

Annex I

DECISIONS ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON
BIOLOGICAL DIVERSITY AT THE FIRST PART OF ITS FIRST EXTRAORDINARY MEETING
Cartagena, 22-24 February 1999

EM-I/1. Decision on the continuation of the first extraordinary meeting
of the Conference of the Parties to the Convention
on Biological Diversity

The Conference of the Parties,

Recalling paragraph 3 of Article 19 of the Convention, 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 effect on the conservation and sustainable use of biological diversity,

Recalling also its decision II/5 of 17 November 1995 on consideration of 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 organisms, by which it agreed to begin a negotiation process to develop a protocol to address the concerns of Parties on those matters,

Recalling further its decision IV/3 of 15 May 1998, by which it agreed to hold an extraordinary meeting of the Conference of the Parties to address all matters relating to adoption of the protocol on biosafety and preparations for the first meeting of the Parties to the Protocol,

Noting the reports of the first five sessions of the Open-ended Ad Hoc Working Group on Biosafety,

Having considered with appreciation the report of the sixth session presented to it by the Chair of the Open-ended Ad Hoc Working Group on Biosafety,

Recognizing that a number of issues remain unresolved before the adoption of the protocol on biosafety,

1. Decides to suspend the first extraordinary meeting of the Conference of the Parties;
2. Decides to request the President of the first extraordinary meeting of the Conference of the Parties and the Bureau of the fourth meeting of the Conference of the Parties, in close consultation with the Executive Secretary, to decide on the date and venue of the resumed session of the first extraordinary meeting to be held as soon as practicable and, in any event, no later than the fifth meeting of the Conference of the Parties;
3. Decides further that the protocol on biosafety shall be called the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;
4. Decides further to transmit the text of the draft protocol set out in appendix I to the report of the sixth meeting of the Open-ended Ad Hoc Working Group on Biosafety, 1/ as well as the statements with respect to the text of the draft protocol contained in that report, to the Conference of the Parties at the resumed session of its extraordinary meeting;
5. Stresses the importance of concentrating at the resumed session on reaching a satisfactory resolution on the core issues and related issues as contained in the draft report of the first part of the meeting; 2/
6. Affirms its determination to complete the negotiation of the Cartagena Protocol on Biosafety for its adoption at the resumed session of the first extraordinary meeting of the Conference of the Parties;

1/ UNEP/CBD/ExCOP/1/2.

2/ See paragraph 52 above.

7. Approves the amount of 480,000 United States dollars supplementary to the programme budget for the biennium 1999-2000 for the resumed session of the extraordinary meeting of the Conference of the Parties, to be funded from savings and surpluses from the BY Trust Fund;

8. Calls upon the Parties and States to provide voluntary contributions to the relevant trust funds of the Convention to cover the cost of the resumed session, including facilitation of participation in the resumed session by developing country Parties, in particular the least developed and small island developing States among them, and Parties with economies in transition.

EM-I/2. Tribute to the Government and people of Colombia

The Conference of the Parties,

Having met in Cartagena de Indias from 22 to 24 February 1999, at the gracious invitation of the Government of the Republic of Colombia,

Deeply appreciative of the special courtesy and warm hospitality extended, and the excellent facilities provided, by the Government and people of the Republic of Colombia to the ministers, members of delegations, observers and members of the secretariat attending the meeting,

Expresses its sincere gratitude to the Government of the Republic of Colombia and to its people for the cordial welcome which they accorded to the meeting and those associated with its work and for their contribution to the considerable progress achieved by the meeting.

Annex II

PACKAGE PROPOSAL ON THE TEXT OF THE DRAFT PROTOCOL: SUBMISSION BY THE EUROPEAN UNION

1. In article 5, paragraph 3 should be retained as in the proposed text in appendix I to document UNEP/CBD/ExCOP/1/2, with a new paragraph 3 bis:

"Without prejudice to Article 5, paragraphs 2 and 3, the Conference of the Parties, serving as the meeting of the Parties, shall, at its first meeting, decide how the provisions of Articles 6, 7, 8 and 9 shall apply to transboundary movements of living modified organisms intended for direct use as food or feed or for processing".

2. The text of article 15 (Handling, transport, packaging and identification), should read as follows:

"1. Each Party shall take measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards, in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

"2. Each Party shall take measures to require that, in accompanying documentation, living modified organisms:

"(a) subject to advance informed agreement are clearly identified as living modified organisms specifying the identity and relevant traits/characteristics; any requirements for safe handling, storage, transport and use; the contact point for further information and, as appropriate, the name and address of the importer and exporter;

"(b) destined for contained use are clearly identified as living modified organisms specifying any requirements for safe handling, storage, transport and use, the contact point for further information;

"(c) intended for direct use as food, feed or processing are clearly indicated as living modified organisms, are accompanied by a list of relevant living modified organisms from among those approved in the party of export, specifying the identity of the living modified organism, specifying where further information may be obtained from the clearing-house mechanism, the contact point for further information.

"3. Each Party shall take measures to require that, in all cases, accompanying documentation includes a declaration that the movement is in conformity with the requirements of this Protocol.

"4. Notwithstanding paragraph 2, the Party of import may indicate that, in relation to imports, these requirements will not apply, or that, according to domestic law, part or all of subparagraph 2 (a) shall apply.

"5. No later than three years following the entry into force of the Protocol, the meeting of the Parties shall review the effectiveness of the requirements of paragraph 2."

3. Articles 31 and 22 should be deleted and a new preambular paragraph included, reading:

"Recognizing that the Parties to the Protocol should implement this Protocol in a manner mutually supportive of their other international obligations".

4. The reference to article 15 in article 4, subparagraph 2 (b), should be retained.

5. (a) In article 21, paragraph 1, the wording should be changed to: "consistent with the objectives of this Protocol";

(b) In article 11, the reference to "or non-Parties" should be retained;

(c) In article 3, subparagraph (k), the reference to article 11 should be deleted.

6. (a) Article 1 should be retained without amendment;

(b) In article 8, paragraph 7 should be deleted.

7. In article 23, the phrase "the relevant provisions of" should be replaced by the phrase: "its domestic measures implementing" and paragraph 2 of the article should be deleted.

8. In article 18, paragraph 5 should be reworded as follows:

"If a notifier withdraws or has withdrawn a notification, a Party must respect the confidentiality of the information submitted".

