 159.

[171] *US-Shrimp/Turtle* Report of the Appellate Body, para 159.

[172] See generally, *US-Shrimp/Turtle* Report of the Appellate Body.

[173] It is not clear whether this rebuttable presumption is intended to apply equally to proof of a violation of Article 2.1, as well.

[174] This provision could not, however, be read to imply that a Member whose measure is *not* applied for one of the legitimate objectives listed in Article 2.2, and/or is *not* in accordance with an international standard, bears the burden under Article 2.2 of demonstrating that its measure does *not* create an unnecessary obstacle to trade. The *prima facie* burden of establishing a violation of Article 2.2 remains on the complaining Member.

Which WTO rules are relevant to Risk Assessment under the Protocol?

891. Both the SPS and the TBT Agreements promote the use of science and risk assessment as a means for justifying trade-related measures. The Protocol's risk assessment procedures were designed along similar lines, and the WTO and Protocol procedures on risk assessment do not directly conflict. However, in some instances the Protocol's risk assessment procedures are more specific, and in other instances the WTO rules are more specific.

892. The SPS Agreement requires Members to take into account risk assessment techniques developed by relevant international organizations. SPS risk assessment is geared towards the control of the impact of pests or diseases on the territory of the Party of import, or on the prevention of adverse effects on human or animal health from additives, contaminants, toxins or disease carrying organisms in food or beverages. Risk assessments under the SPS Agreement must take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

893. Unlike the SPS Agreement, the TBT Agreement does not expressly require a Member to analyze its regulation on the basis of a risk assessment *prior* to putting it into place.[175] However, under Article 2.5, if a Member's technical regulation "may have a significant effect on trade of other Members" that Member is under an obligation, upon the request of another Member, "[to] explain the justification for that technical regulation in terms of the provisions of [TBT Article 2.2–2.4]." If the obligation to justify the measure is triggered, the Party defending the measure will have to follow the relevant elements of a risk assessment in Article 2.2. The relevant elements of consideration for a risk assessment under the TBT Agreement are generally stated as "*inter alia:* available scientific and technical information, related processing technology or intended end-uses of products."

■ Precaution and risk assessment

894. An area of contention during the negotiations was the relationship between the Protocol's references to the precautionary approach, and the WTO rules. The WTO's strong emphasis on the use of science as a basis for risk assessment and decision-making has raised concerns that trade-related measures without sufficient scientific backing could be particularly vulnerable to challenge. The precautionary approach is invoked by governments in circumstances where the potential seriousness or irreversibility of a risk justifies regulatory action even when there is a lack of full scientific certainty.

895. WTO Panel interpretations of the SPS Agreement confirm that a risk assessment must be based on scientific principles, and may not be maintained without sufficient scientific evidence. Panels have not, however, insisted that the science relied upon represent a mainstream scientific opinion, as long as it is based on respected and qualified sources. They have also confirmed that a risk may be evaluated either in quantitative or qualitative terms.[176]

896. The SPS Agreement contains the WTO's most relevant provision on precaution, and might guide a Panel's approach to dealing with the issue in the interpretation of other WTO Agreements. SPS Article 5.7 provides that:

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of

[175] Compare the SPS Agreement, Article 5.1.

[176] *EC-Beef Hormones* Report of the Appellate Body; *EC-Asbestos* Report of the Appellate Body, paras 167–168.

risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

897. The SPS Agreement reflects precaution in Article 5.7 by allowing Members to adopt SPS measures where relevant scientific evidence is insufficient. However, Article 5.7 subjects the right of Members to take "precautionary" measures in these circumstances to four specific conditions:

(i) the measure must be adopted provisionally;

(ii) it must be adopted on the basis of available pertinent information;

(iii) the Member must seek to obtain the additional information necessary for a more objective assessment of the risk; and

(iv) the Member must review the measure within a reasonable period of time.

898. These conditions apply cumulatively, so where one is not met the measure in question will be incompatible with the SPS Agreement.[177]

899. A number of commentators have compared the precautionary provisions of the Protocol and the SPS Agreement to assess their compatibility. Article 5.7 of the SPS Agreement requires the importing Member to adopt only a provisional measure, to seek additional information for a more objective risk assessment, and to review the measure within a reasonable period of time. The Protocol does not explicitly include such obligations. Nevertheless, Article 12 of the Protocol requires the Party of import to review its decision upon request where the Party of export or notifier considers that there has been a change of circumstances or where additional relevant scientific or technical information has become available.

900. With regard to the obligation to review the measure within a reasonable period of time, the WTO Appellate Body has accepted that this should be established on a case-by-case basis depending upon the specific circumstances of the case including the difficulty of obtaining the additional information necessary for the review and the characteristics of the SPS measure.[178] It does not therefore seem to imply a fixed or necessarily brief period for review, but rather the time it takes for new scientific knowledge to become available.

901. Article 5.7 also explicitly requires that any "precautionary" measure be adopted "on the basis of available pertinent information". While the Protocol does not explicitly contain such an obligation, it seems clear that precautionary measures taken under the Protocol, can be applied only after an assessment of existing relevant information.

■ Socio-economic considerations in risk assessment

902. Another area of contention during the negotiations was over the compatibility of the Protocol's provisions on socio-economic considerations, and the WTO Agreements. Some countries were concerned, in particular, whether the Protocol would provide a basis for restricting imports on LMOs on the grounds that these products might lead to a loss of cultural traditions, knowledge and practices, particularly amongst indigenous and local communities. At least one previous GATT Panel had rejected trade restrictions that were justified solely on the grounds that cheap imports would undermine the traditional livelihoods of a certain minority population.[179] Furthermore, the WTO's emphasis on science as the basis for risk assessment and risk management raised concerns that trade-related measures taken under the Protocol, and based on socio-economic considerations, could be challenged.

Under Article 26 of the Protocol, Parties may take into account, when deciding whether or how to allow the import of a LMO, "socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity." The Protocol highlights, in particular, the need to take into account the potential impact on "the value of biological diversity to indigenous and local communities." Further guidance on

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[177] *Japan – Measures Affecting Agricultural Products,* WT/DS76/AB/R, 19 March 1999 [hereinafter, *Japan- Agricultural Products* Report of the Appellate Body].

[178] *Japan-Agricultural Products* Report of the Appellate Body, para 93, where the Panel and the Appellate Body found that a period of three years exceeded a reasonable period of time for a provisional measure to be in place. See also Communication of the European Commission on the Precautionary Principle (2000), which states that the provisional nature of the measures under Article 5.7 of the SPS Agreement is "not bound up with a time limit but with the development of scientific knowledge", p.12.

[179] *Japanese Measures on Imports of Leather*, GATT Panel Report BISD 31S/94 (2 March 1984), p 44.

the implementation of this provision might be expected from the COP/MOP in due course.

903. Risk assessment under the SPS Agreement also involves a mix of scientific and socio- economic considerations. Procedures under the SPS Agreement will differ, depending on whether the risk is to animal or plant life or health, or instead, the risk is human life or health. When assessing risks to animals and plants, Members are to take into account relevant economic factors. These include an assessment of the impact that the eshtablishment or spread of a pest or disease could have on the production or sales of the affected crops, as well as the costs of controlling or eradicating the pest or disease. There is no similar reference to economic concerns in relation to impacts on human health. Compatibility between the Protocol and the WTO is encouraged by the reference, in Article 26, to the need for Parties to implement this provision "consistent with their international obligations".

■ Carrying out and funding risk assessment

904. While the importing Member under the SPS Agreement must base its trade-related measures on a risk assessment, WTO Panels have clarified that the importing Member is not required to carry out the risk assessment itself. It can, for example rely upon assessments made by the exporting Member or by a third party. By contrast, the Protocol, in Article 15, entitles the Party of import to require the notifier to pay for a risk assessment.

Which WTO rules are relevant to Risk Management under the Protocol?

905. Any risk management-related measures imposed by WTO Members that have an impact on trade will be subject to WTO disciplines, and the SPS Agreement may give some indication of how a Panel might assess such measures. The SPS Agreement does not refer to "risk management" as such. It does, however, contain disciplines that govern the elements of risk management as described in Article 16 of the Protocol, including the setting of the appropriate level of protection, and designing measures to achieve that level of protection.

