

# **Biosafety Protocol (Draft Text) 23 February 1999**

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**Contents**

<b>Biosafety Protocol (Draft Text) 23 February 1999</b>	<b>1</b>	Article 7 - Acknowledgement Of Receipt Of Notification	17
<b>Conference of the Parties to the Convention on Biological Diversity</b>		Article 8 - Decision Procedure . . . . .	17
<b>First extraordinary meeting Cartagena, 22-24 February 1999 and (to be completed)</b>	<b>1</b>	Article 9 - Review Of Decisions . . . . .	18
<b>Draft Report Of The Extraordinary Meeting Of The Conference Of The Parties For The Adoption Of The Protocol On Biosafety To The Convention On Biological Diversity</b>	<b>1</b>	Article 10 - Simplified Procedure . . . . .	18
Introduction . . . . .	1	Article 11 - Multilateral, Bilateral and Regional Agreements and Arrangements . . . . .	19
I. Opening of the Meeting . . . . .	2	Article 12 - Risk Assessment . . . . .	19
II. Organizational Matters . . . . .	3	Article 13 - Risk Management . . . . .	19
III. Report On The Credentials Of Representatives To The First Extraordinary Meeting Of The Conference Of The Parties . . . . .	5	Article 14 - Unintentional Transboundary Movements And Emergency Measures . . . . .	20
IV. Report Of The Open-Ended Ad Hoc Working Group On Biosafety . . . . .	6	Article 15 - Handling, Transport, Packaging And Identification . . . . .	20
V. Adoption Of The Protocol And Related Decisions . . . . .	7	Article 16 - Competent National Authorities And National Focal Points . . . . .	21
Annex I . . . . .	9	Article 17 - Information-Sharing And The Biosafety Clearing-House . . . . .	21
Annex II . . . . .	11	Article 18 - Confidential Information . . . . .	22
Annex III . . . . .	12	Article 19 - Capacity-Building . . . . .	23
Annex IV . . . . .	13	Article 20 - Public Awareness And Participation . . . . .	23
Annex V - Draft Protocol On Biosafety . . . . .	14	Article 21 - Non-Parties . . . . .	23
Article 1 - Objective . . . . .	15	Article 22 - Non-Discrimination . . . . .	24
Article 2 - General Provisions . . . . .	15	Article 23 - Illegal Transboundary Movements . . . . .	24
Article 3 - Use Of Terms . . . . .	15	Article 24 - Socio-Economic Considerations . . . . .	24
Article 4 - Scope . . . . .	16	Article 25 - Liability and Redress . . . . .	24
Article 5 - Application Of The Advance Informed Agreement Procedure . . . . .	16	Article 26 - Financial Mechanism And Resources . . . . .	24
Article 6 - Notification . . . . .	17	Article 27 - Conference Of The Parties Serving As The Meeting Of The Parties . . . . .	25
		Article 28 - Subsidiary Bodies And Mechanisms . . . . .	26
		Article 29 - Secretariat . . . . .	26
		Article 30 - Relationship With The Convention . . . . .	27
		Article 31 - Relationship With Other International Agreements . . . . .	27
		Article 32 - Monitoring And Reporting . . . . .	27
		Article 33 - Compliance . . . . .	27

Article 34 - Assessment and Review . . . . .	27
Article 35 - Signature . . . . .	27
Article 36 - Entry Into Force . . . . .	27
Article 37 - Reservations . . . . .	28
Article 38 - Withdrawal . . . . .	28
Article 39 - Authentic Texts . . . . .	28
Annex I - Information Required In Notifications . . . . .	28
Annex II - Risk Assessment . . . . .	29
Objective . . . . .	29
Use of risk assessment . . . . .	29
General principles . . . . .	29
Methodology . . . . .	29
Points to consider . . . . .	30
<b>Metadata</b>	<b>31</b>
SiSU Metadata, document information . . . . .	31

1 **Biosafety Protocol (Draft Text) 23 February 1999**

2 **Conference of the Parties to the Convention on  
Biological Diversity  
First extraordinary meeting Cartagena, 22-24  
February 1999 and (to be completed)**

3 **Draft Report Of The Extraordinary Meeting Of The  
Conference Of The Parties For The Adoption Of The  
Protocol On Biosafety To The Convention On  
Biological Diversity**

4 Rapporteur: Ms. Maria Feliciana Nunes ORTIGAO DE SAM-  
PAIO (Brazil)

5 **Introduction**

6 1. Pursuant to article 19, paragraph 3, of the Convention on Biological Diversity, the Conference of the Parties, by its decision I/9 of 9 December 1994, decided to establish an open-ended ad hoc group of experts, nominated by Governments, 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 might have adverse effects on the conservation and sustainable use of biological diversity, and further decided that the group of experts would consider, as appropriate, existing knowledge, experience and legislation in the field of biosafety, including the views of the Parties and of subregional, regional and international organizations, with a view to presenting a report for the consideration of the Conference of the Parties at its second meeting, so as to enable the Conference of the Parties to reach an informed decision as to the need for and modalities

of a protocol.

2. The Open-ended Ad Hoc Group of Experts on Biosafety met in Madrid from 24 to 28 July 1995. At its first meeting, the Conference of the Parties also established a panel of 15 government-nominated experts to prepare a background document for consideration by the Open-ended Ad Hoc Group. The Panel of Experts met in Cairo from 1 to 5 May 1995.

3. On the basis of the final report and recommendations of the Open-ended Ad Hoc Group of Experts on Biosafety, the second meeting of the Conference of the Parties, by its decision II/5 of 17 November 1995, established an Open-ended Ad Hoc Working Group on Biosafety to develop a draft protocol on biosafety, specifically focusing on the transboundary movement of any living modified organism resulting from modern bio-technology that might have adverse effects on the conservation and sustainable use of biological diversity. The Open-ended Ad Hoc Working Group on Biosafety held six meetings between July 1996 and February 1999 under the chairmanship of Mr. Veit Koester (Denmark). Its first meeting was held in Aarhus, Denmark, from 22 to 26 July 1996, its second, third, fourth and fifth meetings in Montreal, Canada, from 12 to 16 May 1997, 13 to 17 October 1997, 5 to 13 February 1998 and 17 to 28 August 1998 respectively, and its sixth and final meeting in Cartagena, Colombia, from 14 to 22 February 1999.

