



## CONVENTION ON BIOLOGICAL DIVERSITY

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OPEN-ENDED AD HOC WORKING  
GROUP ON BIOSAFETY  
First Meeting  
Aarhus, 22-26 July 1996

### REPORT OF THE FIRST MEETING OF THE OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY

#### Introduction

1. The Open-ended Ad Hoc Working Group of Experts on Biosafety was established in accordance with decision II/5 of the Conference of the Parties to the Convention on Biological Diversity (CBD) at its second meeting, with a mandate to operate in accordance with the terms of reference set out in the annex to that decision. At the invitation of the Government of the Kingdom of Denmark, the first meeting of the Working Group was held in Aarhus, Denmark, from 22 to 26 July 1996.

#### I. ORGANISATION OF THE MEETING

##### A. Opening of the meeting

2. The meeting was opened by Mr. Sarwono Kusumaatmadja, Minister of Environment of Indonesia, in his capacity as President of the second meeting of the Conference of the Parties to the CBD. In his view, the present meeting was an important step in the evolution of the CBD and the first major effort by the international community to seek solutions to concerns regarding the safe transfer, handling and use of living modified organisms (LMOs). The meeting constituted an essential commitment to biosafety, and he hoped that the spirit of mutual understanding which had prevailed hitherto under the Convention would continue during the deliberations of the Working Group. In that context, the international community was hoping that a careful balance would be achieved between the benefits of progress in biotechnology and reducing the associated risks as envisaged in Articles 16 and 19 of the Convention, respectively. The Working Group should thus take into account, in particular, the work done by UNEP on elaborating the International Technical Guidelines for Safety in Biotechnology, on Prior Informed Consent under United Nations auspices, and on trade and the environment under the World Trade Organisation (WTO). Finally, he looked forward to the Working Group reaching a successful conclusion to its long and complex task.

3. Mr. Svend Auken, Minister for Environment and Energy of Denmark, after welcoming participants and expressing his Government's commitment to the development of a biosafety protocol, stressed the need for caution in genetic engineering, which had high positive potential but also unknown risks; the opportunity for preventing serious harmful effects must not be missed. Denmark had enacted legislation on safety in biotechnology in 1986, based on the precautionary principle, and wished to see that principle, which was also embodied in the legal framework of the European Union, applied on a world-wide scale. The Danish approach enjoyed general support from the public and from industry and he did not believe that existing safety procedures should be relaxed. He believed that the main thrust of the biosafety protocol must relate to transboundary movements and must also include a mechanism for "advance informed agreement" in order to meet the concerns of the developing countries. The International Technical Guidelines for Safety in Biotechnology developed by UNEP would be valuable both until the protocol was established and in its implementation.

4. Mr. Jorge Illueca, Assistant Executive Director for Environmental Management of UNEP, speaking on behalf of Ms. Elizabeth Dowdeswell, Executive Director of UNEP, noted the rapid developments in the use of biotechnology and the benefits for developing countries. However, questions regarding the capacity of existing biosafety regulatory approaches highlighted a pressing need for the development of internationally agreed principles for safety in biotechnology. Such a need had been recognised by the United Nations Conference on Environment and Development (UNCED) and the CBD. He referred to the International Technical Guidelines for Safety in Biotechnology as an independent but complementary initiative to the decision to establish the Working Group. The Global Consultation of Government-designated Experts, held in Cairo in December 1995, had further endorsed a related capacity-building requirements programme to be submitted to potential donors for funding. Mr. Illueca also drew attention to a number of other initiatives undertaken jointly by UNEP and the Secretariat of the CBD and relevant governmental, intergovernmental and non-governmental organisations, including the private sector.

5. The Executive Secretary of the CBD, Mr. Calestous Juma, reviewed the status of the establishment of the permanent Secretariat in Montreal and said that much progress had been made in implementing logistical arrangements. He thanked the Government of Canada for its support and for fulfilling its commitments towards the Secretariat. The present meeting, for which he thanked the Government of the Kingdom of Denmark, showed the progress made in the establishment of the permanent Secretariat. The Secretariat was striving to recruit the most suitable people to meet the very demanding requirements ahead in implementing the Convention. Progress had been made in seeking cooperation with other organisations and biodiversity-related conventions, including the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES), the Convention on the Conservation of Migratory Species of Wild Animals (CMS) and the Ramsar Convention on Wetlands of International Importance, Especially as Waterfowl Habitat, and agreements were being negotiated with the World Heritage Convention of the United Nations Educational, Scientific and Cultural Organisation (UNESCO) and the Food and Agriculture Organisation of the United Nations (FAO) to enhance cooperation with the Secretariat of the Convention.

6. Mr. Peter Schei (Norway) summarised the results of the Conference on Alien Species, held in Trondheim, Norway, from 1 to 5 July 1996 at the invitation of the Government of Norway, in cooperation with UNESCO, UNEP, the World Conservation Union (IUCN), the Scientific Committee on Problems of the Environment (SCOPE) and others. The Conference had addressed both the deliberate and accidental introduction of alien species and, particularly, the problems relating to environment, health and socio-economic aspects related to those alien species who become invasive. The Conference had urged Governments and international organisations and institutions to seriously consider invasive species in their ongoing deliberations related to biodiversity and offered its conclusions and recommendations to the Parties and the Conference of the Parties to the CBD as a contribution to its work programme in implementing Article 8. The Conference also concluded that a global strategy and action programme on invasive species was needed and should be developed as soon as possible.

7. A representative of the International Academy of the Environment summarised the results of the workshop entitled "Transboundary Movement of Living Modified Organisms Resulting from Modern Biotechnology: issues and opportunities for policy-makers", held on 19 and 20 July 1996, in partnership with UNEP, the CBD Secretariat and the Government of Switzerland, and with the support of other Governments, intergovernmental organisations and bio-industry organisations. The purpose of the workshop had been to enhance the understanding of issues relating to the transboundary movement of LMOs in the context of access, development, transfer and acquisition of biotechnology and biotechnology products; to share experiences and information that might be useful to countries, organisations and companies in facilitating effective implementation of the UNEP International Technical Guidelines for Safety in Biotechnology; and to share information that might be useful to the work of the Open-ended Ad Hoc Working Group on Biosafety.