906. Once a Member has determined that the risk associated with a product is supported or reasonably warranted by a risk assessment, WTO accords that Member wide discretion in setting the level of exposure to that risk it is willing to tolerate.[180] However, when setting that level of protection, a Member should take into account the objective of minimizing negative trade effects. In the context of interpreting both the SPS Agreement and the GATT, the WTO Appellate Body has indicated that its Members are free to put in place measures that achieve a "zero-risk" level of protection against risks associated with specific products.[181]

907. Article 5 of the SPS Agreement also governs the design of the measure necessary to achieve the level of protection. As has been indicated, the measure should be no more trade restrictive than necessary to achieve the level of protection. For the purposes of risk management, a SPS measure is not more trade restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade. There must be a reasonable relationship between the risk assessment and the design of the measure.

908. Finally, in order to avoid arbitrary or unjustifiable discrimination, the SPS Agreement seeks to ensure that Members achieve a level of consistency in their application of SPS measures when managing risks of a similar nature. This means that Members would need to ensure that LMOs carrying similar risks are regulated in a consistent manner.

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[180] *EC-Beef Hormones* Report of the Appellate Body, para 186.

[181] *EC-Beef Hormones* Report of the Appellate Body; *EC-Asbestos* Report of the Appellate Body, paras 167–168. This right is tempered by the obligation in Article 5.5 to "avoid arbitrary or unjustifiable distinctions in the levels [the Member] considers to be appropriate in different situations, in such distinctions result in discrimination or a disguised restriction on international trade." See *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, 20 October 1998.

Which WTO rules are relevant to transparency and timing of decision-making under the Protocol?

909. WTO rules are designed to ensure that a potential exporter has full notice of any trade-related measures that might affect its product, and that any process implementing those measures is transparent and timely. Both the TBT and the SPS Agreements require Members to establish national "enquiry points", to publish regulations and to notify Members, through the WTO Secretariat, of existing and proposed trade-related measures. Members must have sufficient time to comment on and seek changes to such measures. The WTO's TBT and SPS Committees provide an opportunity for Members to debate and defend proposed and existing trade-related measures.

910. WTO Members are also under an obligation to ensure that their domestic regulatory systems operate without undue delay, and in a way that does not place imported products at a disadvantage to "like" domestic products.

911. These requirements are compatible with the objectives of the Protocol's provisions on "national focal points," information sharing and the Biosafety Clearing-House. The Protocol contains a number of provisions requiring Parties to make information on their national regulatory frameworks and national decisions available to other Parties through the Biosafety Clearing-House. Protocol Parties will however need to be aware that the WTO will share jurisdiction with the Protocol over these requirements, and its dispute settlement system could be invoked to play a role in assessing the reasonableness of Parties decision-making on LMOs, particularly where the Protocol is silent.

How might a Protocol-related dispute arise at the WTO?

912. If a Party of export feels that it has had a trade-related measure imposed upon one of its proposed LMO exports in a way that undermines its rights under the WTO, it could attempt to convince the Party of import to withdraw the measure, either bilaterally, or through the Protocol's own institutions or mechanisms. If the Parties were unable to resolve their differences through the Protocol's own procedures, the dispute could be brought to the WTO, if one Party felt that a measure enacted by another Party undermined its rights under the WTO.

913. The issue might arise as to whether the aggrieved Party would have to seek to resolve its dispute within Protocol procedures before turning to WTO procedures. This will depend, in part, on the extent to which the Protocol Parties are able to design a procedure capable of resolving differences between Parties (see Article 34 of the Protocol, and Article 27 CBD). The SPS Agreement provides, in Article 11 that "[n]othing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement."

Could a non-Party to the Protocol challenge a Protocol-based measure under the WTO?

914. It is, of course, also possible that a dispute related to the Protocol could be raised at the WTO between a Party and a non-Party to the Protocol, where both are WTO Members. A non-Party would not have access to the Protocol's institutions or mechanisms except as an observer. Unlike other MEAs, the Protocol does not authorize the use of specific trade-related measures with regard to non-Parties,[182] although it does require that transboundary movements of LMOs between Parties and non-Parties are undertaken "consistent with the objective of this Protocol" (see commentary on Article 24). It is possible that Parties to the Protocol, in order to implement the domestic systems necessary to regulate LMOs, will apply the same trade-related measures to LMOs imported from non-Parties as they apply to Parties.

[182] See, for example, the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer, Montreal, 26 ILM 1550 (1987) as adjusted and amended, Article 4, banning the trade in regulated substances with non-parties.

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Supplementary materials

Cartagena Protocol on Biosafety to the Convention on Biological Diversity

Convention on Biological Diversity

Conference of the Parties to the Convention on Biological Diversity: Decision II/5

Conference of the Parties to the Convention on Biological Diversity: Decision EM-I/3

Intergovernmental Committee for the Cartagena Protocol: Recommendation 3/5, Annex III – Implementation tool kit

Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements,

Have agreed as follows:

Article 1
OBJECTIVE

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.

Article 2
GENERAL PROVISIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.
2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article 3
USE OF TERMS

For the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) "Export" means intentional transboundary movement from one Party to another Party;

(d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) "Import" means intentional transboundary movement into one Party from another Party;

(f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "Modern biotechnology" means the application of:

   a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

   b. 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;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article 4
SCOPE

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.

Article 5
PHARMACEUTICALS

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

Article 6
TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.
2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article 7
APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.
2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.
3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.
4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 8
NOTIFICATION

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.
2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article 9
ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.
2. The acknowledgement shall state:
   (a) The date of receipt of the notification;
   (b) Whether the notification, prima facie, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article 10
DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant 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 Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

Article 11
PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

   (a) A risk assessment undertaken in accordance with Annex III; and

   (b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant 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 Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article 12
REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

   (a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or

   (b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article 13
SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

   (a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

   (b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

   Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article 14
BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

Article 15
RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article 16
RISK MANAGEMENT

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

   (a) Identifying living modified organisms or specific traits of 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; and

   (b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17
UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

   (a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

   (b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

   (c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

   (d) Any other relevant information; and

   (e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Article 18
HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

   (a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

   (b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

   (c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

Article 19
COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

Article 20
INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

   (a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

   (b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

   (a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

   (b) Any bilateral, regional and multilateral agreements and arrangements;

   (c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

   (d) Its final decisions regarding the importation or release of living modified organisms; and

   (e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 21
CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

   (a) The name and address of the notifier;

   (b) A general description of the living modified organism or organisms;

   (c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

Article 22
CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article 23
PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:

   (a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

   (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

Article 24
NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article 25
ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its

domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article 26
SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Article 27
LIABILITY AND REDRESS

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Article 28
FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 29
CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

   (a) Make recommendations on any matters necessary for the implementation of this Protocol;

   (b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

   (c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

   (d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

   (e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

   (f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to

be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 30
SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.
3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the Bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article 31
SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.
2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.
3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 32
RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article 33
MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article 34
COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article 35
ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article 36
SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article 37
ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.
2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.
3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 38
RESERVATIONS

No reservations may be made to this Protocol.

Article 39
WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.
2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article 40
AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

ANNEX I

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

ANNEX II

INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

ANNEX III

RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, *inter alia*, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. 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.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

   (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

   (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

   (c) An evaluation of the consequences should these adverse effects be realized;

   (d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

   (e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

   (f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

   (a) *Recipient organism or parental organisms*. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name,

origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) *Donor organism or organisms*. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) *Vector*. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) *Insert or inserts and/or characteristics of modification*. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) *Living modified organism*. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) *Detection and identification of the living modified organism*. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) *Information relating to the intended use*. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) *Receiving environment*. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

Convention on Biological Diversity

Preamble

The Contracting Parties,

Conscious of the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components,

Conscious also of the importance of biological diversity for evolution and for maintaining life-sustaining systems of the biosphere,

Affirming that the conservation of biological diversity is a common concern of humankind,

Reaffirming that States have sovereign rights over their own biological resources,

Reaffirming also that States are responsible for conserving their biological diversity and for using their biological resources in a sustainable manner,

Concerned that biological diversity is being significantly reduced by certain human activities,

Aware of the general lack of information and knowledge regarding biological diversity and of the urgent need to develop scientific, technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures,

Noting that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source,

Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat,

Noting further that the fundamental requirement for the conservation of biological diversity is the in-situ conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings,

Noting further that *ex-situ* measures, preferably in the country of origin, also have an important role to play,