4. The first extraordinary meeting of the Conference of the Parties was convened by the Executive Secretary of the Convention on Biological Diversity for the purpose of adopting a protocol on biosafety to the Convention on Biological Diversity, pursuant to decision IV/3 of the Conference of the Parties of 15 May 1998. By paragraph 3 of that decision, the Conference of the Parties decided that the final meeting of the Open-ended Ad Hoc Working Group on Biosafety and an extraordinary meeting of the Conference of the Parties would be held in February 1999

and that those meetings would be held at the seat of the secretariat of the Convention on Biological Diversity in Montreal, Canada, unless an offer to host those meetings was received by the Executive Secretary no later than 1 August 1998. By paragraph 4 of the decision, the Conference of the Parties further decided, in accordance with rule 13 of the rules of procedure, that the agenda of the extraordinary meeting would address all matters relating to, first, the adoption of the protocol on biosafety and, second, preparations for the first meeting of the Parties to the protocol with regard, inter alia, to interim arrangements, taking into account the budgetary provision made for that purpose in accordance with decision IV/17 of 15 May 1998 on the budget of the Trust Fund for the Convention.

10 5. At the invitation of the Government of Colombia, the first part of the extraordinary meeting of the Conference of the Parties for the adoption of the Protocol on Biosafety to the Convention on Biological Diversity was held in Cartagena de Indias on 22 and 23 February 1999.

## 11 I. Opening of the Meeting

12 6. Owing to the inability of Mr. Josef Zlocha (Slovakia), President of the fourth meeting of the Conference of the Parties, to complete his assigned term of office, and in accordance with rule 24 of the rules of procedure for meetings of the Conference of the Parties, Mr. Laszlo Miklos (Slovakia) had assumed the office of President. The first extraordinary meeting of the Conference of the Parties was opened by Mr. Miklos, President of the Conference of the Parties, at 10 a.m. on 22 February 1999.

13 7. The meeting observed a minute of silence in commemoration of the victims of the recent earthquake in Colombia.

14 8. At the opening ceremony, statements were made by Mr. An-

dres Pastrana Arango, President of Colombia, Mr. Laszlo Miklos, President of the fourth meeting of the Conference of the Parties, Mr. Juan Mayr Maldonado, Minister of Environment of Colombia, Mr. Hamdallah Zedan, acting Executive Secretary of the Convention on Biological Diversity, and Mr. Klaus Töpfer, Executive Director of the United Nations Environment Programme (UNEP).

9. Mr. Pastrana, President of Colombia, said that, at the beginning of the new millennium, there were two prospects: the extinction of the human race, or sustainable development. The issues of social justice, human rights and the environment could only be viewed from an integrated, global perspective and international cooperation must be revitalized. 15

Developing countries, especially countries with great environmental wealth, had an obligation to participate actively in the establishment and development of new international environmental law; at the same time, they needed financial assistance and access to modern environmentally sound technologies. Firm political will and true solidarity among nations was required: at stake was the survival of the human race, as had been recognized at the United Nations Conference on Environment and Development in 1992. Science must be subordinated to ethics and to the satisfaction of basic human needs. 16

10. Colombia, which accounted for nearly 13 per cent of the world's biological diversity, was in the vanguard of environmental protection. In 1974, it had been the first Latin American country to draw up a code on natural resources designed to protect the environment. 17

He had placed environmental protection high on the agenda for national reconciliation, as one of the main pillars of peace. Meanwhile, the cultivation of drug crops and the use of chemical precursors were posing a serious threat to the environment, which needed to be addressed through alternative, environ- 18

mentally sustainable development, and international cooperation to prevent the entry of precursors.

19 11. Colombia strongly supported the Convention on Biological Diversity, and also stressed the need for a protocol on biosafety. The establishment of an appropriate regulatory mechanism for the transboundary movement of living modified organisms was a matter of critical necessity. He urged participants to seek agreement in order to be able to tackle in a responsible manner issues involved in the protection of biodiversity such as world food security, human health and survival and an equitable social and economic future for both the industrialized world and the developing countries.

20 12. Mr. Miklos said that there was a consensus in the world community that an instrument was needed to regulate the transboundary movement of living modified organisms.

21 The Conference of the Parties had been confident that the time allotted for the completion of the protocol would be sufficient to resolve the outstanding issues. That time was coming to an end, and the Conference had no mandate to decide on an extension of the regulatory process. It had a historic opportunity to finalize the protocol and the current extraordinary meeting had been convened for that purpose. It must determine whether the outstanding issues really related to the promotion of biodiversity, and whether living modified organisms, or products thereof, posed the greater danger to biodiversity. If the Conference were committed to the promotion of biodiversity, it had to bring out its final product.

22 13. Mr. Zedan said that the Working Group had the demanding task of finalizing the protocol on biosafety. Flexibility and compromise were critical at the last stages of negotiation.

23 If no agreement were reached, the Convention on Biological Diversity would be undermined. The international environmental and trade agreements concluded over the past 50 years had

overlapping mandates; the international community needed to make sure they worked as a whole, and were mutually reinforcing. The international community must recognize the importance of sustainable development and establish the tools to achieve that end.

24 14. Mr. Töpfer said that the process of reaching compromise on a protocol should build a secure basis for addressing biosafety issues. It was not possible to resolve all problems related to biosafety, but the process must be started with the adoption of the protocol, demonstrating that the international community could use modern biotechnology while taking responsibility for its repercussions.

## 25 II. Organizational Matters

### 26 A. Attendance

27 15. All States were invited to participate in the meeting. The following Parties to the Convention accepted the invitation and participated in the extraordinary meeting of the Conference of the Parties: Albania, Algeria, Angola, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Bahamas, Bangladesh, 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, Croatia, Cuba, Czech Republic, Democratic Republic of the Congo, Denmark, Djibouti, Dominican Republic, Ecuador, Egypt, El Salvador, Ethiopia, European Community, Fiji, Finland, France, Gambia, Georgia, Germany, Ghana, Greece, Guatemala, Guinea, Guyana, Haiti, Holy See, Hungary, India, Indonesia, Iran (Islamic Republic of), Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Kiribati, Lao People's Democratic Republic, Latvia, Lesotho, Lithuania,

Madagascar, Malawi, Malaysia, Mali, Mauritania, Mauritius, Mexico, Micronesia (Federated States of), Mongolia, Morocco, Myanmar, Namibia, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Oman, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Rwanda, Saint Kitts and Nevis, Saint Lucia, Samoa, Senegal, Seychelles, Singapore, Slovakia, Slovenia, Solomon Islands, South Africa, Spain, Sri Lanka, Swaziland, Sweden, Switzerland, Sudan, Tajikistan, Thailand, Togo, Tunisia, Turkey, Uganda, Ukraine, United Kingdom of Great Britain and Northern Ireland, Uruguay, Venezuela, Viet Nam, Yemen, Zambia and Zimbabwe.