Annex III

OUTSTANDING ISSUES AND NECESSARY REVISIONS TO THE TEXT OF THE DRAFT PROTOCOL: SUBMISSION BY THE MIAMI GROUP

1. AIA procedure: articles 5 and 6 stay as in the current text (UNEP/BSWG/6/L.2/Rev.2).
2. Documentation:
 - (a) In article 15, substitute "scope of the AIA procedure" for "scope of the Protocol";
 - (b) In article 4, subparagraph 2 (b), delete the reference to article 15 connected with transit.
3. Non-Parties:
 - (a) In article 21, paragraph 1, substitute "compatible with the objective of this Protocol", for "consistent with the objective and principles of this Protocol", and delete the second sentence;
 - (b) In article 11, paragraph 1, delete the words "or non-Parties";
 - (c) In article 3 (k), delete the reference to articles 11 and 14.
4. Precautionary approach:
 - (a) In article 1, substitute the word "Noting" for "In accordance with";
 - (b) In article 8, delete paragraph 7.
5. Illegal transboundary movement (article 23):
 - (a) Substitute the words "its domestic law implementing" for "the relevant provisions of";
 - (b) Delete paragraph 2.
6. Socio-economic considerations (article 24): in paragraph 1, substitute for the existing text the following language:

"Parties, in reaching a decision on the import of living modified organisms under Article 8, may, for the purposes of Article 13, take into account the social and economic implications of adverse impacts on the conservation and sustainable use of biological diversity."
7. Savings clause (article 31) and Non-discrimination (article 22):
 - (a) In article 31, delete everything after the word "Party" in the third line;
 - (b) Delete article 22.
8. Risk assessment (article 12): delete paragraph 3.
9. Risk management (article 13): delete paragraphs 3 and 4.
10. General obligations (article 2): delete paragraph 2.
11. Multilateral, bilateral and regional agreements or arrangements (article 11): substitute the phrase "compatible with the objective of this Protocol" for "consistent with the objectives of this Protocol and provided that such agreements or arrangements do not result in a lower level of protection than that provided for by the Protocol".
12. Review of decisions under advance informed agreement (article 9): delete paragraph 4.
13. Decision procedure for advance informed agreement (article 8): delete paragraph 7.

14. Simplified procedures (article 10): delete the article.
15. Confidentiality (article 18):
 - (a) In paragraph 3, delete the phrase "in accordance with national legislation";
 - (b) In paragraph 6, insert the word "generally" after "shall not".
16. Information sharing (article 17): replace the existing language of subparagraph 3 (d) with the following:

"The final decision in its approval process for living modified organisms to be introduced into its environment, including living modified organisms introduced into the environment for the purposes of producing living modified organisms for consumption or processing, and the risk assessment decision documents on which those decisions are based."

Annex IV

PROPOSAL ON THE TEXT OF THE DRAFT PROTOCOL: SUBMISSION BY THE LIKE-MINDED GROUP OF COUNTRIES

1. In article 5, the like-minded group of countries proposed that the following subparagraphs (a) and (b) should replace paragraphs 1, 2 and 3 of the Chair's revised draft:

(a) "The advance informed agreement procedure in Articles 6, 7, 8 and 9 shall apply prior to the first transboundary movement of all living modified organisms."

(b) "Without prejudice to paragraph 1, the Party of import may decide not to apply the advance informed agreement procedure of this Protocol for the living modified organisms destined exclusively for food, feed or for processing."

2. In article 5, paragraph 4 should remain as it stood.

3. In addition, the representative of the group pointed out that, in an effort to achieve a compromise text during the negotiations, the like-minded group of countries had proposed to surrender its position on certain issues in exchange for the new wording that the group had proposed in article 5, but that it had failed to obtain agreement on that proposal. The issues in question were the following:

- (a) The inclusion of "products thereof" after "living modified organisms" in the protocol;
- (b) The inclusion of a precautionary approach in risk assessment;
- (c) The deletion of paragraphs 3 and 4 in article 11;
- (d) The deletion of article 18;
- (e) The expansion of annex II;
- (f) The development of an article on liability and redress;
- (g) A broader content of socio-economic issues, especially the development of an early warning system on commodities that will lose their market;
- (h) The definition of contained use, because it is imprecise;
- (i) The inclusion of contained use in AIA;
- (j) The inclusion of contained use.

Part Two

RESUMED SESSION OF THE FIRST EXTRAORDINARY MEETING OF THE CONFERENCE OF
THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

I. RESUMPTION OF THE MEETING

1. The first extraordinary meeting of the Conference of the Parties was resumed at the headquarters of the International Civil Aviation Organization (ICAO) in Montreal on Monday, 24 January 2000. The resumed session was preceded by four days of informal consultations, also in Montreal, the first two days being within, and the second two among, the negotiating groups.
2. The resumed session started at 10 a.m. on Monday, 24 January. In his statement, Mr. László Miklós, President of the Conference of the Parties at its fourth meeting, welcomed the participants to Montreal, wished them success in their deliberations, and handed the conduct of the meeting to the President of the first extraordinary meeting of the Conference of the Parties, Mr. Juan Mayr Maldonado, Minister of Environment of Colombia.
3. In his opening statement, Mr. Mayr recalled that he had been holding a series of informal consultations since the extraordinary meeting had suspended its session in Cartagena, with the aim of finding ways to resolve the core issues left over from that session, namely those relating to the scope of the protocol, the issue of commodities, and the relationship of the protocol to other international agreements. Progress had been made in all of those areas, giving him confidence that agreement could be reached and that after a long road of arduous negotiations, the protocol would be signed at the end of the current week. Noting that, beyond the core issues, there were other related issues to be resolved, he proposed that they be tackled as thematic clusters. Saying that the world needed the protocol on biosafety, he pointed out that it would have to set clear standards for biosafety and strike a balance between the benefits which biotechnology could bring and the precautions which were needed to ensure that living modified organisms would not have adverse effects on biodiversity and people. Since the protocol would be the first under the Convention on Biological Diversity, failure by the meeting to fulfil its mandate would seriously undermine the Convention process itself. He concluded by thanking all those who had participated in the earlier negotiations, whose flexibility had made it possible to reduce significantly the number of critical issues still outstanding.
4. Mr. Zedan said that the current meeting could be interpreted as a test of the will of the Parties to give a practical meaning to the provisions of the Convention and its underlying principles, with implications for the credibility of the Convention as a whole. While the failure to reach consensus in Cartagena had cast a shadow, progress had been made in recent months. At the informal consultations held in Vienna in September 1999, core issues had been clearly circumscribed and explored, and suggestions made for bridging the outstanding difficulties. There were grounds for optimism that solutions could be found that would meet the concerns of the various groups. At the same time, however, he cautioned that the complexity of the related trade, health, ecological and regulatory issues should not be underestimated and that the remaining obstacles would be overcome only by compromise on the part of all concerned. He concluded by thanking those Parties to the Convention that had provided financial assistance for the participation of developing countries and countries with economies in transition both in the

informal consultations in Vienna and in the current meeting, namely Australia, Austria, Canada, the Central African Republic, Denmark, the European Community, Finland, France, Kenya, Namibia, Norway, Sweden, Switzerland and the United Kingdom. He also thanked the Government of Canada, the Government of Quebec and the City of Montreal for the support which they continued to provide to the Secretariat and the work of the Convention.

II. ORGANIZATIONAL MATTERS

A. Attendance

5. All States were invited to participate in the resumed session. The following Parties accepted the invitation and participated in the resumed session: Algeria, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Bahamas, Barbados, Belarus, Belgium, Belize, Benin, Bhutan, Bolivia, Botswana, Brazil, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Central African Republic, Chad, Chile, China, Colombia, Comoros, Congo, Cook Islands, Costa Rica, Côte d'Ivoire, Cuba, Czech Republic, Democratic Republic of the Congo, Denmark, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Eritrea, Estonia, Ethiopia, European Community, Finland, France, Gambia, Germany, Ghana, Greece, Guyana, Haiti, Honduras, Hungary, India, Indonesia, Iran (Islamic Republic of), Ireland, Italy, Jamaica, Japan, Jordan, Kenya, Kyrgyzstan, Latvia, Lebanon, Lesotho, Luxembourg, Madagascar, Malaysia, Maldives, Mali, Mauritania, Mexico, Micronesia (Federated States of), Mongolia, Morocco, Namibia, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Oman, Pakistan, Panama, Papua New Guinea, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Rwanda, Saint Kitts and Nevis, Saint Lucia, Samoa, Senegal, Seychelles, Singapore, Slovak Republic, South Africa, Spain, Sri Lanka, Sudan, Swaziland, Sweden, Switzerland, Syrian Arab Republic, Togo, Tonga, Trinidad and Tobago, Tunisia, Turkey, Uganda, Ukraine, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, Uruguay, Venezuela, Vietnam, Zambia, Zimbabwe.