Recognizing the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components,

Recognizing also the vital role that women play in the conservation and sustainable use of biological diversity and affirming the need for the full participation of women at all levels of policy-making and implementation for biological diversity conservation,

Stressing the importance of, and the need to promote, international, regional and global cooperation among States and intergovernmental organizations and the non-governmental sector for the conservation of biological diversity and the sustainable use of its components,

Acknowledging that the provision of new and additional financial resources and appropriate access to relevant technologies can be expected to make a substantial difference in the world's ability to address the loss of biological diversity,

Acknowledging further that special provision is required to meet the needs of developing countries, including the provision of new and additional financial resources and appropriate access to relevant technologies,

Noting in this regard the special conditions of the least developed countries and small island States,

Acknowledging that substantial investments are required to conserve biological diversity and that there is the expectation of a broad range of environmental, economic and social benefits from those investments,

Recognizing that economic and social development and poverty eradication are the first and overriding priorities of developing countries,

Aware that conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential,

Noting that, ultimately, the conservation and sustainable use of biological diversity will strengthen friendly relations among States and contribute to peace for humankind,

Desiring to enhance and complement existing international arrangements for the conservation of biological diversity and sustainable use of its components, and

Determined to conserve and sustainably use biological diversity for the benefit of present and future generations,

Have agreed as follows:

Article 1. Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 2. Use of Terms

For the purposes of this Convention:

"Biological diversity" means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

"Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"Country of origin of genetic resources" means the country which possesses those genetic resources in in-situ conditions.

"Country providing genetic resources" means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.

"Domesticated or cultivated species" means species in which the evolutionary process has been influenced by humans to meet their needs.

"Ecosystem" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

"*Ex-situ* conservation" means the conservation of components of biological diversity outside their natural habitats.

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

"Genetic resources" means genetic material of actual or potential value.

"Habitat" means the place or type of site where an organism or population naturally occurs.

"*In-situ* conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"*In-situ* conservation" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"Protected area" means a geographically defined area which is designated or regulated and managed to achieve specific conservation objectives.

"Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Convention and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it.

"Sustainable use" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

"Technology" includes biotechnology.

Article 3. Principle

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Article 4. Jurisdictional Scope

Subject to the rights of other States, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party:

(a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and

(b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

Article 5. Cooperation

Each Contracting Party shall, as far as possible and as appropriate, cooperate with other Contracting Parties, directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity.

Article 6. General Measures for Conservation and Sustainable Use

Each Contracting Party shall, in accordance with its particular conditions and capabilities:

(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and

(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.

Article 7. Identification and Monitoring

Each Contracting Party shall, as far as possible and as appropriate, in particular for the purposes of Articles 8 to 10:

(a) Identify components of biological diversity important for its conservation and sustainable use having regard to the indicative list of categories set down in Annex I;

(b) Monitor, through sampling and other techniques, the components of biological diversity identified pursuant to subparagraph (a) above, paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use;

(c) Identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity, and monitor their effects through sampling and other techniques; and

(d) Maintain and organize, by any mechanism data, derived from identification and monitoring activities pursuant to subparagraphs (a), (b) and (c) above.

Article 8. *In-situ* Conservation

Each Contracting Party shall, as far as possible and as appropriate:

(a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity;

(b) Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity;

(c) Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use;

(d) Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings;

(e) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas;

(f) Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, *inter alia*, through the development and implementation of plans or other management strategies;

(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;

(h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;

(i) Endeavour to provide the conditions needed for compatibility between present uses and the conservation of biological diversity and the sustainable use of its components;

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

(k) Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations;

(l) Where a significant adverse effect on biological diversity has been determined pursuant to Article 7, regulate or manage the relevant processes and categories of activities; and

(m) Cooperate in providing financial and other support for in-situ conservation outlined in subparagraphs (a) to (l) above, particularly to developing countries.

Article 9. *Ex-situ* Conservation

Each Contracting Party shall, as far as possible and as appropriate, and predominantly for the purpose of complementing *in-situ* measures:

(a) Adopt measures for the *ex-situ* conservation of components of biological diversity, preferably in the country of origin of such components;

(b) Establish and maintain facilities for *ex-situ* conservation of and research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources;

(c) Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions;

(d) Regulate and manage collection of biological resources from natural habitats for *ex-situ* conservation purposes so as not to threaten ecosystems and in-situ populations of species, except where special temporary *ex-situ* measures are required under subparagraph (c) above; and

(e) Cooperate in providing financial and other support for *ex-situ* conservation outlined in subparagraphs (a) to (d) above and in the establishment and maintenance of *ex-situ* conservation facilities in developing countries.

Article 10. Sustainable Use of Components of Biological Diversity

Each Contracting Party shall, as far as possible and as appropriate:

(a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making;

(b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;

(c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;

(d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and

(e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources.

Article 11. Incentive Measures

Each Contracting Party shall, as far as possible and as appropriate, adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity.

Article 12. Research and Training

The Contracting Parties, taking into account the special needs of developing countries, shall:

(a) Establish and maintain programmes for scientific and technical education and training in measures for the identification, conservation and sustainable use of biological diversity and its components and provide support for such education and training for the specific needs of developing countries;

(b) Promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, *inter alia*, in accordance with decisions of the Conference of the Parties taken in consequence of recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice; and

(c) In keeping with the provisions of Articles 16, 18 and 20, promote and cooperate in the use of scientific advances in biological diversity research in developing methods for conservation and sustainable use of biological resources.

Article 13. Public Education and Awareness

The Contracting Parties shall:

(a) Promote and encourage understanding of the importance of, and the measures required for, the conservation of biological diversity, as well as its propagation through media, and the inclusion of these topics in educational programmes; and

(b) Cooperate, as appropriate, with other States and international organizations in developing educational and public awareness programmes, with respect to conservation and sustainable use of biological diversity.

Article 14. Impact Assessment and Minimizing Adverse Impacts

1. Each Contracting Party, as far as possible and as appropriate, shall:

   (a) Introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for public participation in such procedures;

   (b) Introduce appropriate arrangements to ensure that the environmental consequences of its programmes and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account;

   (c) Promote, on the basis of reciprocity, notification, exchange of information and consultation on activities under their jurisdiction or control which are likely to significantly affect adversely the biological diversity of other States or areas beyond the limits of national jurisdiction, by encouraging the conclusion of bilateral, regional or multilateral arrangements, as appropriate;

   (d) In the case of imminent or grave danger or damage, originating under its jurisdiction or control, to biological diversity within the area under jurisdiction of other States or in areas beyond the limits of national jurisdiction, notify immediately the potentially affected States of such danger or damage, as well as initiate action to prevent or minimize such danger or damage; and

   (e) Promote national arrangements for emergency responses to activities or events, whether caused naturally or otherwise, which present a grave and imminent danger to biological diversity and encourage international cooperation to supplement such national efforts and, where appropriate and agreed by the States or regional economic integration organizations concerned, to establish joint contingency plans.

2. The Conference of the Parties shall examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter.

Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16. Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 17. Exchange of Information

1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.

2. Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.

Article 18. Technical and Scientific Cooperation

1. The Contracting Parties shall promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity, where necessary, through the appropriate international and national institutions.

2. Each Contracting Party shall promote technical and scientific cooperation with other Contracting Parties, in particular developing countries, in implementing this Convention, *inter alia*, through the development and implementation of national policies. In promoting such cooperation, special

attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building.

3. The Conference of the Parties, at its first meeting, shall determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.

4. The Contracting Parties shall, in accordance with national legislation and policies, encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies, in pursuance of the objectives of this Convention. For this purpose, the Contracting Parties shall also promote cooperation in the training of personnel and exchange of experts.

5. The Contracting Parties shall, subject to mutual agreement, promote the establishment of joint research programmes and joint ventures for the development of technologies relevant to the objectives of this Convention.

Article 19. Handling of Biotechnology and Distribution of its Benefits

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The 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 adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

Article 20. Financial Resources

1. Each Contracting Party undertakes to provide, in accordance with its capabilities, financial support and incentives in respect of those national activities which are intended to achieve the objectives of this Convention, in accordance with its national plans, priorities and programmes.