28 16. The following States were represented by observers: Saudi Arabia, Thailand and the United States of America.

29 17. Observers from the following United Nations bodies and specialized agencies also attended: Food and Agriculture Organization of the United Nations (FAO), Global Environment Facility (GEF), United Nations Environment Programme (UNEP), World Intellectual Property Organization (WIPO) and World Trade Organization (WTO).

30 18. The following intergovernmental organizations were represented by observers:

31 International Centre for Genetic Engineering and Biotechnology (ICGEB), South Pacific Regional Environment Programme (SPREP) and Arab Centre for Studies of Arid Zones and Drylands (ACSAD).

32 19. The following non-governmental organizations, industry groups and other bodies were also represented by observers: Afri Net, Ag-West Biotech Inc., AgrEvo Belgium, Alcaldía de San Vicente del Caguan, Alcaldía Mayor de Cartagena, American Agricultural Law Association, Amigrans, BIO-Biotech Industry Organization, BIOTECCanada, Bio-technology Industry Organization (BIO), Cambiotech, Canacinttra, Canadian

Federation of Agriculture, Canadian Pharmaceutical Industry (BCG Inc.), Cardique, Centro de Estudios Realidad Social (CERES), Comisión Nacional Para La Biodiversidad, Coordinación Ambiental Bacata Siglo XX, Cooperación Madre Tierra, Corporación Ambiental Bacata XX1, Cooperación para el Desarrollo de las Comunidades, Corporación Nuevo Arco Iris, Corporación Verde de Colombia, Council for Responsible Genetics, Deloitte and Touche, Despadio Primera Dama de la Nación, Dupont, Ecodesarrollo, Ecofondos, Edmonds Institute, Environmental Services, European Group for Ecological Action (ECOROPA), Forum Environment and Development and its Institute for Applied Ecology, Friends of the Earth International, Fundación Ambiental Grupos Ecologicos de Risaralda, Fundación Ceres, Fundación Ecolucion del Caribe, Fundación Grupos Ecologicos de Risalda, Fundación OKAWA, Fundación Proteger, Fundación Semilla, Fundación Social Viva la Ciudadanía, Fundación SWISSAID, German Association of Biotechnology Industries, Good Works International, Green Industry Biotechnology Platform (GIBiP), Greenpeace, Grocery Manufacturers of America (GMA), Grupo Ambientalista de Antioquia, Harvard University, Hoechst Schering AgrEvo GmbH, Hogan and Hartson, Institute for Agriculture and Trade Policy, Instituto Colombiano Agrapeduario (ICA), Instituto Colombiano de Derecho Ambiental, Instituto Latinoamericano de Servicios Legales Alternativos (ILSA), International Chamber of Commerce, International Regional Organization for Plant and Animal Health (OIRSA), Monsanto, NEOTROPICO International Centre for the Study of the Neotropics (INCENT), Novartis Seed AG, O'Mara and Associates, Organización Ambiental OKAWA, Parque Nacional Tayrona, Pioneer Argentina, PNN Old Providence, Programme PNN Corales del Rosario y San Bernardo, Pulsar Internacional, Red de Liderazgo Costeño, Research Foundation for Science, Technology and Ecology, Rhone Poulenc Rorer Pharmaceuticals, Servicio

Nacional de Aprendizaje (SENA), Society for Wildlife and Nature (SWAN) International, Third World Network, Trafico Illegal de Fauna, Universidad de Caldas, Universidad del Atlantico, Universidad Nacional de Colombia sede Medellin, U.S. Grains Council, Washington Biotechnology Action Council/Council for Responsible Genetics, Women Environmental Network Organization and World Wide Fund for Nature (WWF).

33 **B. Confirmation of the Bureau**

34 20. Following a proposal by the President of the Conference of the Parties and in accordance with the practice of previous meetings of the Conference of the Parties, the meeting agreed, by acclamation, that Mr. Juan Mayr Maldonado, Minister of Environment of Colombia, should be invited to be President of the first extraordinary meeting of the Conference of the Parties. Mr. Mayr accepted the invitation. The members of the Bureau continued in office.

35 **C. Adoption of the agenda and organization of work**

36 21. The extraordinary meeting of the Conference of the Parties adopted the following agenda:

- 37 1. Opening of the meeting.
- 38 2. Organizational matters.
- 39 (a) Adoption of the agenda.
- 40 (b) Organization of work.
- 41 3. Report on the credentials of representatives to the first extraordinary meeting of the Conference of the Parties.
- 42 4. Report of the Open-ended Ad Hoc Working Group on Biosafety.

5. Adoption of the Protocol and related decisions.

6. Adoption of the Final Act.

7. Signature of the Final Act.

8. Closure of the meeting.

22. Owing to the complexity of the issues involved, it had not proved possible to conclude negotiations on the draft text of the protocol before the opening of the extraordinary meeting of the Conference of the Parties. Accordingly, following the opening session and adoption of the agenda, the meeting agreed to suspend its work to allow the Working

Group to consider and adopt the report of its Chair to the Conference of the Parties.

**III. Report On The Credentials Of Representatives To The First Extraordinary Meeting Of The Conference Of The Parties**

23. The Chair of the Credentials Committee reported that, of the 134 Parties represented at the meeting, 113 had presented credentials in compliance with rule 18 of the rules of procedure. The credentials of 6 Parties required further clarification and 15 Parties had not yet submitted credentials. The Credentials Committee proposed, and the meeting agreed, that those Parties which had not submitted credentials in full compliance should sign a declaration undertaking to do so within 30 days, and that their participation in the meeting should be provisionally approved, on that understanding.

24. The report of the Credentials Committee was adopted.

#### IV. Report Of The Open-Ended Ad Hoc Working Group On Biosafety

53 25. At its 2nd session, on 22 February 1999, Mr. Koester, Chair of the Open-ended Ad Hoc Working Group on Biosafety, on the invitation of the President, presented to the meeting the report on the outcome of the sixth meeting of the Open-ended Ad Hoc Working Group on Biosafety, as contained in document UNEP/CBD/ExCOP/1/2.