B. Attendance

8. The meeting was attended by representatives of the following States and regional economic integration organisations:

Albania	Denmark	Latvia	Spain
Antigua and Barbuda	Ecuador	Lesotho	Sri Lanka
Argentina	Equatorial Guinea	Madagascar	St. Kitts and Nevis
Armenia	Eritrea	Malawi	Sudan
Australia	Ethiopia	Malaysia	Swaziland
Austria	European Community	Mauritius	Sweden
Belarus	Finland	Mexico	Switzerland
Bhutan	France	Moldova	Tanzania
Bolivia	Georgia	Mongolia	Thailand
Botswana	Germany	Morocco	Tunisia
Brazil	Ghana	Mozambique	Ukraine
Bulgaria	Greece	Myanmar	United Kingdom of Great Britain and Northern Ireland
Burkina Faso	Guinea	Netherlands	Ireland
Cambodia	Holy See	New Zealand	United States of America
Cameroon	Hungary	Nigeria	Uruguay
Canada	India	Norway	Venezuela
Chile	Indonesia	Oman	Viet Nam
China	Iran (Islamic Republic of)	Peru	Zaire
Colombia	Ireland	Philippines	Zambia
Comoros	Italy	Poland	Zimbabwe
Costa Rica	Jamaica	Russian Federation	
Côte d'Ivoire	Japan	Rwanda	
Czech Republic	Kenya	Saudi Arabia	
Democratic People's Republic of Korea	Korea (Republic of)	Slovakia	
		South Africa	

9. The following United Nations bodies and specialised agencies were represented:

Food and Agriculture Organisation of the United Nations (FAO)  
United Nations Conference on Trade and Development (UNCTAD)  
United Nations Environment Programme (UNEP)  
United Nations Educational, Scientific and Cultural Organisation (UNESCO)

10. Representatives of the following intergovernmental organisations were present at the meeting:

O.E.C.D.  
South Pacific Regional Environment Programme

11. The following non-governmental organisations were represented:

AG Biodiversity (German Working Group)	Japan Center for Sustainable Environment and Society (JACSES)
Biotechnology, Working Group	M.S. Swaminathan Research Foundation
Botanic Gardens Conservation International	Mahavishi University of Management
Centre for Mediciste Molekylar Biologi	Max-Planck-Institute
CESAM, Aarhus University	Natural Law Party
Christian Council of Sweden	PLS Consult A/S
Council for Responsible Genetics	Stockholm Environment Institute/Biotechnology Advisory Commission
Development and Peace Foundation	Swedish Society for Nature Conservation
Edmonds Institute	Third World Network
Foundation for International Environmental Law and Development	University of Minnesota
GreenPeace International	West Africa Rice Development Association (WARDA)/CGIAR
Institute for Agriculture and Trade Policy	World Federation for Culture Collections (WFCC)
International Academy of the Environment	
International Service for Acquisition of Agri-Biotech Applications	

12. The following representatives of the private sector were present:

A/F Protein Canada Inc.  
Biodiversity Forum  
Biotechnology Industry Organisation  
COSEMCO  
FBID  
Green Industry Biotechnology Platform (G.I.B.I.P.)  
Japan Bioindustry Association  
Senior Advisory Group on Biotechnology (S.A.G.B.)  
S.A.G.B. Group Limagrain  
SANDOZ

C. Election of officers

13. The Working Group at its 1st and 3rd sessions elected the following officers:

Chairperson: Mr. Veit Koester (Denmark)

Vice-Chairpersons: Mr. Diego Malpede (Argentina)  
Mr. Berhan Gebre Egziabher Tewolde (Ethiopia)  
Mr. Ervin Balazs (Hungary)  
Ms. Sandra M.E. Wint (Jamaica)  
Mr. Gil Sou Shin (Korea)  
Mr. Sateaved Seebaluck (Mauritius)  
Mr. David Gamble (New Zealand)  
Mr. Antonio La Vina (Philippines)

Rapporteur: Mr. Alexander Golikov (Russian Federation)

#### D. Documentation

14. The Working Group had before it the following documentation: provisional agenda (UNEP/CBD/BSWG/1/1); annotations to the provisional agenda (UNEP/CBD/BSWG/1/Add.1); terms of reference for the Open-ended Ad Hoc Working Group (UNEP/CBD/BSWG/1/2); and a note by the Secretariat on elaboration of the terms of reference for the Open-ended Ad Hoc Working Group on Biosafety (UNEP/CBD/BSWG/1/3). Also made available at the meeting were the report of the Open-ended Ad Hoc Group of Experts on Biosafety (UNEP/CBD/COP/2/7) and the report of the Global Consultation of Government-designated Experts on International Technical Guidelines for Safety in Biotechnology (UNEP/Global Consultation/Biosafety/4).

15. Introducing the documentation, Mr. Calestous Juma, Executive Secretary of the CBD, drew attention to decision II/5, paragraph 3, of the Second Meeting of the Conference of the Parties, which had provided no guidance on the nature or content of the documentation required for the meeting. He pointed out that the pre-session documents prepared by the Secretariat had been produced after consultations with the Bureau of the Second Meeting of the Conference of the Parties. He drew particular attention to the report on the elaboration of the terms of reference of the Working Group, contained in document UNEP/CBD/BSWG/1/3, which, he stressed, was meant only to provide relevant information on the terms of reference and was not intended as a document for negotiation.

#### E. Organisation of the meeting

16. The following agenda was adopted by the Ad Hoc Working Group:

1. Opening of the meeting.
2. Election of officers.
3. Organisation of work.
4. Elaboration of a Protocol on Biosafety in accordance with decision II/5 of the Conference of the Parties to the Convention on Biological Diversity.
5. Bureau for future meetings.
6. Dates and venues of meetings of the Open-ended Ad Hoc Working Group on Biosafety for 1997 and 1998.
7. Adoption of the report.
8. Closure of the meeting.

17. At the 3rd session of the meeting, the spokesman for the Group of 77 and China, reporting on the Group's decisions concerning the organisation of work, said that it was important to proceed on a priority basis with consideration of those items on which consensus had been reached at the 1995 Madrid meeting of the Open-ended Ad Hoc Group of Experts on Biosafety, and which had been endorsed by the Conference of the Parties at its second meeting, namely, Sections I, II and III, paragraph 18 (a), of Annex I of document UNEP/CBD/COP/2/7. The three items that had not met with consensus at the Madrid meeting, namely socio-economic considerations, liability and compensation, and financial issues, should be included in the future agenda of the Working Group and

discussed during the present meeting as the opportunity arose. In addition, the Group of 77 and China believed that other issues should be considered, including: capacity-building; moral/ethical considerations; planning for emergency measures; public participation; and the importance of the UNEP International Technical Guidelines for Safety in Biotechnology. He further said that a small ad hoc working group had been established, including at least two members from each regional grouping, to elaborate the Group's position on specific items of concern that should be included in the proceedings of the present and future meetings.