2. The developed country Parties shall provide new and additional financial resources to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures which fulfil the obligations of this Convention and to benefit from its provisions and which costs are agreed between a developing country Party and the institutional structure referred to in Article 21, in accordance with policy, strategy, programme priorities and eligibility criteria and an indicative list of incremental costs established by the Conference of the Parties. Other Parties, including countries undergoing the process of transition to a market economy, may voluntarily assume the obligations of the developed country Parties. For the purpose of this Article, the Conference of the Parties, shall at its first meeting establish a list of developed country Parties and other Parties which voluntarily assume the obligations of the developed country Parties. The Conference of the Parties shall periodically review and if necessary amend the list. Contributions from other countries and sources on a voluntary basis would also be encouraged. The implementation of these commitments shall take into account the need for adequacy, predictability and timely flow of funds and the importance of burden-sharing among the contributing Parties included in the list.

3. The developed country Parties may also provide, and developing country Parties avail themselves of, financial resources related to the implementation of this Convention through bilateral, regional and other multilateral channels.

4. The extent to which developing country Parties will effectively implement their commitments under this Convention will depend on the effective implementation by developed country Parties of their commitments under this Convention related to financial resources and transfer of technology and will take fully into account the fact that economic and social development and eradication of poverty are the first and overriding priorities of the developing country Parties.

5. The Parties shall take full account of the specific needs and special situation of least developed countries in their actions with regard to funding and transfer of technology.

6. The Contracting Parties shall also take into consideration the special conditions resulting from the dependence on, distribution and location of, biological diversity within developing country Parties, in particular small island States.

7. Consideration shall also be given to the special situation of developing countries, including those that are most environmentally vulnerable, such as those with arid and semi- arid zones, coastal and mountainous areas.

Article 21. Financial Mechanism

1. There shall be a mechanism for the provision of financial resources to developing country Parties for purposes of this Convention on a grant or concessional basis the essential elements of which are described in this Article. The mechanism shall function under the authority and guidance of, and be accountable to, the Conference of the Parties for purposes of this Convention. The operations of the mechanism shall be carried out by such institutional structure as may be decided upon by the Conference of the Parties at its first meeting. For purposes of this Convention, the Conference of the Parties shall determine the policy, strategy, programme priorities and eligibility criteria relating to the access to and utilization of such resources. The contributions shall be such as to take into account the need for predictability, adequacy and timely flow of funds referred to in Article 20 in accordance with the amount of resources needed to be decided periodically by the Conference of the Parties and the importance of burden-sharing among the contributing Parties included in the list referred to in Article 20, paragraph 2. Voluntary contributions may also be made by the developed country Parties and by other countries and sources. The mechanism shall operate within a democratic and transparent system of governance.

2. Pursuant to the objectives of this Convention, the Conference of the Parties shall at its first meeting determine the policy, strategy and programme priorities, as well as detailed criteria and guidelines for eligibility for access to and utilization of the financial resources including monitoring and evaluation on a regular basis of such utilization. The Conference of the Parties shall decide on the arrangements to give effect to paragraph 1 above after consultation with the institutional structure entrusted with the operation of the financial mechanism.

3. The Conference of the Parties shall review the effectiveness of the mechanism established under this Article, including the criteria and guidelines referred to in paragraph 2 above, not less than two years after the entry into force of this Convention and thereafter on a regular basis. Based on such review, it shall take appropriate action to improve the effectiveness of the mechanism if necessary.

4. The Contracting Parties shall consider strengthening existing financial institutions to provide financial resources for the conservation and sustainable use of biological diversity.

Article 22. Relationship with Other International Conventions

1. The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.

2. Contracting Parties shall implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea.

Article 23. Conference of the Parties

1. A Conference of the Parties is hereby established. The first meeting of the Conference of the Parties shall be convened by the Executive Director of the United Nations Environment Programme not later than one year after the entry into force of this Convention. Thereafter, ordinary meetings of the

Conference of the Parties shall be held at regular intervals to be determined by the Conference at its first meeting.

2. Extraordinary meetings of the Conference of the Parties shall be held at such other times as may be deemed necessary by the Conference, or at the written request of any Party, provided that, within six months of the request being communicated to them by the Secretariat, it is supported by at least one third of the Parties.

3. The Conference of the Parties shall by consensus agree upon and adopt rules of procedure for itself and for any subsidiary body it may establish, as well as financial rules governing the funding of the Secretariat. At each ordinary meeting, it shall adopt a budget for the financial period until the next ordinary meeting.

4. The Conference of the Parties shall keep under review the implementation of this Convention, and, for this purpose, shall:

   (a) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 26 and consider such information as well as reports submitted by any subsidiary body;

   (b) Review scientific, technical and technological advice on biological diversity provided in accordance with Article 25;

   (c) Consider and adopt, as required, protocols in accordance with Article 28;

   (d) Consider and adopt, as required, in accordance with Articles 29 and 30, amendments to this Convention and its annexes;

   (e) Consider amendments to any protocol, as well as to any annexes thereto, and, if so decided, recommend their adoption to the parties to the protocol concerned;

   (f) Consider and adopt, as required, in accordance with Article 30, additional annexes to this Convention;

   (g) Establish such subsidiary bodies, particularly to provide scientific and technical advice, as are deemed necessary for the implementation of this Convention;

   (h) Contact, through the Secretariat, the executive bodies of conventions dealing with matters covered by this Convention with a view to establishing appropriate forms of cooperation with them; and

   (i) Consider and undertake any additional action that may be required for the achievement of the purposes of this Convention in the light of experience gained in its operation.

5. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State not Party to this Convention, may be represented as observers at meetings of the Conference of the Parties. Any other body or agency, whether governmental or non-governmental, qualified in fields relating to conservation and sustainable use of biological diversity, which has informed the Secretariat of its wish to be represented as an observer at a meeting of the Conference of the Parties, may be admitted unless at least one third of the Parties present object. The admission and participation of observers shall be subject to the rules of procedure adopted by the Conference of the Parties.

Article 24. Secretariat

1. A secretariat is hereby established. Its functions shall be:

   (a) To arrange for and service meetings of the Conference of the Parties provided for in Article 23;

   (b) To perform the functions assigned to it by any protocol;

   (c) To prepare reports on the execution of its functions under this Convention and present them to the Conference of the Parties;

   (d) To coordinate with other relevant international bodies and, in particular to enter into such administrative and contractual arrangements as may be required for the effective discharge of its functions; and

(e) To perform such other functions as may be determined by the Conference of the Parties.

2. At its first ordinary meeting, the Conference of the Parties shall designate the secretariat from amongst those existing competent international organizations which have signified their willingness to carry out the secretariat functions under this Convention.

Article 25. Subsidiary Body on Scientific, Technical and Technological Advice

1. A subsidiary body for the provision of scientific, technical and technological advice is hereby established to provide the Conference of the Parties and, as appropriate, its other subsidiary bodies with timely advice relating to the implementation of this Convention. This body shall be open to participation by all Parties and shall be multidisciplinary. It shall comprise government representatives competent in the relevant field of expertise. It shall report regularly to the Conference of the Parties on all aspects of its work.

2. Under the authority of and in accordance with guidelines laid down by the Conference of the Parties, and upon its request, this body shall:

(a) Provide scientific and technical assessments of the status of biological diversity;

(b) Prepare scientific and technical assessments of the effects of types of measures taken in accordance with the provisions of this Convention;

(c) Identify innovative, efficient and state-of-the-art technologies and know-how relating to the conservation and sustainable use of biological diversity and advise on the ways and means of promoting development and/or transferring such technologies;

(d) Provide advice on scientific programmes and international cooperation in research and development related to conservation and sustainable use of biological diversity; and

(e) Respond to scientific, technical, technological and methodological questions that the Conference of the Parties and its subsidiary bodies may put to the body.

3. The functions, terms of reference, organization and operation of this body may be further elaborated by the Conference of the Parties.

Article 26. Reports

Each Contracting Party shall, at intervals to be determined by the Conference of the Parties, present to the Conference of the Parties, reports on measures which it has taken for the implementation of the provisions of this Convention and their effectiveness in meeting the objectives of this Convention.

Article 27. Settlement of Disputes

1. In the event of a dispute between Contracting Parties concerning the interpretation or application of this Convention, the parties concerned shall seek solution by negotiation.

2. If the parties concerned cannot reach agreement by negotiation, they may jointly seek the good offices of, or request mediation by, a third party.

3. When ratifying, accepting, approving or acceding to this Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that for a dispute not resolved in accordance with paragraph 1 or paragraph 2 above, it accepts one or both of the following means of dispute settlement as compulsory:

(a) Arbitration in accordance with the procedure laid down in Part 1 of Annex II;

(b) Submission of the dispute to the International Court of Justice.