6. The following States were represented by observers: Holy See, Saudi Arabia, Thailand, United States of America.

7. Observers from the following United Nations bodies and specialized agencies also attended: Food and Agriculture Organization of the United Nations, Secretariat of the United Nations Convention to Combat Desertification in those Countries Experiencing Serious Drought and/or Desertification, particularly in Africa, United Nations Environment Programme (UNEP), United Nations Industrial Development Organization (UNIDO), World Trade Organization (WTO).

8. The following intergovernmental organizations were represented by observers: Arab Center for Studies of Arid Zones and Drylands (ACSAD), Commission for Environmental Cooperation (CEC), European Parliament, International Centre for Genetic Engineering and Biotechnology (ICGEB), South Pacific Regional Environment Programme (SPREP).

9. The following non-governmental organizations, industry groups and other bodies were also represented by observers: Action Réseau Consommateur, ACTIONAID, American Farm Bureau Federation, American Seed Trade Association,

American Soybean Association, Anti-Environmental Degradation Education Foundation (AEDEF), AS - PTA Brazil, Associacao Nacional da Conservacao da Natureza-Quercus, Australian GeneEthics Network, Aventis Crop Science, BIONAT, BIOTECCanada, Biotech Action Montreal (BAM), BIO-Biotechnology Industry Organization, Bivings Woodell, Inc., Brandeis University, Canada International, Canadian Environmental Law Association, Canadian Federation of Agriculture, Canadian Institute for Environmental Law and Policy, Canadian Pharmaceutical Industry (BCG Inc.), Canadian Wheat Board, Cargill, Center for International Environmental Law, Competitive Enterprise Institute, Concordia University, Consumer Alert, COTRIMAIIO, Council for Responsible Genetics, Council of Canadians, DNA Plant Technology Corp., Earthlife Africa, ECOROPA, Edmonds Institute, Empresas La Moderna, Environmental Media Services, Escuela para la Conservacion de la Fauna, European Association for Bioindustries (EUROPABIO), FIS/ASSINSEL, Forum Environment and Development, Forum Environment and Development - Working Group on Biological Diversity, Foundation for International Environmental Law and Development, Friends of the Earth, Gardner, Carton & Douglas, German Association of Biotechnology Industry, Gerster Development, GIC, Global Environment and Trade Study (GETS), Global Industry Coalition, Good Works International, Green Dossier, Greenpeace, GRIP-UQAM, Grupo de Reflexion Rural, Güises Montaña Experimental, H.E.A.L., Hoechst Schering AgrEvo GmbH, Institute for Agriculture & Trade Policy (IATP), Institute for Social, Economic and Ecological Sustainability (ISEES), Institute of Science in Society, International Chamber of Commerce International Socio-Ecological Union, INTERPHARMA, IUCN-The World Conservation Union, Korea Institute for Environment and Security, Liga para a Protecca da Natureza, London School of Economics, McGill University, McMaster University, Merck and Co. Inc., Monsanto, Montreal International, MRCI-DDP, National Corn Growers Association, National Farmer's Union, National Union of the Romanian Patronate, National University, New York University, Nijmegen University, Novartis, Objectif Terre-Observatoire de l'Ecopolitique Internationale, Pasteur Mérieux Connaught, PEER, Pfizer Inc., Pharmaceutical Research and Manufacturers of America (PhRMA), Programa Chile, Pulsar Internacional, Sustentable, QPIRG-Concordia (Biotech Working Group), Quebec Public Interest Research Group (QPIRG)-Concordia, Redes Amigos de la Tierra, Reseau Agriculture Durable, Robert Koch Institute, Royal Institute of International Affairs, Royal Society for the Protection of the Birds (RSPB), Rural Advancement Foundation International (RAFI), SAVIA, Science and Environmental Health Network, Simon Fraser University, Smith Kline Beecham, Sobrevivencia-Friends of the Earth (Paraguay), Society for Protection of Nature/Lebanon, Society Promoting Environmental Conservation (SPEC), Solagral, STOP, Society for Wildlife and Nature (SWAN) International, Third World Network, Tinker Institute on International Law and Organizations, U.S. Grains Council, Union des Producteurs Agricoles du Quebec (UPA), Union Nacional de Organizaciones Regionales Campesinos Autonomos, University of Montreal, U.S. Grains Council, Washington Biotechnology Action Council/Council for Responsible Genetics, Westvaco Corporation Women Environmental Network, World Development Movement, World Endangered Species Protection Association, World Resources Institute (WRI), WWF-World Wide Fund for Nature, Worldwatch Institute.

B. Adoption of the revised agenda

10. At the opening meeting of the session, the Conference of the Parties adopted the following revised agenda on the basis of the provisional revised agenda that had been circulated as document UNEP/CBD/ExCOP/1/1/Rev.2:

1. Resumption of the meeting.
2. Organizational matters.
 - (a) Adoption of the revised agenda;
 - (b) Organization of work.
3. Report on the credentials of representatives to the resumed first extraordinary meeting of the Conference of the Parties.
4. Adoption of the draft Protocol and related decisions.
5. Adoption of the report of the first extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity.
6. Closure of the meeting.

C. Organization of work

11. At the opening meeting of the resumed session, on 24 January 2000, the Conference of the Parties decided that plenary meetings would be held both in the conventional fashion and using the setting employed during the first part of the meeting, in Cartagena, and at the informal consultations in Vienna in September 1999, whereby delegations were seated by negotiating group and interventions are made only by the spokespersons of the groups. The format chosen would depend on whichever was considered most conducive to making progress. Plenary meetings using the "Cartagena/Vienna setting" were formal meetings, with interpretation into all official United Nations languages, and would be open to observers in accordance with the rules of procedure for meetings of the Conference of the Parties.

12. The Conference of the Parties also agreed that the President might establish a limited number of ad hoc contact groups, but in any event no more than two at one time, to facilitate progress in the drafting of text once a feeling of agreement had been achieved on concepts. The contact groups would be open to all Parties and other Governments, but not to observer organizations. They would be given specific mandates and time-frames in which to report back to plenary. In order to keep the momentum of the previous days of informal consultations, the Conference of the Parties agreed that initially the two contact groups already established during those consultations should be retained - one chaired by Mr. François Pythoud (Switzerland), dealing with issue of commodities, the other chaired by Mr. John Herity (Canada) on the scope of the protocol.