## II. ELABORATION OF A PROTOCOL ON BIOSAFETY IN ACCORDANCE WITH DECISION II/5 OF THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

### Introductory statements

18. At the 2nd session of the meeting, several representatives made opening statements under agenda item 4.
19. Most of those representatives referred to the great potential benefits of biotechnology for food security, world health and environmental protection.
20. One representative proposed that the protocol apply not only to the transboundary movement of LMOs but should entail all activities related to LMOs which may have an adverse effect on the conservation and sustainable use of biological diversity. Another representative emphasised that assessments of the risks associated with the experimental or commercial release of a LMO must take into account both the characteristics of the organism and of the particular site where the organism might be released.
21. One representative cautioned that, while properly addressing the risks from LMOs resulting from modern biotechnology, the development of the protocol should not cause unnecessary delays to the benefits that biotechnology could bring. He also suggested that the provisions for procedures for advance informed agreement be differentiated and proportionate to the risks involved, and allow for rapid adaptation to scientific and technological progress.
22. Another representative suggested that existing international or regional agreements applicable to the transboundary movement of LMOs should be reviewed with a view to identifying gaps not covered by those agreements and thereby avoid unnecessary duplication.
23. Several representatives noted that areas covered within the scope of the protocol could have an impact on international trade and might thus be covered by WTO agreements. While one representative stressed that that should not affect the scope of the protocol, another representative underlined the importance of consistency between the protocol and agreements under the WTO and the international obligations of the Parties in general.
24. One representative suggested that questions of socio-economic impacts, liability and funding be integrated throughout the deliberations, while others expressed the view that the Working Group should first concentrate on those items in paragraph 3 of its terms of reference.
25. The representative of the Food and Agriculture Organisation of the United Nations (FAO), speaking on behalf of its Director-General, said that the FAO Commission on Plant Genetic Resources

(CPGR) had produced, and made available to the Secretariat of the Convention on Biological Diversity, a draft Code of Conduct on Biotechnology, with protocols on biosafety relating to conservation and sustainable use of plant genetic resources. In 1994, the FAO Council had broadened the mandate of CPGR to include all genetic resources for food and agriculture. Thus, animal and fishery genetic resources would be incorporated in a gradual, step-wise manner. The Conference of the Parties had invited FAO to assist in the process of developing a possible protocol on biosafety. At the second meeting of the Conference of the Parties, FAO had offered to collaborate with the Secretariat, the Conference of the Parties, its subsidiary bodies and important forums such as the present Working Group. Reiterating that offer, he pointed to substantive work by FAO in the areas of agriculture, forestry and fisheries for possible consideration by the Group, including, inter alia, the recent FAO IV International Technical Conference on Plant Genetic Resources for Food and Agriculture, the Code of Conduct for Responsible Fisheries, the International Plant Protection Convention, the International Code of Conduct on the Distribution and Use of Pesticides, which included a PIC programme, and the Codex Alimentarius, which incorporated health and food quality protection.

26. At the 3rd session, for the further consideration of agenda item 4, the Chairperson proposed, and it was agreed, that the debate follow the terms of reference of the Working Group, contained in document UNEP/CBD/BSWG/1/2, paragraph 3:

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

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

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

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

Key concepts and terms to be addressed in the process

27. With regard to elaboration of the key concepts and terms to be addressed, many representatives identified the definition of LMOs as being of primary importance in the development of the draft protocol. Several believed that wide consideration of LMOs resulting from modern biotechnology and clear definition of the term LMOs were of the essence and one representative emphasised that only LMOs that might have an adverse effect on the conservation and sustainable use of biological diversity should be addressed by the protocol. One representative maintained that LMOs were genetically modified organisms (GMOs) produced through genetic modification, whose genetic make-up was unlikely to occur in nature. Another considered that GMOs which could produce organisms such as bacteria and multicellular organisms should be included among LMOs. A third representative considered that LMOs had either to be self-replicating entities, or replicate in host organisms, or have reproductive capabilities; they should be considered in association with gene products to ensure that several important aspects which could have implications for humans and the environment were not overlooked. Some agreed that a clear definition of the term "biotechnology" was of primary importance. Some representatives were of the view that the concept of "release" of LMOs also required strict definition; it must be clear that the concept signified "release in a closed environment". One representative considered that the Working Group was not the appropriate forum for discussion of definitions.

28. Many representatives pointed to the importance of the concept "transboundary movement". Some believed that, in defining the concept, it was necessary to take into account not just the physical movement of organisms, but their behaviour in the receiving environment, including aspects of

handling, use and disposal. One representative considered unintentional movement across national boundaries to be an extremely important issue that should be included in the protocol. He further believed that the protocol should cover the transportation mode used for movements, including container vessels and packaging materials. One representative recommended that the Working Group consider use of the terms "intended and unintended transboundary movement" and expressed the hope that a protocol would also take into account the intended and unintended effects taking place in the environment into which the LMO would be transferred or would spread. Another representative, noting that transboundary movements of organisms had taken place without the legal knowledge of Governments, pointed to the need for the term "boundary" to be very specifically defined. One representative considered that export of LMOs prohibited in one country to another country should be prohibited. In that connection, some representatives noted that the Basel Convention on the international movement of hazardous waste constituted an important precedent.

29. A number of representatives said that, in the context of a transboundary movement of LMOs, the concept of a PIC or advance informed agreement (AIA) procedure was important. One of them believed the Working Group should first clarify the idea of AIA on a conceptual level before looking at the process and mechanism for it.

30. Several representatives believed the issues of liability and compensation in the case of accidents during a transboundary movement to be key concepts for inclusion in the protocol.

31. A number of representatives considered "adverse effect on the conservation and sustainable use of biological diversity" to be a key concept requiring elaboration. One of those representatives, supported by one other, further believed that that concept should include consideration of whether the term "conservation and sustainable use of biological diversity" covered human health and the environment.

32. A number of representatives emphasised that the precautionary principle was a key concept which must be followed at all times and the International Technical Guidelines for Safety in Biotechnology developed by UNEP were seen as a valuable reference for work on that topic, including definitions. One representative stressed that standardised definitions of "safe transfer" and "safety procedures" were essential as the terms had widely varying implications in different countries and another moved that the precautionary principle be considered in terms of the definitions set out in both the UNEP International Guidelines and the Rio Declaration on Environment and Development. Another wished the concept of "biosafety" to be clearly defined, while a third pointed out that the term "safety in biotechnology" had already been defined but agreed that the two terms might not be identical.