4. If the parties to the dispute have not, in accordance with paragraph 3 above, accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II unless the parties otherwise agree.

5. The provisions of this Article shall apply with respect to any protocol except as otherwise provided in the protocol concerned.

Article 28. Adoption of Protocols

1. The Contracting Parties shall cooperate in the formulation and adoption of protocols to this Convention.
2. Protocols shall be adopted at a meeting of the Conference of the Parties.
3. The text of any proposed protocol shall be communicated to the Contracting Parties by the Secretariat at least six months before such a meeting.

Article 29. Amendment of the Convention or Protocols

1. Amendments to this Convention may be proposed by any Contracting Party. Amendments to any protocol may be proposed by any Party to that protocol.
2. Amendments to this Convention shall be adopted at a meeting of the Conference of the Parties. Amendments to any protocol shall be adopted at a meeting of the Parties to the Protocol in question. The text of any proposed amendment to this Convention or to any protocol, except as may otherwise be provided in such protocol, shall be communicated to the Parties to the instrument in question by the secretariat at least six months before the meeting at which it is proposed for adoption. The secretariat shall also communicate proposed amendments to the signatories to this Convention for information.
3. The Parties shall make every effort to reach agreement on any proposed amendment to this Convention or to any protocol by consensus. If all efforts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a two-third majority vote of the Parties to the instrument in question present and voting at the meeting, and shall be submitted by the Depositary to all Parties for ratification, acceptance or approval.
4. Ratification, acceptance or approval of amendments shall be notified to the Depositary in writing. Amendments adopted in accordance with paragraph 3 above shall enter into force among Parties having accepted them on the ninetieth day after the deposit of instruments of ratification, acceptance or approval by at least two thirds of the Contracting Parties to this Convention or of the Parties to the protocol concerned, except as may otherwise be provided in such protocol. Thereafter the amendments shall enter into force for any other Party on the ninetieth day after that Party deposits its instrument of ratification, acceptance or approval of the amendments.
5. For the purposes of this Article, "Parties present and voting" means Parties present and casting an affirmative or negative vote.

Article 30. Adoption and Amendment of Annexes

1. The annexes to this Convention or to any protocol shall form an integral part of the Convention or of such protocol, as the case may be, and, unless expressly provided otherwise, a reference to this Convention or its protocols constitutes at the same time a reference to any annexes thereto. Such annexes shall be restricted to procedural, scientific, technical and administrative matters.
2. Except as may be otherwise provided in any protocol with respect to its annexes, the following procedure shall apply to the proposal, adoption and entry into force of additional annexes to this Convention or of annexes to any protocol:
   (a) Annexes to this Convention or to any protocol shall be proposed and adopted according to the procedure laid down in Article 29;
   (b) Any Party that is unable to approve an additional annex to this Convention or an annex to any protocol to which it is Party shall so notify the Depositary, in writing, within one year from the date of the communication of the adoption by the Depositary. The Depositary shall without delay notify all Parties of any such notification received. A Party may at any time withdraw a previous declaration of objection and the annexes shall thereupon enter into force for that Party subject to subparagraph (c) below;
   (c) On the expiry of one year from the date of the communication of the adoption by the Depositary, the annex shall enter into force for all Parties to this Convention or to any protocol concerned which have not submitted a notification in accordance with the provisions of subparagraph (b) above.

3. The proposal, adoption and entry into force of amendments to annexes to this Convention or to any protocol shall be subject to the same procedure as for the proposal, adoption and entry into force of annexes to the Convention or annexes to any protocol.

4. If an additional annex or an amendment to an annex is related to an amendment to this Convention or to any protocol, the additional annex or amendment shall not enter into force until such time as the amendment to the Convention or to the protocol concerned enters into force.

Article 31. Right to Vote

1. Except as provided for in paragraph 2 below, each Contracting Party to this Convention or to any protocol shall have one vote.

2. Regional economic integration organizations, in matters within their competence, shall exercise their right to vote with a number of votes equal to the number of their member States which are Contracting Parties to this Convention or the relevant protocol. Such organizations shall not exercise their right to vote if their member States exercise theirs, and vice versa.

Article 32. Relationship between this Convention and Its Protocols

1. A State or a regional economic integration organization may not become a Party to a protocol unless it is, or becomes at the same time, a Contracting Party to this Convention.

2. Decisions under any protocol shall be taken only by the Parties to the protocol concerned. Any Contracting Party that has not ratified, accepted or approved a protocol may participate as an observer in any meeting of the parties to that protocol.

Article 33. Signature

This Convention shall be open for signature at Rio de Janeiro by all States and any regional economic integration organization from 5 June 1992 until 14 June 1992, and at the United Nations Headquarters in New York from 15 June 1992 to 4 June 1993.

Article 34. Ratification, Acceptance or Approval

1. This Convention and any protocol shall be subject to ratification, acceptance or approval by States and by regional economic integration organizations. Instruments of ratification, acceptance or approval shall be deposited with the Depositary.

2. Any organization referred to in paragraph 1 above which becomes a Contracting Party to this Convention or any protocol without any of its member States being a Contracting Party shall be bound by all the obligations under the Convention or the protocol, as the case may be. In the case of such organizations, one or more of whose member States is a Contracting Party to this Convention or relevant protocol, the organization and its member States shall decide on their respective responsibilities for the performance of their obligations under the Convention or protocol, as the case may be. In such cases, the organization and the member States shall not be entitled to exercise rights under the Convention or relevant protocol concurrently.

3. In their instruments of ratification, acceptance or approval, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Convention or the relevant protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

Article 35. Accession

1. This Convention and any protocol shall be open for accession by States and by regional economic integration organizations from the date on which the Convention or the protocol concerned is closed for signature. The instruments of accession shall be deposited with the Depositary.

2. In their instruments of accession, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Convention or the relevant protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

3. The provisions of Article 34, paragraph 2, shall apply to regional economic integration organizations which accede to this Convention or any protocol.

Article 36. Entry Into Force

1. This Convention shall enter into force on the ninetieth day after the date of deposit of the thirtieth instrument of ratification, acceptance, approval or accession.
2. Any protocol shall enter into force on the ninetieth day after the date of deposit of the number of instruments of ratification, acceptance, approval or accession, specified in that protocol, has been deposited.
3. For each Contracting Party which ratifies, accepts or approves this Convention or accedes thereto after the deposit of the thirtieth instrument of ratification, acceptance, approval or accession, it shall enter into force on the ninetieth day after the date of deposit by such Contracting Party of its instrument of ratification, acceptance, approval or accession.
4. Any protocol, except as otherwise provided in such protocol, shall enter into force for a Contracting Party that ratifies, accepts or approves that protocol or accedes thereto after its entry into force pursuant to paragraph 2 above, on the ninetieth day after the date on which that Contracting Party deposits its instrument of ratification, acceptance, approval or accession, or on the date on which this Convention enters into force for that Contracting Party, whichever shall be the later.
5. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 37. Reservations

No reservations may be made to this Convention.

Article 38. Withdrawals

1. At any time after two years from the date on which this Convention has entered into force for a Contracting Party, that Contracting Party may withdraw from the Convention by giving written notification to the Depositary.
2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.
3. Any Contracting Party which withdraws from this Convention shall be considered as also having withdrawn from any protocol to which it is party.

Article 39. Financial Interim Arrangements

Provided that it has been fully restructured in accordance with the requirements of Article 21, the Global Environment Facility of the United Nations Development Programme, the United Nations Environment Programme and the International Bank for Reconstruction and Development shall be the institutional structure referred to in Article 21 on an interim basis, for the period between the entry into force of this Convention and the first meeting of the Conference of the Parties or until the Conference of the Parties decides which institutional structure will be designated in accordance with Article 21.

Article 40. Secretariat Interim Arrangements

The secretariat to be provided by the Executive Director of the United Nations Environment Programme shall be the secretariat referred to in Article 24, paragraph 2, on an interim basis for the period between the entry into force of this Convention and the first meeting of the Conference of the Parties.

Article 41. Depositary

The Secretary-General of the United Nations shall assume the functions of Depositary of this Convention and any protocols.

Article 42. Authentic texts

The original of this Convention, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary- General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Convention.