54 26. The Open-ended Ad Hoc Group of Experts on Biosafety, established under decision I/9 of the Conference of the Parties, had met in Madrid from 24 to 28 July 1995. The first meeting of the Conference of the Parties had also established a panel of 15 government-nominated experts to prepare a background document for consideration by the Open-ended Ad Hoc Group of Experts on Biosafety. The Panel of Experts had met in Cairo from 1 to 5 May 1995.

55 27. On the basis of the final report and recommendations of the Open-ended Ad Hoc Group of Experts on Biosafety, the second meeting of the Conference of the Parties, held in Jakarta, Indonesia, from 6 to 17 November 1995, by its decision II/5, had established an Open-ended Ad Hoc Working Group on Biosafety to negotiate a protocol on biosafety, specifically focusing on the transboundary movement of any living modified organism resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity.

56 28. The Open-ended Ad Hoc Working Group on Biosafety had held six meetings between July 1996 and February 1999. He said that it had been a challenging experience and a privilege to have been able to chair all six meetings.

57 29. At its first meeting, in Aarhus, Denmark, from 22 to 26 July 1996, the Working Group had held preliminary discussions on

52 a number of issues including: the key concepts and terms to be addressed in the process; the form and scope of advance informed agreement procedures; and the relevant categories of living modified organisms resulting from modern biotechnology. The Working Group had also developed a list of possible items to be dealt with in a protocol on biosafety that was to guide work at successive meetings.

30. At its second meeting, in Montreal, Canada, from 12 to 16 May 1997, the Working Group had organized its work strictly in plenary. Country representatives had initiated discussion on the elaboration of a protocol on biosafety and Governments had been invited to propose draft legal text on articles listed in the Chairman's summary of events. The government submissions would form the basis for discussion at the third meeting. 58

31. At its third meeting, in Montreal, from 13 to 17 October 1997, the Working Group had produced a consolidated draft text that was to serve as the basis for future negotiations. At that same meeting, it had also established its two sub-working groups and two contact groups. 59

32. At its fourth meeting, in Montreal, from 5 to 13 February 1998, the Working Group had entered into the negotiating phase of its task. 60

33. At its fourth meeting, held in Bratislava, Slovakia, from 4 to 15 May 1998, the Conference of the Parties, in its decision IV/3, had decided that two more meetings should be held to finalize the biosafety protocol. 61

34. At its fifth meeting, in Montreal, from 17 to 28 August 1998, the Working Group had managed to focus further the elements and articles that formed the protocol. 62

35. The sixth and final meeting had been held in the city of Cartagena, Colombia, from 14 to 22 February 1999. The meeting had initially been scheduled to end on 19 February 1999 63

but, owing to the overwhelming number of outstanding issues, 67  
work had continued until 22 February 1999.

64 36. At the conclusion of its sixth meeting, the Working Group  
had still been unable to present a consensus text for adoption.  
Considering that outcome of the process, however, due  
account should be paid to the immensity of the task facing  
the Group from the outset and to the fact that it had only  
had six meetings to complete that task. Furthermore, half  
of those meetings had been spent establishing the basis for  
negotiations, because all the substantive provisions in the draft  
text were based on submissions from Governments.

65 37. He stressed that the Group had nonetheless made consid-  
erable progress. At its sixth meeting, it had begun by consid-  
ering a text with over 670 square brackets, reflecting, inter alia,  
that 15 of the issues most central to the negotiations were still  
unresolved. By the conclusion of that meeting, it had consid-  
erably reduced the number of outstanding issues and, in docu-  
ment UNEP/CBD/BSWG/6/L.2/Rev.2, had prepared a draft text  
which offered far greater potential for the attainment of a final  
consensus text. That progress had been made possible by the  
good will, flexibility and spirit of compromise exhibited by all at  
the meeting.

66 38. In conclusion, he expressed his appreciation to all those  
that had contributed to that progress and, in particular, to the  
members of the extended Bureau, including the various co-  
chairs, and of the secretariat, for all their hard work, commit-  
ment, advice and support; to the Executive Director of UNEP,  
for his support prior to and during the course of the sixth meet-  
ing; and to the Minister of Environment of Colombia, Mr. Mayr,  
for his continued optimism and tireless efforts that had been an  
inspiration to all.

## V. Adoption Of The Protocol And Related Decisions

### A. Adoption of the protocol 68

69 39. At its 2nd session, on 22 February 1999, the meeting  
decided, on the suggestion of the President, to establish,  
under the chairmanship of the President, an informal contact  
group of 10 members representing groups of delegations,  
which would review outstanding contentious issues in draft  
articles 4 and 5. The 10 members would represent the group  
of Central American and Caribbean countries, the group of  
Central and Eastern European countries, the European Union,  
the negotiating group known at the meeting as the “like-minded  
group of countries”, comprising four representatives, and the  
negotiating group known as the “Miami group”, comprising two  
representatives.

70 40. At its 3rd session, on 24 February 1999, the President re-  
ported to the meeting that, despite long and arduous negoti-  
ations in the informal group through the entire day and most  
of the night, in an effort to close the gap between the different  
positions and to agree on a final text for the protocol, final con-  
sensus on all points had not been reached. Instead, the group  
had decided to submit, for the consideration of the meeting, two  
proposals, one from the European Union and the other from the  
Miami group.

71 41. The representative of Germany, on behalf of the European  
Union and its member States, introduced a package proposal  
on the text of the draft protocol. The elements of that proposal  
are contained in annex II to the present report.

72 42. The representative of Canada, speaking on behalf of the  
Miami group, requested that the report of the extraordinary  
meeting should reflect the conclusion that consensus had not  
been reached on either the text of a protocol, as submitted to  
the Working Group in document UNEP/BSWG/6/L.2/Rev.2 and

subsequently placed before the Conference of the Parties in the report of the Chair of the Group (UNEP/CBD/ExCOP/1/2), or the European Union proposals as set forth in annex II to the present report. He conveyed the group's commitment to take part in further informal consultations on the outstanding issues and its confidence that a solution would be found.