33. Another key concept identified by several speakers was the exchange of information. One representative considered that existing sources should be reviewed and ways and means of exchanging information should be suggested for direct agreements, while another thought that the four issues of public awareness, public access to information, informing of local communities and availability of interpretable information to countries lacking necessary capacity were involved. A third representative noted that the question of intellectual property rights would undoubtedly arise under that topic.

34. Some representatives considered that the release of LMOs in centres of origin and genetic diversity should be properly addressed in the protocol: the types of release, types of LMOs and purpose of release should be identified and there should be a common understanding of the terms "release" and "centres of origin and genetic diversity". One delegation suggested that great attention should be paid to the threats posed to the wild relatives of released LMOs and prime consideration given to the precautionary principle to ensure that adverse effects were minimised or eliminated and

furthermore, successful experience in greenhouse or field release should not be used as the basis for release of a particular LMO in another country which should be effected only in accordance with the specific geographical conditions and cultural practice of that country.

35. One representative considered that a clear definition of the phrase "unjustifiable constraints to trade" was required. The need to lay down minimum standards for national legislation was raised by another representative.

36. One representative considered that the concept of "modern biotechnology" required further consideration with a view to clarification.

37. One other representative considered novel traits to be a key concept.

38. Several representatives said that the concept of risk assessment/ management needed to be elaborated.

#### Form and scope of advance informed agreement procedures

39. With regard to the form and scope of AIA procedures in connection with a transboundary movement of LMOs, a number of representatives believed that such procedures constituted a highly important part of a protocol. Several representatives felt that in developing the provisions of an AIA procedure, procedures set out in other international instruments could be taken advantage of, noting in particular the Basel Convention. Some representative suggested that the development of AIA procedures should take into account the operational guidelines and principles developed by the Forest Stewardship Council. While several representatives said that AIA needed to be flexible and based on experience from existing PIC procedures, one representative observed that PIC procedures for hazardous wastes and chemicals might not necessarily be appropriate for application to LMOs.

40. A number of representatives considered that AIA procedures should apply only to an initial transboundary movement of an LMO. Some delegations suggested that, for subsequent movements, a notification would be sufficient. A notification should contain data relevant to safety and the information contained therein would depend on the characteristics of the LMO, the intended use and the circumstances of the transboundary movement.

41. One representative, speaking on behalf of a regional economic integration organisation and its member States, said that the provisions of an AIA procedure and a notification procedure should be differentiated and proportionate to the risks involved. He also suggested this would allow for rapid adaptation to scientific and technological progress.

42. It was also necessary to bear in mind the different capacities of parties to handle information on environmental risks. Several representatives expressed the view that capacity-building must be an integral part of AIA procedures. Another representative believed that operationalisation of AIA procedures was contingent on addressing matters of infrastructure. By enabling importing States to carry out their own risk assessment and risk management decisions, one representative considered that the establishment of AIA procedures would preserve the autonomy of the decision-making process of that country.

43. Some representatives said that an AIA mechanism should be workable and practical and not represent an undue barrier to technical cooperation and commercialisation it should be consistent with WTO. One of them believed that AIA needed to take into account human health and specific regional

environmental conditions. Several representatives described what they believed should be the content of an AIA procedure. One representative suggested that there was a need for some kind of initial outline and offered to draw up a framework paper, in no way definitive, for discussion at the meeting.

Relevant categories of LMOs resulting from modern biotechnology

44. Some representatives said that an AIA mechanism should apply only to those categories of LMOs which had been assessed as posing a potential risk. With regard to the identification of relevant categories of LMOs resulting from modern biotechnology, which was recognised as a priority activity for the Working Group, some representatives said it was necessary to establish clear understanding of, and early agreement on, the classes of organisms under consideration in the negotiation process. One representative considered it useful to consider categories in terms of plants, animals and micro-organisms and to identify the potential risk factors relating to each of the organisms within those categories. An agreed categorisation would assist in establishing which, if any, existing international agreements might be applicable to some categories of LMOs and relevant in developing a protocol on biosafety. In addition, categorisation according to the degree of assessed potential risk to biological diversity would appear to be relevant in considering an AIA procedure. Another representative said the AIA procedures should target specific categories of LMOs that posed risks to the conservation and sustainable use of biological diversity, but noted that there were a number of ways of classifying LMOs.

45. A representative of an NGO said that, while placing LMOs in broad biological classes C plants, animals, micro-organisms C would be a useful element in biosafety assessment, any attempt to establish risk classifications for LMOs would be unrealistic, as biosafety risk associated with a given LMO would be different under different geographical, ecological and climatic conditions. Field trials carried out in one location would likely be irrelevant to another ecosystem, and risk assessments should be scientifically assessed on a case-by-case basis in each new ecosystem into which it might be introduced.

46. One representative recalled that the principles of confidentiality and protection of information were subject to the objectives of the Convention, but that such principles were, in fact, supportive of the Convention's objectives. A representative of an NGO recognised the importance of striking a balance between honouring intellectual property rights and the need for importing countries to have full access to all available information on the LMO in question to take informed decisions.

47. One representative noted that the elaboration of an AIA procedure depended on the definition of key concepts and categories for the protocol. A representative emphasised the importance of distinguishing between "movement" and "transfer" in the elaboration of AIA procedures. He noted the AIA procedures would apply only to intentional transfer, and it might also be necessary to adopt similar procedures to cover unintentional possible movement whereby LMOs might have an adverse effect on the conservation and sustainable use of biological diversity.

48. Some representatives called for the establishment of national focal points by all parties to the protocol. A number of representatives believed that the information-sharing process and transparency would be improved through the establishment of a central information gathering house.

49. On the proposal of the Chairperson, the Working Group then proceeded to an exchange of views on the elements for the content of an international framework on biosafety, as contained in section III, paragraph 18 (a), of annex I to the report of the Open-ended Ad Hoc Group of Experts on Biosafety.

All activities related to LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, including research and development, handling, transfer, use and disposal

50. Some delegations expressed the view that the above element contained in the Madrid report was no longer valid for discussion at this stage as it had been superseded by operative paragraph 1 of decision II/5 of the Conference of the Parties (UNEP/CBD/COP/2/19). Particular concern was expressed as regards the topic on research and development, which was deemed a matter of national competence.