Done at Rio de Janeiro on this fifth day of June, one thousand nine hundred and ninety- two.

Annex I. Identification and Monitoring

1. Ecosystems and habitats: containing high diversity, large numbers of endemic or threatened species, or wilderness; required by migratory species; of social, economic, cultural or scientific importance; or, which are representative, unique or associated with key evolutionary or other biological processes;
2. Species and communities which are: threatened; wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value; or social, scientific or cultural importance; or importance for research into the conservation and sustainable use of biological diversity, such as indicator species; and
3. Described genomes and genes of social, scientific or economic importance.

Annex II – Part 1. Arbitration

Article 1

The claimant party shall notify the secretariat that the parties are referring a dispute to arbitration pursuant to Article 27. The notification shall state the subject-matter of arbitration and include, in particular, the articles of the Convention or the protocol, the interpretation or application of which are at issue. If the parties do not agree on the subject matter of the dispute before the President of the tribunal is designated, the arbitral tribunal shall determine the subject matter. The secretariat shall forward the information thus received to all Contracting Parties to this Convention or to the protocol concerned.

Article 2

1. In disputes between two parties, the arbitral tribunal shall consist of three members. Each of the parties to the dispute shall appoint an arbitrator and the two arbitrators so appointed shall designate by common agreement the third arbitrator who shall be the President of the tribunal. The latter shall not be a national of one of the parties to the dispute, nor have his or her usual place of residence in the territory of one of these parties, nor be employed by any of them, nor have dealt with the case in any other capacity.
2. In disputes between more than two parties, parties in the same interest shall appoint one arbitrator jointly by agreement.
3. Any vacancy shall be filled in the manner prescribed for the initial appointment.

Article 3

1. If the President of the arbitral tribunal has not been designated within two months of the appointment of the second arbitrator, the Secretary-General of the United Nations shall, at the request of a party, designate the President within a further two-month period.
2. If one of the parties to the dispute does not appoint an arbitrator within two months of receipt of the request, the other party may inform the Secretary-General who shall make the designation within a further two-month period.

Article 4

The arbitral tribunal shall render its decisions in accordance with the provisions of this Convention, any protocols concerned, and international law.

Article 5

Unless the parties to the dispute otherwise agree, the arbitral tribunal shall determine its own rules of procedure.

Article 6

The arbitral tribunal may, at the request of one of the parties, recommend essential interim measures of protection.

Article 7

The parties to the dispute shall facilitate the work of the arbitral tribunal and, in particular, using all means at their disposal, shall:

(a) Provide it with all relevant documents, information and facilities; and

(b) Enable it, when necessary, to call witnesses or experts and receive their evidence.

Article 8

The parties and the arbitrators are under an obligation to protect the confidentiality of any information they receive in confidence during the proceedings of the arbitral tribunal.

Article 9

Unless the arbitral tribunal determines otherwise because of the particular circumstances of the case, the costs of the tribunal shall be borne by the parties to the dispute in equal shares. The tribunal shall keep a record of all its costs, and shall furnish a final statement thereof to the parties.

Article 10

Any Contracting Party that has an interest of a legal nature in the subject-matter of the dispute which may be affected by the decision in the case, may intervene in the proceedings with the consent of the tribunal.

Article 11

The tribunal may hear and determine counterclaims arising directly out of the subject-matter of the dispute.

Article 12

Decisions both on procedure and substance of the arbitral tribunal shall be taken by a majority vote of its members.

Article 13

If one of the parties to the dispute does not appear before the arbitral tribunal or fails to defend its case, the other party may request the tribunal to continue the proceedings and to make its award. Absence of a party or a failure of a party to defend its case shall not constitute a bar to the proceedings. Before rendering its final decision, the arbitral tribunal must satisfy itself that the claim is well founded in fact and law.

Article 14

The tribunal shall render its final decision within five months of the date on which it is fully constituted unless it finds it necessary to extend the time-limit for a period which should not exceed five more months.

Article 15

The final decision of the arbitral tribunal shall be confined to the subject-matter of the dispute and shall state the reasons on which it is based. It shall contain the names of the members who have participated and the date of the final decision. Any member of the tribunal may attach a separate or dissenting opinion to the final decision.

Article 16

The award shall be binding on the parties to the dispute. It shall be without appeal unless the parties to the dispute have agreed in advance to an appellate procedure.

Article 17

Any controversy which may arise between the parties to the dispute as regards the interpretation or manner of implementation of the final decision may be submitted by either party for decision to the arbitral tribunal which rendered it.

Annex II – Part 2. Conciliation

Article 1

A conciliation commission shall be created upon the request of one of the parties to the dispute. The commission shall, unless the parties otherwise agree, be composed of five members, two appointed by each Party concerned and a President chosen jointly by those members.

Article 2

In disputes between more than two parties, parties in the same interest shall appoint their members of the commission jointly by agreement. Where two or more parties have separate interests or there is a disagreement as to whether they are of the same interest, they shall appoint their members separately.

Article 3

If any appointments by the parties are not made within two months of the date of the request to create a conciliation commission, the Secretary-General of the United Nations shall, if asked to do so by the party that made the request, make those appointments within a further two-month period.

Article 4

If a President of the conciliation commission has not been chosen within two months of the last of the members of the commission being appointed, the Secretary-General of the United Nations shall, if asked to do so by a party, designate a President within a further two-month period.

Article 5

The conciliation commission shall take its decisions by majority vote of its members. It shall, unless the parties to the dispute otherwise agree, determine its own procedure. It shall render a proposal for resolution of the dispute, which the parties shall consider in good faith.

Article 6

A disagreement as to whether the conciliation commission has competence shall be decided by the commission.

Conference of the Parties to the Convention on Biological Diversity: Decision II/5

Decision II/5: CONSIDERATION OF THE NEED FOR AND MODALITIES OF A PROTOCOL FOR THE SAFE TRANSFER, HANDLING AND USE OF LIVING MODIFIED ORGANISMS

The Conference of the Parties,

Recalling Article 19, paragraph 3, of the Convention on Biological Diversity,

Recognizing the link between paragraphs 3 and 4 of Article 19,

Recognizing also the link between Articles 8(g) and 19, paragraph 3,

Recalling its decision I/9 made at its first meeting, held in Nassau, Bahamas, from 28 November to 9 December 1994,

Having considered the report and recommendations prepared for its second meeting by the Open-ended Ad Hoc Group of Experts on Biosafety, which met in Madrid from 24-28 July 1995,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also that, although considerable knowledge has accumulated, significant gaps in knowledge have been identified, specifically in the field of interaction between living modified organisms (LMOs) resulting from modern biotechnology and the environment, taking into account the relatively short period of experience with releases of such organisms, the relatively small number of species and traits used, and the lack of experience in the range of environments, specifically those in centres of origin and genetic diversity,

Noting that there is a need for further analysis of existing national, regional and international regulations and legally binding instruments of relevance to the impact of LMOs on the conservation and sustainable use of biological diversity,

Affirming that international action on biosafety should offer an efficient and effective framework for the development of international cooperation aimed at ensuring safety in biotechnology through effective risk assessment and risk management for the transfer, handling and use of any LMO resulting from modern biotechnology that may have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health, and taking also into account Articles 8(g) and 19, paragraph 4, of the Convention,

Considering that, although there are existing international agreements of relevance to the impact of LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, none of these specifically address the transboundary movements of such LMOs, and therefore there is an urgent need to give attention to this issue,

Taking into account that the large majority of delegations present at the meeting of the Open-ended Ad Hoc Group of Experts on Biosafety favoured the development, within the context of an international framework for safety in biotechnology, of a protocol on biosafety under the Convention on Biological Diversity,

Stressing the importance of the urgent finalization of the United Nations Environment Programme International Technical Guidelines on Safety in Biotechnology and that this could contribute to the development and implementation of a protocol on biosafety, but noting that this does not prejudice the development and conclusion of such a protocol,

Noting that guidelines on biosafety, including the proposed United Nations Environment Programme International Technical Guidelines on Safety in Biotechnology, may be used as an interim mechanism during the development of the protocol and to complement it after its completion, for the purposes of facilitating the development of national capacities to assess and manage risks, establish adequate information systems and develop expert human resources in biotechnology,

1. *Decides* to seek solution to the above-mentioned concerns through a negotiation process to develop, in the field of the safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focusing on transboundary movement, of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement;

2. *Decides* to establish an Open-ended Ad Hoc Working Group under the Conference of the Parties which shall operate in accordance with the terms of reference in the annex to this decision;

3. *Requests* the Executive Secretary of the Convention to make the necessary arrangements for the Open-ended Ad Hoc Working Group to meet as soon as possible, at least once before the next meeting of the Conference of the Parties.