73 43. He introduced a proposal, on behalf of the Miami group, on the text of the draft protocol, the elements of which are contained in annex III to the present report, and recommended, further, that the report of the current part of the first extraordinary meeting of the Conference of the Parties should refer to all the proposals on the table and should also note those articles that had been provisionally adopted by the Working Group.

74 44. The representative of Ethiopia, speaking on behalf of the like-minded group of countries, introduced that group's proposal. The elements of the proposal are contained in annex IV to the present report.

75 45. Following the introduction of those proposals, a number of representatives, some speaking on behalf of regional groups, made statements. While regretting the failure of the informal contact group to reach final consensus on the few outstanding issues, many representatives commended the President on the open and transparent manner in which he had conducted the negotiations in the group, as well as on his vision, dedication, courage and patience, thanks to which considerable progress had been made, bringing the meeting very close to consensus. Accordingly, they expressed their confidence that the success which had eluded them at the current part of the meeting would be within their grasp when the meeting resumed.

76 46. The representatives taking the floor further commended the organizers on the excellent preparations for the meeting and expressed their appreciation to the people and Government of Colombia.

47. Many, pledging their willingness to continue their endeavours to reach consensus, hoped that those endeavours would finally lead to a protocol which would be good for the environment and good for the world. 77

48. One representative regretted that, in the draft text before the meeting, only lip service was paid to the precautionary approach; that the provisions on scope indicated what was not covered rather than what was covered; that the responsibility for compliance was shifted to domestic legislation; and that the philosophy of the protocol was to protect international trade. Another hoped that the environment and human health would be taken into consideration and that the interests of humanity would prevail over the quest for short-term profits. 78

49. One representative expressed the view that it was better to defer the solution and to have a stronger protocol in the future than to settle now for an unsatisfactory solution and a weak protocol, while another warned his fellow participants that, if the meeting failed in its task to adopt a protocol, history would not forgive them. 79

50. The representative of one non-governmental organization, speaking on behalf of 13 non-governmental organizations at the meeting, said that, while the outcome of the negotiations at the current part of the meeting had perhaps been predictable, the meeting's failure boded ill for the future of the planet. At the same time, a weak protocol would have sent a most undesirable signal to the world and, on the positive side, it was to be hoped that the intensity of the negotiations in Cartagena would encourage countries, especially developing countries, to develop their own legal frameworks in the area of biosafety. 80

## B. Articles provisionally adopted by the Open-ended Ad Hoc Working Group on Biosafety and core issues and related issues remaining before the Conference of the Parties

82 51. At its sixth meeting, the Open-ended Ad Hoc Working Group on Biosafety had provisionally adopted a number of draft articles and annexes. The articles, numbered as in the text of the draft protocol contained in annex V to the present report, are the following: article 16, on competent national authorities and national focal points; article 19, on capacity-building; article 26, on financial mechanism and resources; article 27, on the Conference of the Parties serving as the meeting of the Parties; article 28, on subsidiary bodies and mechanisms; article 29, on the secretariat; article 30, on the relationship with the Convention; article 32, on monitoring and reporting; article 33, on compliance; article 34, on assessment and review; article 35, on signature; article 36, on entry into force; article 38, on withdrawal; and article 39, on authentic texts. In addition, the Working Group had also provisionally adopted, under article 3, on the use of terms, the definitions of the terms “exporter”, “importer”, “living modified organism”, “living organism”, “modern biotechnology”, and “regional economic integration organization” and had also provisionally adopted annexes I and II.

83 52. The core issues and related issues that remained before the first extraordinary meeting of the Conference of the Parties, as identified in informal consultations under the chairmanship of the President on Monday and Tuesday, 22 and 23 February 1999, were articles 4, 5, 6, 15, 21, 22, 23, 24 and 31. It was agreed by all the negotiating groups at the meeting that the essential core issues among those identified above were articles 4, 5 and 31.

## 8481 C. Adoption of decisions

85 53. At its 3rd session, on 24 February 1999, the meeting adopted two decisions. The first, which had been circulated in document UNEP/CBD/ExCOP/1/L.4, concerned suspension of the first extraordinary meeting of the Conference of the Parties and its reconvening at a date to be decided, as well as interim arrangements. The second conveyed a tribute to the Government and people of Colombia. The text of the decisions is contained in annex I to the present report.

## D. Suspension of the meeting

86 87 54. The Rapporteur informed participants that, in the light of its decision to suspend the meeting, the report of the meeting would be considered and adopted at the resumed session. The meeting took note of the draft report of the first part of the first extraordinary meeting of the Conference of the Parties, contained in document UNEP/CBD/ExCOP/1/L.2.

88 89 55. Following the adoption of the decisions, the Executive Director of UNEP expressed his thanks to all those involved in the organization and conduct of the meeting for their dedication and hard work and, in particular, to the people of Cartagena for their warmth and hospitality. Following the customary exchange of courtesies, the President declared the meeting suspended at 5 a.m. on Wednesday, 24 February 1999.

(To be completed).

## Annex I

90 91 Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its First Extraordinary Meeting Cartagena, 22-24 February 1999 and (to be continued)

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

93 The Conference of the Parties,

94 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 re-  
sulting from biotechnology that may have adverse effect on the  
conservation and sustainable use of biological diversity,

95 Recalling also its decision II/5 of 17 November 1995 on con-  
sideration of the need for and modalities of a protocol setting  
out appropriate procedures, including, in particular, advance in-  
formed agreement, in the field of the safe transfer, handling and  
use of any living modified organisms, by which it agreed to be-  
gin a negotiation process to develop a protocol to address the  
concerns of Parties on those matters,

96 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,

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

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

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

100 1. Decides to suspend the first extraordinary meeting of the

Conference of the Parties;

2. Decides to request the President of the first extraordinary 101  
meeting of the Conference of the Parties and the Bureau of the  
fourth meeting of the Conference of the Parties, in close consul-  
tation with the Executive Secretary, to decide on the date and  
venue of the resumed session of the first extraordinary meet-  
ing 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 102  
the Cartagena Protocol on Biosafety to the Convention on Bio-  
logical Diversity;

4. Decides further to transmit the text of the draft protocol set 103  
out in appendix I to the report of the sixth meeting of the Open-  
ended Ad Hoc Working Group on Biosafety,<sup>1</sup> as well as the  
statements with respect to the text of the draft protocol con-  
tained in that report, to the Conference of the Parties at the  
resumed session of its extraordinary meeting;

\*\*1 UNEP/CBD/ExCOP/1/2. 104

5. Stresses the importance of concentrating at the resumed 105  
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;<sup>2</sup>

6. Affirms its determination to complete the negotiation of the 106  
Cartagena Protocol on Biosafety for its adoption at the resumed  
session of the first extraordinary meeting of the Conference of  
the Parties;

7. Approves the amount of 480,000 United States dollars sup- 107  
plementary 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.