Transboundary movement of LMOs resulting from modern biotechnology and other transboundary issues, including unintended movement of LMOs resulting from modern biotechnology across national boundaries and their potential adverse effects

51. On the proposal of the Chairperson, the Working Group agreed that, since the substance of this element had been covered in the preceding discussion, there was no need to take it up separately.

52. One representative, however, suggested the creation of a fund under the protocol to address the impacts of unintended releases.

53. One representative, speaking on behalf of a regional economic integration organisation and its member States, said that it was necessary to consider the kind of transboundary movements the protocol should cover. In the context of transboundary movement of LMOs resulting from modern biotechnology which may have adverse effect on the conservation and sustainable use of biodiversity, the protocol should only cover issues related to risks to the environment, also taking into account risks to human health. In considering transboundary movement, one should keep in mind other important interrelated subjects to be clarified in elaborating the protocol, such as the scope of LMOs covered under the protocol.

54. The representative of the European Community said that, concerning the intended transboundary movement of LMOs, one must consider the transfer of LMOs from one State to another. There was no need to cover transport as such, as one should not duplicate existing provisions contained in United Nations rules governing transportation of dangerous goods. Unintended transboundary movement that was likely to have significant effects on the environment of third countries should be covered by the protocol in terms of provision for information exchange in respect of the territories affected. Concerning transboundary movement for contained use, the protocol should not create unwarranted additional administrative requirements, since the possibility of adverse effects on the environment resulting from LMOs in installations was unlikely if containment measures were satisfactory. Moreover, unnecessary barriers to the transfer of LMOs between research institutes and culture collections should not be created.

55. With regard to that part of the element referring to other transboundary issues, the representative of one non-governmental organisation stressed that there could be transboundary consequences as a result of an LMO even if the organism itself did not cross the border.

The release of LMOs resulting from modern biotechnology in centres of origin and genetic diversity

56. On the proposal of the Chairperson, the Working Group agreed that, since the substance of this element had been touched upon in the preceding discussion, there was no need to take it up separately.

### Mechanisms for risk assessment and risk management

57. Several representatives expressed the view that the establishment of risk assessment and management mechanisms was an internal matter since it must take local characteristics into account. Therefore, if it was deemed necessary to include in the protocol provisions relating to risk assessment and risk management, they should be limited general principles. Reference was also made in this context to the UNEP International Technical Guidelines for Safety in Biotechnology as a potentially valuable source of guidance for risk assessment and management and to the importance of the national decision-making authorities having risk assessment responsibilities.

58. A group of delegations said risk assessment should be based on scientific data and should take account of: the characteristics of the organisms concerned and their potential to have adverse effects on the environment, and on conservation and sustainable use of biodiversity; and the potential receiving environment. Those countries also believed that the possibilities for mutual acceptability of data and authorisation procedures between parties to the protocol should be pursued.

59. Other representatives pointed to the need to build the necessary capacities in developing countries so that they could conduct the necessary assessments. One of those representatives said that the issue of risk assessment was closely linked to that of funding.

60. Several representatives said that the relevant information for risk assessment should be provided in a transparent manner. The information should be shareable by the world community so that the knowledge base of countries could be updated and remain current. One of those representatives suggested that there was a need to assess carefully the risks associated with the transfer of LMOs under research and development agreements, as well the risks of pathogenic non-LMOs entering a country through LMOs.

61. Another representative suggested that risk assessment should also cover risks to human health and welfare.

62. The representative of the European Community considered that the prior assessment and consequent management of risk was the key to safety and highlighted the valuable guidance and information provided by the UNEP International Technical Guidelines for Safety in Biotechnology in that respect. An important objective of the protocol was to ensure that the competent authorities and focal points in receiving countries were given and/or had access to information relevant to proper risk assessment and risk management.

63. One representative drew attention to the document, "Enabling the safe use of biotechnology - principles and practices", a set of comprehensive details on risk assessment and risk management that complemented the UNEP International Technical Guidelines for Safety in Biotechnology, and noted that these could facilitate the establishment of appropriate regulatory frameworks in countries lacking such capacity.

### Procedure for advance informed agreement

64. On the proposal of the Chairperson, the Working Group agreed that, since the substance of this element had been touched upon in the preceding discussion, there was no need to take it up separately.

### Facilitation of exchange of information from all publicly available sources, including local communities

65. There was general agreement on the importance of a transparent system of information exchange for the success of the protocol.

66. One representative suggested that all transboundary movements could be notified with the assistance of the clearing-house mechanism through the national focal points. That mechanism could also be used to provide information on the safety of LMOs.

67. The same representative said that Article 19, paragraph 4, of the Convention seemed to meet the requirements of the protocol as far as information exchange was concerned, and could be incorporated into the protocol as it stood. Others, however, felt that the modalities to give effect to Article 19, paragraph 4, had to be further developed within the protocol.

68. Another representative said that the general provision of information could address issues of concern that countries might have about LMOs.

69. The representative of an industry organisation said that the industrial community in the United States had had considerable experience in research, development and commercialisation of transgenic plants and was willing to cooperate with the Secretariat to provide the information it had developed on biosafety procedures and regulations.

#### Capacity-building in all the aspects required for biosafety

70. All representatives stressed the importance of capacity-building for the success of the protocol. Some, however, believed that such measures should not be dependent on the adoption of the protocol but should be undertaken to give effect to Article 8 (g) of the CBD. One representative suggested that capacity-building could be covered in the protocol by including the general provisions of Article 18, paragraph 2, of the CBD.

71. One representative suggested that, as a first step, existing capacity-building mechanisms, including regional programmes, could be evaluated to determine the extent to which they matched needs.

72. Other representatives emphasised the importance of capacity-building and noted that it would be meaningless without adequate funding and without the transfer of technology.

73. The need for subsequent meetings of the open-ended Ad Hoc Group was confirmed. In this regard, a representative on behalf of a group of countries requested the Secretariat to submit, for the consideration of the Conference of the Parties at its third meeting, an estimate of the staffing resources needed to handle matters related to the development of the protocol.

#### Definition of terms

74. One representative proposed that the definitions of terminology found in existing instruments should be used.

75. The representative of the European Community said that, in defining LMOs resulting from modern biotechnology, the protocol should reflect existing international definitions, such as those contained in the UNEP International Technical Guidelines for Safety in Biotechnology and in the recent comprehensive biotechnology directives of the European Union. The term should consequently cover

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any biological entity capable of replication or of transferring genetic material in which the genetic material had been altered in a way that did not occur naturally by mating and/or natural recombination. Thus, the LMOs resulting from applying certain techniques of alteration of genetic material would be included, while LMOs resulting from certain other techniques should not, per se, be considered to result in an LMO.