Annex to decision II/5

TERMS OF REFERENCE FOR THE OPEN-ENDED AD HOC WORKING GROUP

1. The Open-ended Ad Hoc Working Group should be composed of representatives, including experts, nominated by Governments and regional economic integration organizations.

2. The Open-ended Ad Hoc Working Group shall, in accordance with operative paragraph 1 of the present decision:

   (a) elaborate, as a priority, the modalities and elements of a protocol based on appropriate elements from Sections I, II and III, paragraph 18 (a), of Annex I of the report of the Open-ended Ad Hoc Group of Experts on Biosafety;

   (b) consider the inclusion of the elements from Section III, paragraph 18 (b), and other elements, as appropriate;

3. The development of the draft protocol shall, as a priority:

   (a) elaborate the key concepts and terms that are to be addressed in the process;

   (b) include consideration of the form and scope of advance informed agreement procedures;

   (c) identify relevant categories of LMOs resulting from modern biotechnology.

4. The protocol will have to reflect that its effective functioning requires that Parties establish or maintain national measures, but the absence of such national measures should not prejudice the development, implementation and scope of the protocol.

5. The protocol will take into account the principles enshrined in the Rio Declaration on Environment and Development and, in particular, the precautionary approach contained in Principle 15 and will:

   (a) not exceed the scope of the Convention;

   (b) not override or duplicate any other international legal instrument in this area;

   (c) provide for a review mechanism;

   (d) be efficient and effective and seek to minimize unnecessary negative impacts on biotechnology research and development and not to hinder unduly access to and transfer of technology.

6. The provisions of the Convention will apply to the protocol.

7. The process will take into full account the gaps in the existing legal framework identified through analysis of existing national and international legislation.

8. The process shall be guided by the need for all Parties to cooperate in good faith and to participate fully, with a view to the largest possible number of Parties to the Convention ratifying the protocol.

9. The process will be carried out on the basis of the best available scientific knowledge and experience, as well as other relevant information.

10. The process of developing a protocol should be conducted as a matter of urgency by an open-ended ad hoc group, which will report on progress to each subsequent meeting of the Conference of the Parties. The Open-ended Ad Hoc Working Group should endeavour to complete its work in 1998.

Conference of the Parties to the Convention on Biological Diversity: Decision EM-I/3[1]

ADOPTION OF THE CARTAGENA PROTOCOL AND INTERIM ARRANGEMENTS

The Conference of the Parties,

Recalling paragraph 3 of Article 19, by which the Parties are required to 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 adverse effects on the conservation and sustainable use of biological diversity,

Recalling its decision II/5 on consideration of the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms, by which it agreed to begin a negotiating process to develop a protocol to address the concerns of Parties on those matters,

Noting the reports of the six sessions of the Open-ended Ad Hoc Working Group on Biosafety,

Noting the valuable informal preparatory work carried out under the chairmanship of His Excellency Juan Mayr Maldonado in Montreal on 1 July 1999, in Vienna from 15 to 19 September 1999 and in Montreal from 20 to 22 January 2000,

Taking note of the UNEP International Technical Guidelines on Safety in Biotechnology,

Considering the needs of developing country Parties and Parties with economies in transition to evaluate the risks to their biodiversity and to make informed decisions associated with the transboundary movement of living modified organisms,

Considering also that arrangements are required pending the entry into force of the Cartagena Protocol on Biosafety to prepare for its effective operation once it enters into force,

I. Adoption of the Cartagena Protocol

1. *Decides* to adopt the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, as set out in the annex to the present decision;

2. *Requests* the Secretary-General of the United Nations to be the Depositary of the Protocol and to open it for signature at the United Nations Office at Nairobi during the fifth meeting of the Conference of the Parties from 15 May 2000 to 26 May 2000 and at the United Nations Headquarters in New York from 5 June 2000 to 4 June 2001;

3. *Calls upon* the Parties to the Convention on Biological Diversity to sign the Protocol from 15 May 2000 or at the earliest opportunity thereafter and to deposit instruments of ratification, acceptance or approval or instruments of accession, as appropriate, as soon as possible;

4. *Further calls upon* States that are not Parties to the Convention to ratify, accept, approve or accede to it, as appropriate, without delay, thereby enabling them also to become Parties to the Protocol;

II. Intergovernmental Committee for the Cartagena Protocol (ICCP)

5. *Decides* to establish an open-ended ad hoc Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP);

[1] UNEP/CBD/EXCOP/1/3 Annex.

6. *Decides* that the Intergovernmental Committee shall undertake, with the support of the Executive Secretary, the preparations necessary for the first meeting of the Parties, at which time it will cease to exist, taking into account the budgetary provisions adopted by the Conference of the Parties;

7. *Notes* that the rules of procedure for the Conference of the Parties to the Convention shall apply, mutatis mutandis, to meetings of the Intergovernmental Committee;

8. *Decides* that the Chair of the Intergovernmental Committee shall be Ambassador Philemon Yang (Cameroon), and invites the Intergovernmental Committee to convene, at the present meeting of the Conference of the Parties, an organizational meeting for the purpose of electing its Bureau from among the representatives of the Parties present;

9. *Decides* that the Intergovernmental Committee shall hold its first meeting in late 2000;

10. *Requests* the Executive Secretary, in consultation with the Bureau of the Intergovernmental Committee to develop a work plan for the Committee for consideration and approval by the Conference of the Parties to the Convention on Biological Diversity at its fifth meeting;

11. *Calls* upon the Parties to the Convention and other States and regional economic integration organizations to designate a focal point for the Intergovernmental Committee and to inform the Executive Secretary accordingly;

12. *Encourages* Parties, States and regional economic integration organizations to provide the Intergovernmental Committee, through the Executive Secretary, information on their existing programmes for regulating living modified organisms; and to provide related technical assistance, including training, to interested Parties and States;

13. *Requests* the Executive Secretary to commence preparatory work on the functioning of the biosafety clearing-house referred to in Article 20 of the Protocol, subject to the availability of resources referred to in the table following paragraph 20 of the present decision;

III. Roster of experts

14. *Decides* to establish a regionally balanced roster of experts nominated by Governments, in fields relevant to risk assessment and risk management related to the Protocol, to provide advice and other support, as appropriate and upon request, to developing country Parties and Parties with economies in transition, to conduct risk assessment, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movements of living modified organisms;

15. *Requests* the Executive Secretary to explore ways and means of obtaining financial resources to enable developing countries Parties and Parties with economies in transition to make full use of the roster of experts and to report thereon to the Conference of the Parties;

16. *Calls upon* Parties to promote regional cooperation for this initiative and invites international organizations, particularly those of the United Nations system, to also support within their mandates, this initiative.

…

Intergovernmental Committee for the Cartagena Protocol: Recommendation 3/5, Annex III, Implementation tool kit[1]

This implementation tool kit provides a compilation, as a checklist, of obligations found in the Cartagena Protocol on Biosafety. These obligations are organized in the following categories:

- **Administrative tasks (initial and future)**
- **Legal requirements and/or undertakings**
- **Procedural requirements (AIA and Article 11)**

I. ADMINISTRATIVE TASKS

	Tasks	**Article**	✔
	Initial actions		
1.	Designate one national authority responsible for liaison with the Secretariat and provide name/address to Secretariat.	19(1),(2)	
2.	Designate one or more competent authorities responsible for performing administrative functions under the Protocol and provide name(s)/address(es) to the Secretariat. If more than one, indicate the types of LMOs for which each competent authority is responsible.	19(1),(2)	
3.	Provide to the Biosafety Clearing-House: – any relevant existing laws, regulations or guidelines, including those applicable to the approval of LMO-FFPs; and – any bilateral, regional or multilateral agreements or arrangements.	20(3)(a)–(b), 11(5), 14(2)	
4.	Specify to the Biosafety Clearing-House cases in which import may take place at the same time as the movement is notified.	13(1)(a)	
5.	Specify to the Biosafety Clearing-House imports of LMOs exempted from the AIA procedures.	13(1)(b)	
6.	Notify the Biosafety Clearing-House if domestic regulations shall apply with respect to specific imports.	14(4)	
7.	Provide the Biosafety Clearing-House with a point of contact for receiving information from other States on unintentional transboundary movements in accordance with Article 17.	17(2)	
8.	Notify the Secretariat if there is a lack of access to the Biosafety Clearing-House and hard copies of notifications to the Clearing House should be provided.	(e.g., 11(1))	
	Follow-up actions		
9.	Provide to the Biosafety Clearing-House: – Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Art. 15; – Final decisions concerning the import or release of LMOs; and – Article 33 reports.	20(3)(c)-(e)	
10.	Make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements.	25(3)	

[1] UNEP/CBD/ICCP/3/10.