13. The Conference of the Parties further agreed that a legal drafting group would need to be set up as soon as possible to ensure internal and cross-article consistency in the text of the protocol. On the proposal of the Bureau, the group would be chaired by Ms. Lynn Holowesko (Bahamas) and would be open-ended. For the sake of effectiveness and continuity, it would have a core membership of 15 representatives (three from each of the United Nations regions, who could each be supported by two or three advisors). All regional groups were requested to designate their representatives in the legal drafting group to enable it to begin its work as soon as possible.

14. At the 3rd plenary meeting of the resumed session, held in the "Cartagena/Vienna setting" on 25 January 2000, the Conference of the Parties agreed on the following core membership of the open-ended legal drafting group: Canada, Cameroon, China, Colombia, Ethiopia, European Community (adviser), Hungary, Mexico, Netherlands (adviser), Nigeria (adviser), Norway (adviser), Philippines, Poland, Republic of Korea, South Africa, Switzerland, United Kingdom of Great Britain and Northern Ireland, United States of America (adviser), Uruguay, Zimbabwe (adviser).

III. REPORT ON THE CREDENTIALS OF REPRESENTATIVES TO THE RESUMED
FIRST EXTRAORDINARY MEETING OF THE CONFERENCE OF THE
PARTIES

15. At the 1st (opening) plenary meeting of the resumed session, on 24 January 2000, the Conference of the Parties agreed to the proposal of the Bureau that the Credentials Committee established at the first session of the meeting, in Cartagena, would continue its work under the chairmanship of Ms Ilona Jepsen (Latvia), Vice President of the Bureau of the Conference of the Parties. The Conference of the Parties agreed that it would consider the item as soon as the head of the Credentials Committee was ready to report on the matter.

16. At the 10th plenary meeting of the resumed session, held in the conventional setting on 28-29 January 2000, the Chair of the Credentials Committee reported that, of the 129 Parties and four non-Parties represented at the resumed session of the extraordinary meeting of the Conference of the Parties, the credentials of 109 were in compliance with rule 18 of the rules of procedure. The credentials of seven Parties required further clarification and 17 of the Parties had not yet submitted credentials. All those Parties that had not submitted credentials in full compliance had undertaken to provide credentials within the next 30 days. The Credentials Committee proposed, and the Conference of the Parties agreed, that their participation in the meeting should be provisionally approved, on that understanding.

17. The report of the Credentials Committee was adopted.

IV. ADOPTION OF THE DRAFT PROTOCOL AND RELATED DECISIONS

18. At the 1st (opening) meeting of the resumed session, the representative of the Secretariat drew attention to the documentation for the meeting, as listed in the annex to the annotated provisional revised agenda (UNEP/CBD/ExCOP/1/1/Rev.2/Add.1). She recalled that, by paragraph 4 of its decision EM-I/1, the Conference of the Parties had decided to transmit to its resumed session the text of the draft protocol set out in appendix I to the report of the sixth meeting of the Open-ended Ad Hoc Working Group on Biosafety (UNEP/CBD/ExCOP/1/2), as well as the statements with respect to the text of the draft protocol contained in that report. Both the report of the sixth meeting of the Ad Hoc Working Group and the draft report of the extraordinary meeting of the Conference of the Parties (UNEP/CBD/ExCOP/1/L.2/Rev.1) were available at the resumed session. The text of the draft protocol as contained in appendix I to the report of the sixth meeting of the Working Group (hereinafter "the Cartagena text") was identical to that reproduced in annex V to the draft report of the extraordinary meeting.

19. The representative of Ethiopia, also speaking on behalf of the like-minded group of countries, expressed the view that the two contact groups established during the informal negotiations should henceforth be merged and should deal with those issues under articles 4 and 5 as a whole.
20. At the 2nd plenary meeting of the resumed session, held in the "Cartagena/Vienna setting" on 24 January 2000, the Conference of the Parties considered how to further organize the work of the contact groups. The President reported that the two chairs of the contact groups had expressed a desire for further meetings of their respective groups to consider the outstanding issues.
21. The representative of Switzerland, speaking on behalf of the compromise group, pointed to the positive dynamics already generated in the discussions in the contact groups and said that it was necessary to see what elements of article 5 of the draft protocol could be merged.
22. The representative of Ethiopia, speaking on behalf of the like-minded group of countries, said that it was unacceptable to designate a particular group of living modified organisms as being outside the scope of the protocol. Any exemptions from the provisions of the protocol had to be considered with caution on a case-by-case and article-by-article basis, with no blanket exemptions. While agreeing that the contact group on commodities should continue its work, he believed that the deliberations of the contact group on the scope of the protocol had no purpose unless they also took into account the relevant elements of article 5. The representative of the European Commission, speaking on behalf of the European Union, noting the progress made, said that the contact group on commodities still needed time to focus its deliberations and to reach conclusions on other issues, such as those under article 15, and the contact group on scope needed to consider a number of outstanding issues relevant to article 5, as well as the question of annexes. It would thus be desirable for the contact groups to meet further. In addition, he believed it would be useful to initiate discussions to examine the important question of the relationship between the protocol and other international agreements, such as the World Trade Organization (WTO) Agreements and, in that connection, to assess whether progress could be made with respect to article 31.
23. The representative of Canada, speaking on behalf of the Miami group, said that, while the contact group on scope should also examine issues under article 5, with the exception of commodities, he did not wish the two contact groups to be merged.
24. The representative of Hungary, speaking on behalf of the Central and Eastern European group, supporting the suggestion made by the representative of the like-minded group of countries, proposed that the contact group on scope temporarily suspend its work and that the contact group on commodities continue its consideration of the issue of commodities, in the hope that the outcome of its activity could help solve the outstanding problems.
25. Following the discussion, the Conference of the Parties agreed that the contact groups would each reconvene and would report on the outcome of their work to the plenary, meeting in the "Cartagena/Vienna setting", at 10 a.m. on Tuesday, 25 January 2000. It was to be understood that, in their work, the contact group on commodities would focus particularly on the issue of commodities and the other contact group would broaden the scope of its

deliberations on article 4 to also take into account other elements of article 5. It was also agreed that consideration of the issues arising under article 31 would be considered at a later time.

26. At the 3rd plenary meeting of the resumed session, the Conference of the Parties, meeting in the "Cartagena/Vienna setting", heard reports from the chairs of the two contact groups, on scope and on commodities, respectively, on the work of the groups to date.

27. Mr. Pythoud, chair of the contact group on commodities, said that the group had resolved the issues surrounding article 17 (Information-sharing and biosafety clearing-house) and suggested the maintenance of the Cartagena text. On article 15 (Handling, transport, packaging and identification), the contact group had held conceptual discussions, based on the proposal submitted by the European Union (UNEP/CBD/ExCOP/1/L.2/Rev.1, annex II). On the basis of the discussions, a chair's draft of the article would be prepared and submitted for the further consideration of the contact group. With regard to the proposed additional article 9 bis in the President's non-paper, the contact group had stressed that the basis for a decision on importing living modified organisms intended for direct use as food or feed, or processing, needed to be the national regulatory system. However, it had been noted that there was a need to address the situation of a country that lacked such a regulatory system. Extensive discussions had been held on the approach to be adopted, in particular, whether procedures should be set out in the protocol, or whether the emphasis should be on capacity-building and close collaboration between exporter and importer countries.