76. The Chairperson suggested that existing legal instruments be combed for definitions that had already been negotiated and said that a glossary of terms had been submitted to the Secretariat by a representative of the biotechnology industry.

#### Implementation mechanisms

77. On the subject of implementation in general, a considerable number of representatives recommended that the Conference of the Parties at its third meeting should consider deciding that, pending the completion and entry into force of the protocol on biosafety, the UNEP International Technical Guidelines on Safety in Biotechnology may be used as an interim mechanism during development of the protocol and to complement it after its completion for the purposes of facilitating national capacities to assess and manage risk, establish adequate information systems and develop expert human resources in biotechnology, taking into account that the use of those Guidelines should not in any way prejudice the development and conclusion of such a protocol.

78. With regard to institutions to administer or implement the protocol, a number of representatives considered that existing structures should be used, while one opined that a new independent, international body should be established for that purpose. Another representative favoured the use of existing structures but said that the creation of a new body should not be precluded. One other thought that the implementing mechanism should ensure smooth communication and easy access for parties to the protocol, especially at the early stage -- to that end, a single simplified mechanism was needed to avoid overlapping and unnecessary expense. In the view of another representative the flexibility essential to the protocol could be achieved by the addition of annexes to the basic text.

79. A number of representatives considered that bodies at both a national and international level were needed for implementation and most of them pointed to the value of using national focal points to serve as an interface with Governments. The value of regional cooperation was stressed by some representatives.

80. One representative, speaking on behalf of a regional group, believed that society as a whole, not just Governments, should be involved in the complex issues of biosafety and that national monitoring committees were therefore necessary. The group also considered that a multidisciplinary approach to decision-making should be adopted at institutional levels in order to reassure researchers and the public that various aspects of biosafety had been taken into account, that the question of an arbitration body to settle disagreements should be studied, that civil society at all levels - local and international - should be involved in the implementation mechanism and that emergency plans, including global response, should be prepared for application in the event of an accident.

81. A considerable number of representatives stressed the importance of capacity-building to ensure that countries, especially developing countries where the necessary expertise was lacking, would be able to implement the protocol. They recommended that the Conference of the Parties at its third meeting consider the development of guidance to the financial mechanism for the provision of financial resources to developing countries for capacity-building to implement the UNEP Guidelines. Some representatives suggested exploring other existing sources of finance such as UNEP, UNDP, UNIDO

and bilateral and multilateral arrangements.

82. In connection with capacity-building, some other representatives referred to the need for structured training programmes for that purpose. One representative emphasised that capacity-building should go hand-in-hand with elaboration of the protocol, while another considered that implementation capacity should precede the establishment of such an instrument. One other representative pointed out that capacity-building in biosafety was not synonymous with capacity-building in biotechnology, although both required financial input through international procedures.

83. In connection with the AIA, one representative speaking on behalf of a regional economic integration organisation and its member States, said that, in the case of transboundary movement of LMOs covered by the protocol, the protocol should ensure that, where appropriate, parties receive and/or have access to information relevant to proper risk assessment and risk management, and the protocol should also provide for adequate procedures. The organisation and its member States believed that there should be a two-pronged approach to the development of these procedures:

(a) A procedure for explicit/implicit advance informed agreement for some cases of transboundary movement; and

(b) A procedure for prior/simultaneous notification for other cases of transboundary movement.

Those procedures will be an important part of the protocol and great care must be taken to elaborate the appropriate procedures for the appropriate kind of LMOs or activities. Alongside those procedures, the development and/or maintenance of international information exchange systems relating to transboundary movement was necessary for proper functioning of the protocol.

84. On the proposal of the Chairperson, the Working Group then proceeded to an exchange of views on the elements for the content of an international framework on biosafety, as contained in section III, paragraph 18 (b), of annex I to the report of the Open-ended Ad Hoc Group of Experts on Biosafety. Although the three issues in question had not enjoyed consensus at that meeting, their inclusion had been supported by many delegations.

85. One representative drew attention to the reservations already expressed by a number of delegations on the issues in question. He acknowledged the importance of these issues, but considered that since transboundary movements of genetically modified crops had already begun, there was a need to move forward urgently in preparing a protocol on biosafety. Supported by one representative speaking on behalf of a regional economic integration organisation and its member States, he believed that at the current stage it was inappropriate to discuss issues that had not enjoyed consensus.

#### Socio-economic considerations

86. A number of representatives and one representative speaking on behalf of a regional economic integration organisation and its member States considered that, while socio-economic considerations and impacts of modern biotechnology represented a complex and important issue, which did involve serious concerns, the issue went beyond the framework of a biosafety protocol and the present Working Group was not competent to address it. Some representatives believed the issue should be excluded from the protocol and made the subject of a separate agreement, perhaps negotiated by a separate forum.

87. The EU suggested that a study on social/economic issues was not necessary at this time, because many such studies already existed. These studies could be listed by the Secretariat for information purposes.

88. On the other hand, a number of representatives, including one representative speaking on behalf of a regional group, believed the issue of socio-economic considerations and impacts of biotechnology to be of central importance to countries, in particular developing countries with their rich genetic and biological diversity. A number stressed that socio-economic considerations should be enshrined in the protocol. It was noted that, in addition to economic impacts such as income distribution, the negative socio-economic impacts of LMOs could include erosion of agricultural and other biological diversity; risks to sustainable use of existing biodiversity; and the threats of transgenic animals and plants to the cultural and religious order of some countries. One representative highlighted the difficulty in assessing socio-economic impacts, which often took a long time to manifest themselves. Pointing out that it was considered appropriate for the protocol to apply to the health of both the environment and of the individual, the representative of one regional group asked why some representatives considered that it was not important for a protocol to take into account the health of a society.

89. On the question of the competence of the Working Group to consider the issue, several representatives observed that the Group was open-ended and could call upon any expertise required. Another representative suggested that there was no forum other than the present meeting or the Conference of the Parties qualified to deal with the issue.

90. One NGO observer said that the European Union had already rejected certain uses of bovine growth hormone (BGH) for socio-economic reasons, including its impact on agriculture. Thus, socio-economic considerations were not a separate or new issue, but one aspect of existing modalities of a protocol. Several representatives stressed the sovereign right of States to reject LMOs which did not have clear advantages and which had a negative socio-cultural effect; that provision was not embodied in WTO and should be part of the present protocol.