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

110 The Conference of the Parties,

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

112 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,

113 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.

114 **Annex II**

115 Package Proposal On The Text Of The Draft Protocol:

116 Submission By The European Union

117 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,

108 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 See paragraph 52 above.

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.

125 “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.

126 “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.

127 “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.”

128 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”.

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

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

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

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

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

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

135 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”. 136

### Annex III 137

Outstanding Issues And Necessary Revisions To The Text Of The Draft Protocol: 138

Submission By The Miami Group 139

1. AIA procedure: articles 5 and 6 stay as in the current text (UNEP/BSWG/6/L.2/Rev.2). 140

2. Documentation: 141

(a) In article 15, substitute “scope of the AIA procedure” for “scope of the Protocol”; 142

(b) In article 4, subparagraph 2 (b), delete the reference to article 15 connected with transit. 143

3. Non-Parties: 144

(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; 145

(b) In article 11, paragraph 1, delete the words “or non-Parties”; 146

(c) In article 3 (k), delete the reference to articles 11 and 14. 147

4. Precautionary approach: 148

(a) In article 1, substitute the word “Noting” for “In accordance 149

- with”;
- 150 (b) In article 8, delete paragraph 7.
- 151 5. Illegal transboundary movement (article 23):
- 152 (a) Substitute the words “its domestic law implementing” for “the relevant provisions of”;
- 153 (b) Delete paragraph 2.
- 154 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.”
- 155 7. Savings clause (article 31) and Non-discrimination (article 22):
- 156 (a) In article 31, delete everything after the word “Party” in the third line;
- 157 (b) Delete article 22.
- 158 8. Risk assessment (article 12): delete paragraph 3.
- 159 9. Risk management (article 13): delete paragraphs 3 and 4.
- 160 10. General obligations (article 2): delete paragraph 2.
- 161 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”.
- 162 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.”

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

176 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.

177 The issues in question were the following:

178 (a) The inclusion of “products thereof” after “living modified organisms” in the protocol;

179 (b) The inclusion of a precautionary approach in risk assessment;

180 (c) The deletion of paragraphs 3 and 4 in article 11;

181 (d) The deletion of article 18;

182 (e) The expansion of annex II;

183 (f) The development of an article on liability and redress;

184 (g) A broader content of socio-economic issues, especially the development of an early warning system on commodities that will lose their market;

185 (h) The definition of contained use, because it is imprecise;

186 (i) The inclusion of contained use in AIA;

187 (j) The inclusion of contained use.

188 **Annex V - Draft Protocol On Biosafety<sup>1</sup>**

189 The Parties to this Protocol,

<sup>1</sup>Text of the draft protocol as contained in appendix I to the report of the

Being Parties to the Convention on Biological Diversity, hereinafter referred to as “the Convention”, 190

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention, 191

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, 192

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, 193

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, 194

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, 195

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity, 196

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, 197

Have agreed as follows: 198

sixth meeting of the Open-Ended Ad Hoc Working Group on Biosafety (UNEP/CBD/ExCOP/1/2).

199 **Article 1 - Objective**

200 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 effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

201 **Article 2 - General Provisions**

- 202 1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.
- 203 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.
- 204 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.
- 205 4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the con-

servation 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 its 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. 206

**Article 3 - Use Of Terms** 207

For the purposes of this Protocol: 208

- (a) "Conference of the Parties" means the Conference of the Parties to the Convention. 209
- (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. 210
- (c) "Export" means intentional transboundary movement from one Party to another Party. 211
- (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. 212
- (e) "Import" means intentional transboundary movement into one Party from another Party. 213
- (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. 214
- (g) "Living modified organism" means any living organism that 215

possesses a novel combination of genetic material obtained through the use of modern biotechnology.

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

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

218 (i) In vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles,

219 (ii) 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.

220 (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.

221 (k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 11, 14 and 21 transboundary movement extends to movement between Parties and non-Parties.

#### 222 **Article 4 - Scope**

223 1. This Protocol shall, subject to paragraph 2 below, apply to the transboundary movement, handling and use of living modified organisms that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

224 2. Without prejudice to the right of the Parties to subject all living

modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to:

(a) Transboundary movements of living modified organisms that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as may be specified in an annex to the Protocol; 225

(b) Transit of living modified organisms, except as regards Articles 2, 14 and 15, and intentional transboundary movements of living modified organisms destined for contained use, except as regards Articles 2, 14, 15 and 17, paragraphs 1, 2, 3 (a) and 3 (b); 226

(c) Transboundary movements of living modified organisms that are pharmaceuticals for humans. 227

#### 228 **Article 5 - Application Of The Advance Informed Agreement Procedure**

229 1. Subject to Article 4, paragraph 2, the advance informed agreement procedure in Articles 6, 7, 8 and 9 shall apply prior to the first intentional transboundary movements of living modified organisms for intentional introduction into the environment of the Party of import.

230 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.

231 3. The Parties may, under their respective domestic laws, require procedures consistent with advance informed agreement for living modified organisms other than those specified in paragraph 1 above.

232 4. Subject to paragraph 3 above, the advance informed agreement procedure shall not apply to the intentional transboundary

movements 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.

## 233 Article 6 - Notification

- 234 1. The Party of export shall notify, or require the exporter to ensure notification in writing to, 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 5, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.
- 235 2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

## 236 Article 7 - Acknowledgement Of Receipt Of Notification

- 237 1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.
- 238 2. The acknowledgement shall state:
- 239 (a) The date of receipt of the notification;
- 240 (b) Whether the notification, prima facie, contains the information referred to in Article 6;
- 241 (c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 8.
- 242 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. 243

## Article 8 - Decision Procedure 244

1. Decisions taken by the Party of import shall be in accordance with Article 12. 245
2. The Party of import shall, within the period of time referred to in Article 7, inform the notifier, in writing, whether the intentional transboundary movement may proceed: 246
- (a) After no less than ninety days without a subsequent written consent; 247
- (b) Only after the Party of import has given its written consent. 248
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 (b) above: 249
- (a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism; 250
- (b) Prohibiting the import; 251
- (c) Requesting additional relevant information in accordance with its domestic legal framework or Annexes I and II. 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; 252
- (d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time. 253

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

255 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.