28. Mr. Herity, chair of the contact group on scope, said that, with regard to pharmaceuticals, transit and contained use, the contact group had heard explanations of the positions held and the background to them, and one negotiating group had prepared a paper setting out the specific articles which it considered to be inapplicable to those three elements. He intended to hold informal discussions with members of each of the negotiating groups and would subsequently reconvene the contact group to pursue the deliberations.

29. The President requested each of the chairs to attempt to produce a paper, setting out both the progress made in the contact group and any outstanding issues, for the consideration of the Conference of the Parties at its next plenary session.

30. Following the statements of the spokespersons for the negotiating groups, the President said that he would be glad to participate in an informal dialogue to clarify the approach to be taken in addressing the third core issue, namely, the relationship of the protocol to existing international agreements. He hoped that a discussion on that subject could be initiated in the near future.

31. With regard to the papers to be produced by the chairs of the two contact groups, for discussion in plenary, the President stressed that the aim would be to move forward from the Cartagena text, without opening any issues that had not been identified as core and related issues in Cartagena.

32. The representative of Canada, speaking on behalf of the Miami group, said that there was also a need to take account of the statements by negotiating groups that were annexed to the draft report of the extraordinary

meeting of the Conference of the Parties and to look at a number of issues and concerns which had been raised by them. He believed that a small group should begin to consider such a group of issues.

33. The Conference of the Parties also considered the elements that should be taken up within the thematic cluster related to the third core issue, namely, the relationship of the protocol to other international agreements. The President recalled that, in the informal consultations, there had been a proposal from the compromise group that such a cluster should comprise not only article 31 (Relationship with other international agreements) but also articles 22 (Non-discrimination) and 24 (Socio-economic considerations); article 2 (General provisions), paragraph 4; and article 8 (Decision procedure), paragraph 7. On the other hand, the like-minded group of countries had suggested that article 8, paragraph 7, should be dealt with separately.

34. The representative of Canada, speaking on behalf of the Miami group, pointed out that, if the cluster were made too small, further contact groups would have to be set up to address related issues. The Miami group favoured a cluster which comprised at least articles 31, 22 and 24, and further considered it essential for article 8, paragraph 7, which related to the precautionary principle, to be discussed. He said that the issue of trade with non-Parties also had to be addressed.

35. The representative of the European Commission, speaking on behalf of the European Union, said that if there was a desire for further discussion of article 2, paragraph 4, then it should take place in the cluster centred around article 31, although his group was satisfied with the text as it stood. Article 8, paragraph 7, as an expression of the overarching precautionary principle, was extremely important, and there was a linkage between it and the way in which other international agreements expressed the idea of how to proceed in areas of scientific uncertainty. On the other hand, he was unsure of the need to discuss the issue of non-Parties, as the draft protocol now contained a sound provision in that regard.

36. The representative of Switzerland, speaking on behalf of the compromise group, said that he supported the proposal that the article 31 as it currently existed in the draft protocol should be deleted entirely and its content be reflected in the preamble. Additionally, article 2, paragraph 4, and article 8, paragraph 7, as well as articles 22 and 24, should all be discussed together, although there might conceivably be a case for initially separating off article 8, paragraph 7, on a purely temporary basis.

37. The representative of the Russian Federation, speaking on behalf of the Central and Eastern European group, said that his group would join the consensus view on article 8, paragraph 7.

38. The representative of the Philippines, speaking on behalf of the like-minded group of countries, said that the group felt that the cluster should comprise articles 31 and 22 only. Article 2, paragraph 4, would certainly be raised during the discussion, but the group did not favour the implication that an issue from one cluster could be discussed anew in another.

39. The President proposed that the cluster should comprise only articles 31 and 22.

40. The representative of Canada, speaking on behalf of the Miami group, said that his group could not agree to that proposal. He urged that the meeting should follow the principle that if one group had a concern, the others should agree to discuss it.

41. The representative of the Philippines, speaking on behalf of the like-minded group of countries, said that her group was remaining faithful to the agreement made in Cartagena, namely that the negotiations were to restart from where they had been suspended. That meant that the current discussion had to focus on the three core issues, a principle which had been reiterated in the informal discussions in Montreal and Vienna, although the door was not closed to the raising of related issues at the same time.

42. The President proposed that all participants should give thought on how to proceed, basing their considerations on his own non-paper, and that bilateral informal discussions should be held, to seek a way forward. That would ensure a level of maturity in the discussion when the contact group was finally established, which might be the following day, after the two existing contact groups had reported on their progress.

43. At the 4th plenary meeting of the resumed session, held in the "Cartagena/Vienna setting" on 25 January 2000, the Conference of the Parties heard further interim progress reports from the chairs of the two contact groups.

44. Mr. Pythoud, chair of the contact group on commodities, reported on progress in finalizing the wording for article 9 bis and said that the contact group needed to meet once more to attempt to reach a solution and to also adequately address article 15.

45. Mr. Herity, chair of the contact group on scope, said that, following further discussions and informal consultations, the contact group had produced a working draft text for its deliberations, albeit with many square brackets. That working draft contained a relatively clean text for article 4, as well as wording for new draft articles on living modified organisms in transit, on pharmaceuticals and on living modified organisms in containment. Discussions had also been held on notification of transit, although no agreement had been reached on the need for such an article or on its wording. He concluded by announcing his intention to pursue the fruitful informal consultations that were taking place with the spokespersons of the negotiating groups. He would report to a subsequent meeting of the contact group on the outcome of his consultations.

46. The Conference of the Parties requested the chair of the contact group on scope to convene a further meeting of the group to endeavour to conclude its work and to report to the plenary, in the "Cartagena/Vienna setting", on the outcome of its deliberations.

47. In light of the fact that there was currently no scheduled meeting of the contact group on commodities, the Conference of the Parties agreed to establish a contact group on articles 31 and 22, to be chaired by Mr. Philemon Yang (Cameroon), to examine the issues in the President's non-paper and to report to the next meeting of the plenary.

48. In their statements, the spokespersons of the negotiating groups noted the progress made in the contact groups, welcomed the chance to consult

informally with the chair of the contact group on commodities, and supported the establishment of the contact group to deal with the third core issue.

49. At the 5th plenary meeting of the resumed session, held in the "Cartagena/Vienna setting" on 26 January 2000, the Conference of the Parties, heard further interim progress reports from the chairs of the contact groups.

50. Mr. Pythoud, chair of the contact group on commodities, reported that progress had been made, but that the group needed to meet once more in order adequately to address article 15 of the draft protocol.

51. Mr. Herity, chair of the contact group on scope, said that no further consultations had been held since the previous plenary meeting. There was now a need for informal consultations to explore groups' flexibility with regard to contained use and pharmaceuticals for human use, and the time was fast approaching when the contact groups on commodities and on scope should meet together to explore issues of joint relevance.

52. Mr. Yang, chair of the contact group on articles 31 and 22, said that only limited progress had been made. The contact group had met for a fruitful exchange of ideas, but had worked only on article 31. He said that the contact group would now start its consideration of article 22.