91. Several representatives emphasised the importance of a mechanism for risk assessment and environmental impact assessment and pointed to the need for that to take into account socio-economic considerations.

92. One NGO observer considered that there was a need for provisions for public participation in assessing the impact of new technologies. Another said that large-scale research was necessary to assess public perceptions on socio-economic impacts of modern biotechnology and observed that that was a costly exercise. Others countered that studies had already been made on such impacts, *inter alia*, by FAO and ILO and the German Parliament. The latter study had revealed that introduction of products of modern biotechnology benefited predominately the large-scale farmers, to the disadvantage of small-scale agricultural production and the situation of rural women. It was suggested that the Secretariat of the CBD take available studies into account, and several representatives called upon it to produce detailed documentation on socio-economic considerations and impacts for forwarding to the next meeting of the Working Group or Conference of the Parties, as appropriate.

93. One representative, speaking on behalf of the Group of 77 and China, said that because socio-economic considerations were considered to be of such importance, the Group would form a committee to elaborate a viable method of incorporating such concerns into the protocol.

94. One representative outlined several broad elements that might serve as a possible framework for a background paper, to be prepared by the Secretariat, on socio-economic considerations pertaining

to the development of the protocol.

#### Liability and compensation

95. Several representatives, including one speaking on behalf of a regional group, said that, as the establishment of responsibility was a prerequisite to implementing the objectives of the protocol, the direct relationship between the question of liability and compensation and the implementation mechanisms of the protocol should be explicitly addressed within the protocol. According to one representative, the notion of liability comprised the foundation of legality; if there was no explicit allowance for compensation in the protocol, the principle of legality would be jeopardised. Another representative suggested that the protocol expressly set out penalties and sanctions for violation of such responsibilities, including legal procedures for claiming compensation from exporters. Some representatives said that an insurance scheme should be set up in that respect.

96. Noting that the issue of liability and compensation was not new and had been addressed by a number of international conventions, one representative recommended that the protocol reflect those provisions on the subject set out in existing agreements. He emphasised that the dual issue of liability and obtaining compensation was complicated and difficult. Several representatives recommended that the Secretariat prepare a working paper on the matter for consideration by the Working Group or the Conference of the Parties at a future meeting.

97. One representative pointed out that Article 14, paragraph 2, of the Convention gave the Conference of the Parties a mandate to study the issue of liability and redress, including compensation for damage to biological diversity. Another representative, speaking on behalf of a regional economic integration organisation and its member States, said that, pending further consideration of the issue by the Conference of the Parties, the meeting should not prejudice that discussion by addressing it prematurely. He also said that the organisation and the member States he represented were prepared to participate in a process of information exchange to clarify how to address the issues of liability and compensation on the domestic level.

#### Financial matters

98. One representative considered that financial considerations pertaining to the implementation of the protocol were already served by existing international mechanisms; thus, there was no need to establish a new mechanism within the protocol. Another representative said that implementation of the protocol hinged on capacity-building and, as that presupposed adequate financial resources, financial mechanisms should be defined within the protocol. That view was supported by another representative, who considered existing regional, national and international financial mechanisms to be inadequate. In his view, the implementation of the protocol in developing countries would require additional financial resources. One representative believed that, although existing financial mechanisms would play an important role in implementing the protocol, there was still a need to establish a mechanism for the provision of additional resources specifically for the implementation of the provisions of the protocol.

99. One representative, speaking on behalf of a regional economic integration organisation and its member States, considered that, as the protocol would be an instrument for the implementation of the Convention, the financial provisions of the Convention would also apply to the protocol. Resources for the implementation of the protocol should therefore be provided in accordance with Articles 20 and 21 of the Convention.

100. One representative believed that the polarisation of views on this issue was a result of the divergent concerns of the developing and industrialised countries regarding erosion of biological diversity and financial implications, respectively, and called upon participants to search for common ground.

#### Structure of the protocol

101. Several representatives introduced proposals for the possible structure of the protocol. These proposals were subsequently circulated as conference room papers.

102. Following discussion involving many representatives, it was decided to set up a contact group, comprising not more than two representatives from each of those delegations or groups of delegations that had made proposals on the protocol's structure, to consolidate the proposals into a single document, not necessarily the subject of consensus, including in a logical order all the elements put forward. The contact group's role would be essentially editorial and it would not consider any new elements. It was further decided that not more than one representative of the Central and Eastern European Group could attend the contact group as an observer.

#### Scope of the protocol

103. One representative, speaking on behalf of a regional economic integration organisation and its member States and stressing that his remarks were without prejudice to the discussion on the structure of the protocol, said that the scope of the protocol was determined by, *inter alia*, the definitions of "transboundary movement", of "LMOs resulting from modern biotechnology", and of the term "that may have adverse effect on the conservation and sustainable use of biological diversity". In determining which LMOs resulting from modern biotechnology may have adverse effect, it was necessary to consider the characteristics of the organisms involved and of the environment in which they were to be applied, as well as the intended use. The scope could relate (a) to LMOs resulting from modern biotechnology, except to those LMOs and activities which were unlikely to have adverse effect on the conservation and sustainable use of biological diversity and which were specified in an annex; or (b) to LMOs resulting from modern biotechnology which may have adverse effect on the conservation and sustainable use of biological diversity and which were specified in an annex. In both cases the protocol should provide for adequate flexible mechanisms for adaptation of those annexes and for simplified procedures, on the basis of risk assessment. In considering the issue of how to identify relevant categories of LMOs resulting from modern biotechnology, the following is taken into consideration:

(a) In assessing which LMOs may have adverse impacts, account should be taken of the fact that organisms may behave differently in different environments and that an organism which is safe in one environment may have adverse effects in another;

(b) For certain LMOs resulting from modern biotechnology, risk assessment had shown that it was unlikely that they would have adverse effects in a specific environment. However, so far no categories of LMOs resulting from modern biotechnology had been identified for which it could be generally concluded that they were unlikely to have adverse effects;

(c) Categories which are unlikely to have an adverse effect can be identified on the basis of the properties of the organisms and/or the intended use.

104. The representative of the European Community said that, concerning the extent to which

human health should fall under the scope of the protocol, the prime concern of the protocol was the risk to the environment. In that context, risks to human health also had to be taken into account, since negative impacts on the environment could also have negative results for human health.

### III. BUREAU FOR FUTURE MEETINGS

105. The Working Group took up agenda item 5 at the 8th session of the meeting, on 25 July 1996, and agreed on the recommendation reflected in paragraph 1130 below.