I. ADMINISTRATIVE TASKS

11.	Monitor the implementation of obligations under the Protocol and submit to the Secretariat periodic reports at intervals to be determined.	33	
12.	Notify the Biosafety Clearing-House of any relevant changes to the information provided under part I above.		

II. LEGAL REQUIREMENTS AND/OR UNDERTAKINGS

	Tasks	**Article**	✔
1.	Ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.	2(2)	
2.	Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for LMOs that may be exported as LMO-FFPs.	8(2) 11(2)	
3.	Ensure that any domestic regulatory framework used in place of the AIA procedures is consistent with the Protocol.	9(3)	
4.	Ensure that AIA decisions are taken in accordance with Article 15.	10(1)	
5.	Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.	15(1),(2)	
6.	Establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.	16(1)	
7.	Take appropriate measures to prevent the unintentional transboundary movements of LMOs, including measures such as requiring a risk assessment prior to the first release of an LMO.	16(3)	
8.	Endeavor to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.	16(4)	
9.	Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House, and, where appropriate, relevant international organizations, when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of and LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.	17(1)	
10.	Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.	18(1)	
11.	Take measures to require that documentation accompanying LMO-FFPs – clearly identifies that they "may contain" LMOs and are not intended for intentional introduction into the environment; and – provides a contact point for further information.	18(2)(a)	
12.	Take measures to require that documentation accompanying LMOs destined for contained use: – Clearly identifies them as LMOs; – Specifies any requirements for their safe handling, storage, transport and use; – Provides a contact point for further information; and – Provides the name and address of individuals or institutions to which they are consigned.	18(2)(b)	

II. LEGAL REQUIREMENTS AND/OR UNDERTAKINGS

13.	Take measures to require that documentation accompanying LMOs that are intended for intentional introduction in the environment and any other LMOs within the scope of the Protocol: – Clearly identifies them as LMOs – Specifies the identify and relevant traits and/or characteristics; – Provides any requirements for the safe handling, storage, transport and use; – Provides a contact point for further information; – Provides, as appropriate, the name and address of the importer and exporter; and – Contains a declaration that the movement is in conformity with the requirements of the Protocol.	18(2)(c)	
14.	Provide for the designation of confidential information by notifiers, subject to the exclusions set forth in Article 21(6).	21(1),(6)	
15.	Ensure consultation with notifiers and review of decisions in the event of disagreement regarding claims of confidentiality.	21(2)	
16.	Ensure the protection of agreed-upon confidential information and information claimed as confidential where a notification is withdrawn.	21(3),(5)	
17.	Ensure that confidential information is not used for commercial purposes without the written consent of the notifier.	21(4)	
18.	Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs, taking also into account risks to human health.	23(1)(a)	
19.	Endeavor to ensure that public awareness and education encompass access to information on LMOs identified in accordance with the Protocol that may be imported.	23(1)(b)	
20.	In accordance with relevant domestic laws, consult with the public in decision making under the Protocol, while respecting confidential information.	23(2)	
21.	Endeavor to inform the public about the means of public access to the Biosafety Clearing-House.	23(3)	
22.	Adopt appropriate measures aimed a preventing and, if appropriate, penalizing transboundary movements in contravention of domestic measures to implement the Protocol.	25(1)	
23.	Dispose, at its expense, of LMOs that have been the subject of an illegal transboundary movement through repatriation or destruction, as appropriate, upon request by an affected Party.	25(2)	

III. PROCEDURAL REQUIREMENTS: ADVANCED INFORMED AGREEMENT

	Tasks	**Article**	✔
1.	Provide written acknowledgement of receipt of notification to notifier within 90 days, including:		
	– Date of receipt of notification;	9(2)(a)	
	– Whether notification meets requirements of Annex I;	9(2)(b)	
	– That the import may proceed only with written consent and whether to proceed in accordance with the domestic regulatory framework or in accordance with Article 10; **OR**	10(2)(a), 9(2)(c)	
	– Whether the import may proceed after 90 days without further written consent.	10(2)(b)	
2.	Communicate in writing to the notifier, within 270 days of receipt of notification: – Approval of the import, with or without conditions; – Prohibition of the import; – A request for additional relevant information in accordance with domestic regulatory framework or Annex I; or – Extension of the 270 day period by a defined period of time; **AND**	10(3)(a)–(d)	

III. PROCEDURAL REQUIREMENTS: ADVANCED INFORMED AGREEMENT

	Except where approval is unconditional, the reasons for the decision, including the reasons for the request for additional information or for an extension of time.	10(4)	
3.	Provide in writing to the Biosafety Clearing-House the decision communicated to the notifier.	10(3)	
4.	Respond in writing within 90 days to a request by an Exporting Party for a review of a decision under Article 10 where there has been a change in circumstances or additional relevant scientific or technical information has been made available, providing the reasons for the decision upon review.	12(2),(3)	

IV. PROCEDURAL REQUIREMENTS: LIVING MODIFIED ORGANISMS FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING

	Tasks	**Article**	✔
1.	Upon making a final decision regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, inform the Biosafety Clearing-House within 15 days of making that decision, including the information listed in Annex II.	11(1)	
2.	Except in the case of field trials, provide hard copies of the final decision to the National Focal Point of Parties that have notified the Secretariat in advance that they do not have access to the Biosafety Clearing-House.	11(1)	
3.	Provide additional information contained in paragraph (b) of Annex II about the decision to any Party that requests it.	11(3)	
4.	In response to the posting of a decision by another Party, a Party that decides to import may take a decision on the import of LMO-FFPs: – either as approved under the domestic regulatory framework consistent with the Protocol; **OR** – in the absence of a regulatory framework, on the basis of a risk assessment in accordance with Annex III within no more than 270 days. In this case, a declaration must be made to the Biosafety Clearing-House.	11(4),(6)	

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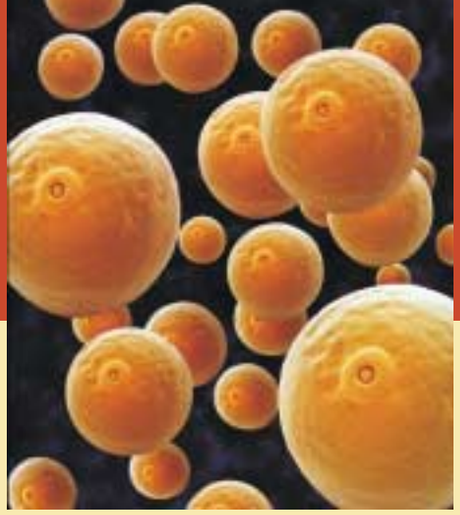

IUCN – The World Conservation Union

Founded in 1948, The World Conservation Union brings together States, government agencies and a diverse range of non-governmental organizations in a unique world partnership: nearly 980 members in all, spread across some 140 countries.

As a Union, IUCN seeks to influence, encourage and assist societies throughout the world to conserve the integrity and diversity of nature and to ensure that any use of natural resources is equitable and ecologically sustainable.

The World Conservation Union builds on the strengths of its members, networks and partners to enhance their capacity and to support global alliances to safeguard natural resources at local, regional and global levels.

The Foundation for International Environmental Law and Development (FIELD)

FIELD is a London-based, international NGO which works to enable countries, organizations and communities to gain access to environmental justice through the rules and institutions of international law.

FIELD was established in 1989 to respond to the growing threats to the global environment and the increasing complexity of the rules and institutions designed to respond to those threats. FIELD's work involves research, teaching and legal training, as well as providing legal advice and assistance. FIELD works with a range of international organizations and institutions, from NGOs to governments, in three programme areas; Biological Diversity and Marine Resources; Climate Change and Energy; and Trade, Investment and Sustainable Development.

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