53. The Conference of the Parties agreed that the contact group on articles 31 and 22 would continue to meet for the rest of the day, in preparation for a later plenary meeting. It also agreed that the contact group on commodities would continue its deliberations for a further two hours, and that the chair of the contact group on scope would pursue his informal consultations for two hours. After that time, those two contact groups would be merged into one, under the joint chairmanship of Mr. Pythoud and Mr. Herity, which would meet to produce a text on articles 4 and 5 in time for submission to plenary.

54. It was thus intended that consideration of each of the three core issues should have reached the same state of advancement by the 6th plenary meeting of the resumed session.

55. The representative of Canada, speaking on behalf of the Miami group, welcomed the progress made, but noted that his group still saw a need for discussion of further issues, such as article 8, paragraph 7.

56. The representative of the Islamic Republic of Iran, speaking on behalf of the like-minded group of countries, also welcomed the progress made. At the same time, however, he cautioned that the contact group on commodities should not lose sight of its main focus.

57. The spokespersons for the other three negotiating groups also welcomed the progress made.

58. At the 6th plenary meeting of the resumed session, held in the "Cartagena/Vienna setting" on 26 January 2000, the Conference of the Parties heard progress reports from the chairs of the contact groups.

59. Mr. Pythoud, speaking as chair of the contact group on commodities, reported on the group's discussions on article 15 (Handling, transport, packaging and identification) which had been based on the Cartagena text and

had also taken account of the proposal on the subject set out in the package proposal submitted in Cartagena by the European Union (UNEP/CBD/ExCOP/1/L.2/Rev.1, annex II).

60. The contact group had prepared a draft text of article 15 which reflected a large measure of agreement. Although a number of square brackets remained, he was optimistic that the group could find the appropriate wording. In sum, he believed that the contact group had met its mandate and that its texts of articles 15 and 8 bis would soon be ready for consideration in a broader forum.

61. Speaking as a co-chair of the combined contact group on scope and commodities, Mr. Herity drew attention to a summary paper circulated by the contact group which contained a new draft of article 4, an article 4 bis (on pharmaceuticals for humans) and an article 4 ter (on transit and transboundary movement). He was optimistic that further consultations could resolve the outstanding issues.

62. Speaking as a co-chair of the combined contact group, Mr. Pythoud pointed out that the new structure for the issues set out in the summary paper presented them in a more logical way. There had been extensive discussion of article 4 ter, but Parties supported the concept in principle. The group believed that notification of first transit of living modified organisms, not including those for food, feed or processing, would need to be addressed in another provision yet to be considered by it.

63. Mr. Yang, the chair of the contact group on articles 31 and 22, pointed to the group's proposal, set out in a working paper, that articles 31 and 22 be deleted and their content reflected in three preambular paragraphs. The proposal, which was based on the President's non-paper, reflected only an initial round of consultation and might need to be revisited and further refined.

64. The representative of the European Commission, speaking on behalf of the European Union, said that the proposals concerning articles 31 and 22 needed further examination, particularly as his negotiating group considered that article 22 continued to be useful and relevant.

65. The Conference of the Parties requested the chairs and co-chairs of the contact groups to hold further consultations and submit to the next plenary session, draft texts on the three core clusters of issues.

66. On the question of the application of the precautionary principle/precautionary approach in the protocol, the representative of Canada, speaking on behalf of the Miami group, said that the protocol itself was an expression of such an approach. However, he believed that, because both the preamble and article 1 contained references to the precautionary approach, it was superfluous to also make reference to it in draft article 8, paragraph 7, where the concept was expressed differently than in principle 15 of the Rio Declaration on Environment and Development.

67. The representative of the European Commission, speaking on behalf of the European Union, said that the protocol should not leave open the question of how the precautionary principle should be applied - it needed to be on the basis of science-based risk assessment. He believed that an additional, more

operational and practical provision concerning the precautionary principle was needed under article 8 or in a new article 8 bis.

68. The representative of Switzerland, speaking on behalf of the compromise group, said that the precautionary principle was a cornerstone of the protocol and pointed to the need to set out a precise basis on which to apply it. It would be difficult to progress in the negotiations on articles 31 and 22 without taking due account of the precautionary principle, and the matter should be included in the mandate of the contact group dealing with that core cluster.

69. The representative of Ethiopia, speaking on behalf of the like-minded group of countries, said that article 8, paragraph 7, should be retained as it was. However, since there were differing views, and the precautionary principle was central to the question of safety, it was necessary to discuss the issue.

70. The representative of Hungary, speaking on behalf of the Central and Eastern Europe group, said that the precautionary principle was the basis of the protocol and needed to be implemented.

71. At the 7th plenary meeting of the resumed session, held in the "Cartagena/Vienna setting" on 27 January 2000, the Conference of the Parties heard further progress reports from the chairs of the contact groups.

72. Mr. Yang reported that some of the negotiating groups saw a need to revisit the language proposed for the preamble, while one group had not yet met to discuss it.

73. Mr. Herity reported that a small number of brackets had been reintroduced into the text on scope, but he was confident that those issues could be resolved within a short time.

74. Mr. Pythoud reported that, in the text on commodities, some of the final areas of disagreement probably would not be resolved in the contact group, but would be submitted to plenary. Work on article 8 bis had concentrated on content rather than the position of the article in the protocol, but that issue would probably be resolved shortly.

75. Noting that consideration of trade issues also had to take account of the issue of the precautionary approach, the President asked for comments on article 8, paragraph 7, in the light of the work of Mr. Yang's group.

76. The representative of Canada, speaking on behalf of the Miami group, welcomed the deletion of article 22, and said that the language at present proposed for the preamble was the absolute minimum that his group would be able to accept. His group also felt that article 8, paragraph 7, should be deleted, since the whole protocol itself was based on the precautionary approach.

77. The representative of the European Commission, speaking on behalf of the European Union, said that the very important issue of what a country should do to protect its biodiversity in the face of potential risks deserved its own operative paragraph, and that therefore, article 8, paragraph 7, should be retained in some form or other.

78. The representative of Switzerland, speaking on behalf of the compromise group, suggested that the focus should be on finding wording that expressed a practical implementation of the precautionary principle, as currently contained in article 8, paragraph 7.

79. The representative of the Russian Federation, speaking on behalf of the Central and Eastern European group, said that his group could accept the wording of article 8, paragraph 7, as it currently stood.

80. The representative of Ethiopia, speaking on behalf of the like-minded group of countries, said that the precautionary principle had to be explicitly mentioned in the protocol. His group had initially not been in favour of the wording of article 8, paragraph 7, but was now prepared to accept it as it stood.

81. The President said that since the precautionary principle was such an important issue, he would extend the mandate of Mr. Yang's group to cover article 8, paragraph 7. The group would be co-chaired by Mr. Pythoud.

82. At the invitation of the President, the spokespersons of the negotiating groups listed the issues which they felt should still be discussed.

83. After a discussion, the President requested Mr. Nobs (Switzerland) to consult with the negotiating groups in order to determine which of the non-core issues might be resolved expeditiously, and to advise him before the following plenary. On the basis of Mr Nobs' findings, the President said, he would decide how to proceed.

84. At the 8th plenary meeting of the resumed session, held in the "Cartagena/Vienna setting" on 27 January 2000, the Conference of the Parties heard further progress reports from the chairs and co-chairs of the contact groups.