256 6. Parties concerned shall cooperate with a view to identifying, as soon as possible, the extent to which in relation to the procedures, and the cases in which, an intentional transboundary movement may not proceed between them without explicit consent.

257 7. Lack of full scientific certainty or scientific consensus regarding the potential adverse effects of a living modified organism shall not prevent the Party of import from prohibiting the import of the living modified organism in question as referred to in paragraph 3 (b) above.

258 8. 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.

#### 259 **Article 9 - Review Of Decisions**

260 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 its decisions regarding intentional transboundary movements. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements, as well as the Biosafety Clearing-House, and shall give details of the reasons for its decision.

261 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 8 where the Party of export or the notifier considers that:

262 (a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based;

263 (b) Additional relevant scientific or technical information has become available.

264 3. Parties of import shall respond to such requests in writing within ninety days and provide details on the basis of their decision.

265 4. The Party of import may, at its discretion, require a risk assessment for subsequent imports of a living modified organism.

#### 266 **Article 10 - Simplified Procedure**

267 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 objectives of this Protocol, specify in advance to the Biosafety Clearing-House:

268 (a) Cases for which intentional transboundary movement can take place at the same time as the movement is notified to the Party of import: such notifications may apply to subsequent similar movements to the same Party;

269 (b) Living modified organisms to be exempted from the advance informed agreement procedure.

270 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.

271 **Article 11 - Multilateral, Bilateral and Regional Agreements  
and Arrangements**

272 1. Parties may enter into multilateral, bilateral and regional agreements and arrangements with Parties or non-Parties regarding intentional transboundary movements of living modified organisms, consistent with the objectives 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.

273 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 entry into force of this Protocol.

274 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.

275 4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety ClearingHouse of its decision.

276 **Article 12 - Risk Assessment**

277 1. Risk assessments conducted pursuant to this Protocol shall be undertaken in a scientifically sound manner in accordance with Annex II and taking into account recognized risk assessment techniques. Such risk assessments shall be based at a minimum on information provided in accordance with Article 6 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.

278 2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 8. It may require the exporter to carry out the risk assessments.

279 3. Financial responsibility for conducting risk assessments shall rest with the notifier.

**Article 13 - Risk Management**

280 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.

282 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.

283 3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring risk assessments to be carried out prior to the first release of a living modified organism.

284 4. Without prejudice to paragraph 2 above, each Party, in order to ensure genomic and trait stability in the environment, shall endeavour to ensure that any living modified organism, whether imported or locally developed, undergoes a period of observation commensurate with its life-cycle or generation time as the case may be before it is put to its intended use.

285 5. Parties shall cooperate with a view to:

286 (a) Identifying living modified organisms or specific traits of liv-

ing modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;

287 (b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

288 **Article 14 - Unintentional Transboundary Movements And Emergency Measures**

289 1. Each Party shall take appropriate measures to notify affected or potentially affected

290 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 living modified organisms 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 Parties know of the above situation.

291 2. Each Party shall, no later than the date of entry into force of the Protocol for it, make available to the Biosafety Clearing-House the relevant details of the point of contact for the purposes of receiving notifications under this Article.

292 3. Any notification arising from paragraph 1 above should include:

293 (a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organisms;

294 (b) A point of contact for further information;

295 (c) Information on the circumstances and estimated date of the

release, and on the use of the living modified organism in the originating Party;

(d) 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;

(e) Any other relevant information. 297

298 4. 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, 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.

299 **Article 15 - Handling, Transport, Packaging And Identification**

300 1. The Parties shall take measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of the Protocol:

(a) 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 biodiversity, taking also into account risks to human health; 301

(b) Are clearly identified, including in accompanying documentation specifying: 302

(i) the presence, identity and relevant characteristics and/or traits; 303

304 (ii) any requirements for safe handling, storage, transport and use;

305 (iii) the contact point for further information and, as appropriate, the name and address of the importer and exporter;

306 (iv) a declaration that the movement is in conformity with the requirements of this Protocol, except that the Party of import may indicate that, in relation to imports, these requirements will not apply.

307 2. 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, taking into consideration the results of consultations with other international bodies.

### 308 **Article 16 - Competent National Authorities And National Focal Points**

309 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.

310 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 infor-

mation 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. 311

### **Article 17 - Information-Sharing And The Biosafety Clearing-House** 312

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: 313

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; 314

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing countries, in particular the least developed countries and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin. 315

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. 316

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:

318 (a) National laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedures;

319 (b) Any multilateral, bilateral and regional agreements and arrangements;

320 (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 12, including, where appropriate, relevant information regarding products thereof, i.e., processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

321 (d) Its final decisions regarding the importation or release of living modified organisms;

322 (e) Reports submitted by it pursuant to Article 32, including those on implementation of the advance informed agreement procedures.

323 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 at its first meeting, and kept under review thereafter.

#### 324 **Article 18 - Confidential Information**

325 1. The Party of import shall permit the notifier to identify infor-

317 mation submitted under the procedures of this Protocol or required by the importing Party as part of the advance informed agreement process 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 and an opportunity for consultation and for an internal review of the decision prior to disclosure. 326

3. Each Party shall, in accordance with its national legislation, protect confidential information received under the Protocol, including any confidential information received in the context of the advance informed agreement process 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. 327

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier. 328

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of all information identified as confidential, including information on which the Party and the notifier disagree as to its confidentiality. 329

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential: 330

(a) The name and address of the notifier; 331

(b) A general description of the living modified organism or organisms; 332

333 (c) A summary of the risk assessment of the effects on the con-  
 334 servation and sustainable use of biological diversity, taking also  
 into account human health;

334 (d) Any methods and plans for emergency response.

### 335 **Article 19 - Capacity-Building**

336 1. The Parties shall cooperate in the development and/or  
 strengthening of human resources and institutional capaci-  
 ties 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 islanddeveloping  
 States among them, and in Parties with economies in transi-  
 tion, including through existing global, regional, subregional  
 and national institutions and organizations and, as appropriate,  
 through facilitating private sector involvement.