106. The Chairperson reminded the meeting of its decision that the establishment of a ten-member Bureau for the present meeting was not to constitute a precedent for future meetings of the Working Group.

### IV. DATES AND VENUES OF MEETINGS OF THE OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY FOR 1997 AND 1998

107. The Working Group took up agenda item 6 at the 8th session of the meeting, on 25 July 1996, and agreed on the recommendation reflected in paragraph 1140 below.

### V. FUTURE WORK OF THE WORKING GROUP

108. It was agreed that the basic document for consideration at the first meeting in 1997 should be one containing the views of Governments and the European Community on the contents of the future protocol. In that connection, it was decided that, taking into account the discussions at the current meeting, Governments should submit their views to the Secretariat no later than 31 December 1996. In doing so, Governments should address the issues in a succinct way and, if necessary, expand on their position in a separate document clearly indicating to which items of the annex their views related. Views not related to any of the items included in the annex should be specifically identified. The Secretariat should compile the views submitted, arranging them according to the annex elaborated at the current meeting. The document should be finalised and distributed to Governments by early March 1997.

109. It was also agreed that the Secretariat should compile a background document on existing international agreements consisting of:

(a) Any inputs received from Governments assessing the implications for the Open-ended Ad Hoc Working Group's work in identifying gaps in the existing international legal framework arising from international agreements which those Governments consider relevant;

(b) An overview of similar procedures in existing legal instruments to assist in the development of a AIA/notification procedure in a Protocol.

(c) Responses from the secretariats of the international agreements identified in the Report of the Panel of Experts on Biosafety which met in Cairo in May 1995 (see Annex II to Annex IV of document UNEP/CBD/COP/2/7) to the following questions which the Secretariat could put to the other

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secretariats concerned:

- (i) What is the objective of the international agreement?
- (ii) To what extent, if any, does the international agreement cover LMOs resulting from modern biotechnology?
- (iii) Is the international agreement currently being applied, or could it be applied, to the oversight of LMOs resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity?
- (iv) What obligations or disciplines contained in the international agreement could be assessed as being relevant to the Terms of Reference for the Biosafety Protocol negotiations?
- (v) Is the international agreement currently being revised/renegotiated, or when will the next revision/renegotiation be undertaken? What is the expected timing for completing such revisions/renegotiations? Is it expected that the next revised text of the international agreement will address the impact of LMOs resulting from modern biotechnology on the conservation and sustainable use of biological diversity?

110. In response to a question from one representative, the Secretariat clarified that it did have sufficient resources to initiate work on the background document. The additional resources required to pursue this work would be reflected in the proposed budget for the Secretariat to be submitted to the third meeting of the Conference of the Parties.

111. There was extensive discussion, but no agreement, on a proposal that the Secretariat should prepare a study on the socio-economic impacts of biotechnology. Several representatives believed that such a study was essential for the Working Group to reach a decision on the place of socio-economic aspects under the Protocol, while others expressed the view that the Working Group should avoid overloading the Secretariat and that the compilation of a bibliography of the many relevant existing studies would suffice. The Working Group requested the Secretariat to compile a bibliography of relevant literature regarding both positive and negative potential socio-economic effects of biotechnology.

112. The Working Group decided that the Secretariat compile definitions already contained in binding international agreements of the terms proposed for definition in the protocol. This compilation should indicate the legal source of the definitions it includes and should be distributed to Governments by 1 October 1996. Governments may then submit to the Secretariat, by 1 January 1997, additional definitions of these terms contained in national or regional legislation, which shall also be made available for the consideration of the second meeting of the Open-ended Ad Hoc Working Group.

## VI. RECOMMENDATIONS TO THE CONFERENCE OF THE PARTIES AT ITS THIRD MEETING

113. The Working Group decided to recommend to the Conference of the Parties that a ten-member Bureau should be established and to leave to the Conference of the Parties the decision as to whether

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the Bureau should be of a permanent nature.

114. The Working Group also decided to recommend to the Conference of the Parties that it should hold two meetings in 1997, both of five days' duration, the provisional dates being 12-16 May and 13-17 October.

#### VII. ADOPTION OF THE REPORT

115. The Open-ended Ad Hoc Working Group adopted the present Report on 26 July 1996.

#### VIII. CLOSURE OF THE MEETING

116. At the closure of the Meeting, delegates wished to express their gratitude to the Government of Denmark and to the people of Aarhus for the support and warm hospitality extended to them.

117. The Meeting was closed on 26 July 1996.

Annex

Possible Contents of the Protocol on Biosafety

A. Items included in all proposals:

Title  
Preamble  
Use of terms/Definitions  
Advance informed agreement  
Information sharing  
Relationship with other international agreements  
Institutional framework for the functioning of the Protocol  
Settlement of disputes  
Amendment  
Final clauses

B. Items included in some but not all proposals:

Objectives  
Scope  
Jurisdictional scope  
General obligations  
Criteria to determine the use of AIA and/or notification procedures  
Notification procedure  
Considerations for risk assessment and risk management  
Mechanisms for risk assessment  
Mechanisms for risk management  
Emergency procedures  
Minimum national standards on biosafety  
Designation of competent authority and national focal point  
Capacity building  
Transport and packaging requirements for the transfer of LMOs  
Handling, transport and transit requirements for LMOs  
Transboundary movement between parties  
Transboundary movement from a party through States which are not parties  
Illegal traffic  
Duty to reimport  
Technical information network  
Public awareness  
Clearing-house  
Mechanisms for bilateral agreements  
Liability/Liability and compensation  
Consultations on liability  
Monitoring and compliance  
Financial issues  
Socio-economic considerations  
Review and adaptation  
Signature

Accession  
Right to vote  
Entry into force  
Reservations and declarations  
Withdrawal  
Depositary  
Authentic texts  
Annexes

Appendix I: Terms proposed for definition:

Living Modified Organisms (LMOs)  
Transboundary movement  
Transfer  
Safe transfer  
Competent authority  
Familiarity  
Adverse effects  
Contained use  
Intended/deliberate release  
Unintended release  
Focal point  
Risk assessment  
Risk management  
Modern biotechnology  
Advance Informed Agreement/Prior informed consent  
Minimum national standards  
Biosafety  
Limited field trial  
Handling of LMOs  
Use of LMOs  
Centres of origin  
Centres of genetic diversity  
Compensation  
Accidental release  
Open environment  
Open field trial  
Accidental

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