85. Mr. Yang, reporting on the results of the consultations in the contact group he now co-chaired with Mr. Pythoud, said that the group had prepared a text for article 8, paragraph 7, which had been agreed in principle by all of the negotiating groups, although one of them had also suggested an alternative text. No agreement had yet been reached on the preambular text to replace articles 31 and 22, and he sought further guidance on that issue.

86. Mr. Nobs, reporting on his consultations with regard to the non-core issues to be resolved, said that solutions had been found for the question of risk assessment as contained in articles 12 and article 13, paragraph 4, and for article 23 (Illegal transboundary movements), although one aspect needed to be referred to the legal drafting group. No solution had been found concerning the situation of non-Parties, as reflected in articles 21 and 11 (Multilateral, bilateral and regional agreements and arrangements), but he was confident that the issue would be resolved shortly. A question was pending for article 18 (Confidential information). In addition, one negotiating group was unable to accept the proposal concerning article 24 (Socio-economic considerations). He believed that, with further consultations, agreement could be reached within the available time.

87. The President requested that the nominated individuals pursue their efforts and consultations and strive to provide agreed text to the

Secretariat to enable it to be incorporated into the draft consolidated text of the protocol, if necessary leaving square brackets where there were outstanding issues or options. If no agreement could be reached, he would provide a President's text. The consolidated text would be presented for adoption to the plenary of the Conference of the Parties, meeting in the "Cartagena/Vienna setting", at 10 a.m. on Friday, 28 January 2000. He himself would continue high-level consultations to seek out the views on the entire package.

88. The spokespersons for the negotiating groups expressed their approval for the procedure proposed by the President, although one of them pointed to the possible need for time to await government responses to new draft text that became available.

89. At the 9th plenary meeting of the resumed session, held in the "Cartagena/Vienna setting" on 28 January 2000, the President informed the Conference of the Parties that he had held a round of bilateral meetings and consultations until the early hours of the morning and there had been substantial progress. He reported that there were still some outstanding issues to be resolved, but he was optimistic that the remaining gaps could be bridged by further consultations. He hoped that it would thus be possible to arrive at a consensus draft text of the protocol, for submission to the Conference of the Parties at its next plenary session, which he proposed to reconvene later in the day.

90. At the 10th plenary meeting of the resumed session, held in the conventional setting on 28-29 January 2000, the Conference of the Parties took up the final draft text of the Cartagena Protocol on Biosafety submitted by the Legal Drafting Group (UNEP/CBD/ExCOP/1/L.5).

91. Introducing the draft, the President said that, following intensive negotiations, the remaining obstacles that had blocked agreement during the first part of the meeting had been overcome, as a result of the hard work and flexibility shown by all concerned. He recommended that the Conference of the Parties adopt the draft text with one amendment, namely, that paragraph 2 (a) of draft Article 18 be changed to read:

"Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies them as "may contain" living modified organisms and 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 entry into force of this Protocol."

92. The Conference of the Parties then adopted by acclamation the draft text of the Cartagena Protocol on Biosafety submitted by the Legal Drafting Group, with the amendment introduced orally by the President. The text of the Cartagena Protocol as adopted is contained in the annex to decision EM-I/3 contained in the annex to the present report.

93. Following the adoption of the Protocol, the President expressed his heartfelt thanks to all who had participated in steering the long process of negotiation to a successful conclusion. He believed that, as a result, they would also enjoy the gratitude of the whole world. The adoption, however, marked only the beginning of the great challenges that lay ahead.

94. Mr. Klaus Töpfer, Executive Director of UNEP, said that the adoption of the Cartagena Protocol was a historic event that gave the right signal for future global cooperation. He believed that the successful conclusion of the negotiations was due to the tireless and even-handed activity of the President of the extraordinary meeting and his staff. He also expressed his gratitude to Mr. Veit Koester (Denmark) for his work as Chair of the Open-ended Ad Hoc Working Group on Biosafety. Acknowledging that thanks were due to a great many individuals who, over a period of years, had shown commitment to attaining the Protocol, he congratulated the ministers attending the meeting who, at what seemed to be the last moment, had provided the political guidance and wisdom to enable a positive outcome. Ratification and implementation of the Protocol would be an outstanding signal of commitment to safety in biotechnology, and, in that respect, he underlined the need for capacity-building in the developing countries to facilitate implementation of the Protocol on their part. Finally, he expressed the hope that use would be made of the "Cartagena/Vienna setting" in considering ways of helping the developing countries to make the most use of the Cartagena Protocol.

95. Also at the 10th plenary meeting of the resumed session, and subsequent to the adoption of the Protocol, Mr. Marcel Vernooij (Netherlands), Vice-President of the Conference of the Parties, introduced draft decision UNEP/CBD/ExCOP/1/L.6 on adoption of the Cartagena Protocol and interim arrangements. He explained that the draft decision, which had been approved by the Bureau, was a consensus text resulting from the consultations coordinated by Mr. John Ashe (Antigua and Barbuda).

96. Draft decision UNEP/CBD/ExCOP/1/L.6 was adopted by consensus as decision EM-I/3. The text of the decision is contained in the annex to the present report.

97. Following the adoption of the Cartagena Protocol, statements were made by the representatives of France, Canada, Argentina, Uganda, Ethiopia (speaking also on behalf of the like-minded group), the European Community, Switzerland, Hungary, Burkina Faso, Japan, United States of America, Kenya, and Portugal (on behalf of the European Union). Statements were also made on behalf of environmental non-governmental organizations represented at the meeting and by a representative of the Global Industry Coalition.

98. The representative of France saluted the extraordinary success represented by the adoption of the Protocol. While naturally regretting the loss of those elements of its negotiating position which it had conceded, France considered the outcome of the negotiations was a victory for the environment and a great step forward towards a fairer international system. The task now ahead was to build on the agreement and actually implement the provisions of the protocol, side-by-side with equitable rules on trade. With regard to the work ahead, she extended to the Conference of the Parties her Government's offer to host the first meeting of the newly established Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), which was to take place before the end of 2000.

99. The Conference of the Parties accepted with gratitude the offer by France to host the first meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety.

100. The representative of Canada expressed the gratitude of all Canadians for the valiant efforts. The Protocol ensured that all living modified

organisms were governed by it or an appropriate international system. It also, for the first time in an environmental agreement, provided for the application of the precautionary approach in the decision-making process. The Protocol would allow all countries to adopt the precautionary approach, just as Canada did in its own legislation. It also set workable requirements for the handling, transportation, packaging and identification of living modified organisms. It was the beginning of a new level of sophistication in multilateral environmental agreements, and a clear reflection of the will around the world for governments to reconcile trade and economic policies with concern for the environment. Although his negotiating mandate had placed limits on him, he felt that the conclusion of the Protocol was important and therefore supported its adoption by consensus. In the same way as his international counterparts, he would be taking it back to his colleagues in the Canadian cabinet. Expressing his admiration for the President's energy, skill and perseverance, as well as his extraordinary stamina, he said that it was a fitting tribute to him and to the people of Colombia that the agreement would be known as the Cartagena Protocol.