337 2. For the purposes of implementing paragraph 1 above, in  
 relation to cooperation, the needs of developing country Par-  
 ties, in particular the least developed and small island develop-  
 ing 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, capa-  
 bilities and requirements of each Party, include scientific and  
 technical training in the proper and safe management of bio-  
 technology, and in the use of risk assessment and risk manage-  
 ment 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 20 - Public Awareness And Participation**

1. The Parties shall:

(a) Promote and facilitate public awareness, education and par-  
 ticipation concerning safety in the 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 cooper-  
 ate, as appropriate, with other States and international bod-  
 ies;

(b) Endeavour to ensure that public awareness and educa-  
 tion encompass access to information on living modified organ-  
 isms identified in accordance with this Protocol that may be im-  
 ported.

2. The Parties shall, in accordance with their respective laws,  
 consult the public in the decision-making process regarding liv-  
 ing modified organisms and shall make the results of such de-  
 cisions available to the public, while respecting confidential in-  
 formation in accordance with Article 18.

3. Each Party shall endeavour to inform its public about the  
 means of public access to the Biosafety Clearing-House.

### **Article 21 - Non-Parties**

1. Transboundary movements of living modified organisms  
 between Parties and non-Parties shall be consistent with the  
 objective and principles of this Protocol. The Parties are en-  
 couraged to conduct such transboundary movements in accor-  
 dance with multilateral, bilateral and regional agreements and  
 arrangements with non-Parties under Article 11.

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, their territory.

347 **Article 22 - Non-Discrimination**

348 1. The Parties shall ensure that measures taken to implement this Protocol, including risk assessment, do not discriminate unjustifiably between or among imported and domestically produced living modified organisms.

349 2. The Parties shall also ensure that measures taken to implement this Protocol do not create unnecessary obstacles to international trade.

350 **Article 23 - Illegal Transboundary Movements**

351 1. Each Party shall adopt appropriate domestic measures aimed at preventing and penalizing transboundary movements of living modified organisms carried out in contravention of the relevant provisions of this Protocol. Such transboundary movements shall be deemed illegal.

352 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.

353 3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

354 **Article 24 - Socio-Economic Considerations**

355 1. The Parties, in reaching a decision on import, 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. 356

**Article 25 - Liability and Redress** 357

The Conference of the Parties serving as the meeting of the Parties 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 any ongoing processes in international law on these matters, and shall endeavour to complete this process within four years. 358

**Article 26 - Financial Mechanism And Resources** 359

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. 360

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. 361

3. Regarding the capacity-building referred to in Article 19 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with 362

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 States among them.

363 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 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.

364 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.

365 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 multilateral, bilateral and regional channels.

#### 366 **Article 27 - Conference Of The Parties Serving As The Meeting Of The Parties**

367 1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

368 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.

369 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.

370 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:

371 (a) Make recommendations on any matters necessary for the implementation of this Protocol;

372 (b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

373 (c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

374 (d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 32 of this Protocol and, as well, reports submitted by any subsidiary body;

375 (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;

376 (f) Exercise such other functions as may be required for the

implementation of this Protocol.

377 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.

378 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.

379 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.

380 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 28 - Subsidiary Bodies And Mechanisms

381  
382 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, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

383 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.

384 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 29 - Secretariat

385  
386 1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

387 2. Article 24, paragraph 1, of the Convention on the functions

of the Secretariat shall apply, mutatis mutandis, to this Protocol. 395

388 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.

### 389 **Article 30 - Relationship With The Convention**

390 Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

### 391 **Article 31 - Relationship With Other International Agreements**

392 The provisions of this Protocol shall not affect the rights and obligations of any Party to the Protocol deriving from any existing international agreement to which it is also a Party, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity.

### 393 **Article 32 - Monitoring And Reporting**

394 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 33 - 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. 396

### **Article 34 - 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. 398

### **Article 35 - Signature**

This Protocol shall be open for signature by States and regional economic integration organizations at United Nations Headquarters in New York from 24 May 1999 to 23 May 2000. 400

### **Article 36 - Entry Into Force**

1. This Protocol shall enter into force on the ninetieth day after the date of the deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention. 401

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 37 - Reservations

No reservations may be made to this Protocol.

#### Article 38 - 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 Depository.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depository, or on such later date as may be specified in the notification of the withdrawal.

#### Article 39 - 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.

#### Annex I - Information Required In Notifications

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name, identity and domestic classification, if any, of the biosafety level in the State of export of the living modified organism.

(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, i.e., 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.

423 (k) A previous and existing risk assessment report consistent  
with Annex II.

424 (l) Suggested methods for safe handling, storage, transport and  
use, including packaging, labelling, documentation, disposal  
and contingency procedures, where appropriate.

425 (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.

426 (n) Result and purpose of any notification by the exporter to  
other Governments regarding the living modified organism to  
be transferred.

427 (o) A declaration that the above-mentioned information is fac-  
tually correct.

## 428 **Annex II - Risk Assessment**

### 429 **Objective**

430 1. The objective of risk assessment, under this Protocol, is to  
identify and evaluate the potential adverse effects of living mod-  
ified organisms on the conservation and sustainable use of bi-  
ological diversity in the likely potential receiving environment,  
taking also into account the risk to human health.

### 431 **Use of risk assessment**

432 2. Risk assessment is, inter alia, used by competent author-  
ities to make informed decisions regarding living modified or-  
ganisms.

## **General principles**

3. Risk assessment should be carried out in a scientifically 434  
sound and transparent manner, and can take into account ex-  
pert advice of, and guidelines developed by, relevant interna-  
tional organizations.

4. Lack of scientific knowledge or scientific consensus should 435  
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 prod- 436  
ucts thereof, i.e., processed materials that are of living modi-  
fied organism origin, containing detectable novel combinations  
of replicable genetic material obtained through the use of mod-  
ern biotechnology, should be considered in the context of the  
risks posed by the non-modified recipients or parental organ-  
isms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case 437  
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 439  
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, 440  
the following steps:

(a) An identification of any novel genotypic and phenotypic 441

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 the risk to human health;

442 (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;

443 (c) An evaluation of the consequences should these adverse effects be realized;

444 (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;

445 (e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks;

446 (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.

#### 447 **Points to consider**

448 9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

449 (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; 450

(c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range; 451

(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; 452

(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; 453

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability; 454

(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; 455

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biodiversity and centres of origin of the likely potential receiving environment. 456

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