101. The representative of Argentina expressed her gratitude to the President for the skilled way in which he had directed the negotiations. All knew how difficult the task had been, and it was only fitting that so much effort should be crowned with the adoption of the Protocol. Argentina had been a member of a group faced with a difficult undertaking, that of negotiating its inclusion within the Protocol. The complex task had taken place in an atmosphere of pragmatism and good will, and its success signified a very important milestone in the history of international environmental law. She wished to express the gratitude of her delegation to all the members of the Miami group for their solidarity with her country, as well as to the delegations within the like-minded group for their readiness to understand Argentina's situation.

102. The representative of Uganda thanked the President for his tireless efforts in steering the negotiations to a successful conclusion. While the Government of Uganda recognized the potential role of modern biotechnology in agriculture, pharmaceutical research and development, it was also aware of risks associated with the transfer, handling and release of genetically modified organisms. It therefore supported the precautionary principle, notably because Uganda's human and institutional capacity in biotechnology and biosafety was still low.

103. The representative of Ethiopia, speaking also on behalf of the like-minded group, expressed his warm gratitude to the President, who had steered the negotiations well, as well as to all the Governments that had provided support for the participation of developing countries in the negotiating process. He was particularly grateful to the Government of Canada for spearheading efforts for capacity-building in developing countries in safety in biotechnology, an area that the Global Environment Facility would be expected to support for the implementation of the Protocol. Such support would lay the basis for a safer world. During the extraordinary meeting of the Conference of the Parties, the like-minded group, whose member countries included 80 per cent of the world's population and an even higher percentage of its biological diversity, had proved its worth as a negotiating entity and he expressed his warmest thanks and appreciation to all who had provided support for its work.

104. The representative of the European Community thanked the President for his outstanding achievement in the negotiations, which had led to a major breakthrough for international agreements on trade and the environment. The political leadership shown would help build confidence, ease public concern over the trade in living modified organisms and result in predictability for the biotechnology industry.

105. The representative of Switzerland, speaking also on behalf of the compromise group, praised the successful outcome of the negotiations which had resulted in a Protocol that would be useful for all of society, including industry, non-governmental organizations and civil society. He thanked the members of the other negotiating groups who, he said, had admirably shown that they were able to put the attainment of consensus before the pursuit of their own interests. Finally, he thanked the members of the compromise group, which he suggested might be kept active in one way or another in future meetings.

106. The observer from an environmental non-governmental organization, speaking also on behalf of the majority of environmental non-governmental organizations represented at the meeting, expressed her appreciation for the openness of the process that had led to a historic agreement, the first treaty to recognize living modified organisms as something distinctive and to apply the precautionary approach. In the course of the past year, countries had shown a tendency to put environment before trade, and she urged continued vigilance in that connection. She thanked the people from Canada for their support in Montreal and said that the Protocol represented a first major step in a long journey toward achieving international protection. She looked forward to future negotiations on a liability regime under the Protocol.

107. The representative of Hungary noted that the adoption of the Protocol represented a real solution to an important safety issue. It was of importance for the Convention on Biological Diversity as a whole. He expressed his country's gratitude to the President and to his staff for the successful handling of the difficult negotiations, as well as to the non-governmental organizations for their very useful advice and suggestions.

108. The representative of Burkina Faso also joined the expressions of congratulation and gratitude.

109. The representative of Japan expressed his country's gratitude and congratulations to the President. As the largest importer of living modified organisms, particularly in food, Japan had wanted a Protocol that would be acceptable to all. He was particularly pleased, after such arduous negotiations, that it had been adopted by consensus, a consensus which his country had been pleased to join.

110. The representative of the United States of America, noting that his country was not a Party to the Convention on Biological Diversity, expressed gratitude for the courtesy with which it had been allowed to express its concerns. Saying that the Protocol as adopted was a great improvement on the version with which the process had started, he paid tribute to the open-minded spirit in which the negotiations had been conducted. Their success would permit all countries to harness the promise of technology, that of feeding more people on less land while using less water, and to do so without improperly limiting trade. He expressed his gratitude to the Minister of the

Environment of Canada, and to the President and his staff, without whose commitment the successful outcome would not have been possible.

111. The representative of the Global Industry Coalition thanked the President for his determined and skilful leadership, which had resulted in the successful adoption of the Protocol. That was a significant step forward, and the Coalition had been proud to offer constructive support to the creation of a workable framework for the protection of biodiversity, which would bring great social and economic benefits.

112. The representative of Kenya congratulated the President on the successful conclusion of the negotiations, brought about by his tireless efforts, as well as by the efforts of all the participants. She looked forward to welcoming them all to the signing ceremony, which would begin in Nairobi on the occasion of the fifth meeting of the Conference of the Parties to the Convention on Biodiversity.

113. The representative of Portugal, also speaking on behalf of the European Union, noted that the world had had great expectations of the negotiations, and the meeting had not disappointed them. All involved were indebted both to the President and to Mr. Koester, former Chairman of the Open-ended Ad Hoc Working Group on Biosafety. Saying that the present moment was not an end, but the beginning of a process, he expressed confidence that there would be support for the process of implementation from the public, from civil society and from the non-governmental organizations.

V. ADOPTION OF THE REPORT

114. The present report was adopted by the Conference of the Parties at the 10th plenary meeting of the resumed session, held in the conventional setting on 28-29 January 2000 on the basis of the draft report that had been circulated as document UNEP/CBD/ExCOP/1/L.2/Rev.1 and Add.1 and 2.

VI. CLOSURE OF THE MEETING

115. The President declared the first extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity closed at 6.10 a.m. on Saturday, 29 January 2000.

Annex

DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON
BIOLOGICAL DIVERSITY AT THE RESUMED SESSION OF ITS FIRST EXTRAORDINARY
MEETING
Montreal, 24-29 January 2000

EM-I/3. 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 Depository 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);

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;

IV. Administrative and budgetary matters

17. Reconfirms the budget as approved in its decision IV/17, which includes an amount of US\$ 1,078,800 for the Protocol on Biosafety for the year 2000 under the Trust Fund for the Convention on Biological Diversity (BY);

18. Takes note of the amounts supplementary to the funding estimates for the Special Voluntary Trust Fund (BE) for Additional Voluntary Contributions in Support of Approved Activities for the biennium 1999-2000 specified by the Executive Secretary and included in the table below and invites Parties and States to make contributions to that fund;

19. Invites the Executive Director of the United Nations Environment Programme, in cooperation with the Executive Secretary, to identify the necessary financial, technical and staff resources, which the United Nations

Environment Programme can make available to the Executive Secretary to assist the latter in the organization of the expert and/or regional meetings;

20. Decides to consider the budget for the Protocol on Biosafety for the biennium 2001-2002 at the fifth meeting of the Conference of the Parties.

Table

SUPPLEMENTARY BUDGET FOR BIOSAFETY TO THE SPECIAL VOLUNTARY TRUST FUND (BE)
FOR ADDITIONAL VOLUNTARY CONTRIBUTIONS IN SUPPORT OF APPROVED ACTIVITIES
1999-2000
(thousands of United States dollars)

			2000
A.	Meetings		
	ICCP Bureau meeting.		40
	Biosafety clearing-house common format meeting	30 participants	140
B.	Biosafety clearing-house		41
C.	Roster of experts		50
	Subtotal		271
D.	Programme support costs (13 per cent)		35
TOTAL			306

Annex to decision EM-I/3

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 organisations.

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 Article 15; 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 UNDER ARTICLE 15

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.

