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OPEN-ENDED AD HOC WORKING GROUP
ON BIOSAFETY
Second meeting
Montreal, 12-16 May 1997

REPORT OF THE SECOND MEETING OF THE OPEN-ENDED WORKING GROUP ON BIOSAFETY

Introduction

1. The second meeting of the Open-ended Ad Hoc Working Group of Experts on Biosafety, established in accordance with decision II/5 of the Conference of the Parties to the Convention on Biological Diversity, was held in Montreal, Canada, from 12 to 16 May 1997.

I. ORGANIZATION OF THE MEETING

A. Opening of the meeting

2. The meeting was opened by Mr. Veit Koester (Denmark), in his capacity as Chairman of the Open-ended Ad Hoc Working Group. He recalled that the Conference of the Parties had entrusted the Working Group with the task of drafting a protocol on biosafety, and, in its decision III/20, had called upon it to conclude its work by the end of 1998. The recent session of the Commission on Sustainable Development in New York had also recognized the importance of that work, and had called upon the Open-ended Working Group to complete it rapidly. At the present meeting, the Group should concentrate on the core issues and identify elements that should form part of a protocol on biosafety. Such an approach would enable draft text of a protocol to be reviewed at the Working Group's third meeting, in October 1997. The Working Group should also provide clear directives as to the work that it wished the Secretariat to do.

3. Mr. Hamdallah Zedan, Chief, Biodiversity Unit, UNEP, speaking on behalf of the Executive Director, recalled that the Conference of the Parties, at its third meeting, had affirmed its support for a two-track approach through which the promotion of the application of the UNEP International Technical Guidelines for Safety in Biotechnology could contribute to the development and implementation of a protocol on biosafety without prejudicing the development and conclusion of such a protocol. It had also requested the Global Environment Facility (GEF) to provide financial resources to developing country parties to the Convention for purposes of capacity-building in biosafety. Since that time, the Bureau of the African Ministerial Conference on the Environment (AMCEN) at its ninth meeting had requested UNEP to formulate and submit to GEF an appropriate biosafety project proposal through which African countries could be assisted to develop national, subregional or regional biosafety mechanisms. With the assistance of the Government of the Netherlands, a capacity-building programme for safety in biotechnology and the implementation of the UNEP Guidelines was being developed in collaboration with UNEP. At its nineteenth session in early 1997, the UNEP Governing Council had, in its decision 19/16, urged Governments and subregional, regional and global organizations to promote safety in biotechnology and cooperate in the mutual sharing of biosafety information. That would involve, inter alia, designating biosafety focal points to apply the Guidelines, contributing relevant information to the International Register on Biosafety and using all available mechanisms for mutual sharing of information contained in international databases. Many countries around the world were in the process of formulating their national biosafety mechanisms and submitting their project proposals for GEF support. UNEP, together with sister GEF implementing agencies, stood ready to assist as appropriate. There was a welcome synergy in all of those positive developments, which augured well for the success of the work of the Working Group. Finally, he expressed the hope that the Working Group, by concentrating on the core issues, would be able to identify and formulate elements, which would lead to the completion in 1998 of the protocol on biosafety.

4. The Executive Secretary of the Convention on Biological Diversity, Mr.•alestous Juma, pledged the support of the Secretariat to the work of the Working Group. Work on biosafety was one of the main activities which the Conference of the Parties had entrusted to the Secretariat. After thanking the Government of Canada, the Province of Quebec and the City of Montreal for their assistance in the establishment of the Secretariat in Montreal, he also thanked the Government of Denmark, the European Community, and the Governments of Norway, Sweden and the United Kingdom whose generous

contributions had helped representatives of least developed countries and small island developing States to travel to the present meeting. Having reviewed the relevant work in which the Secretariat had been involved since the third meeting of the Conference of the Parties, he said that most of the issues related to the implementation of the Convention would contribute to the planned discussions on the review of the operations of the Convention. The necessary material for that review was being collected and it was envisaged that an expert workshop would be convened in November on the modus operandi of the Convention, likely to be one of the most important issues to be discussed at the next meeting of the Conference of the Parties. The progress made in implementing the decisions of the third meeting of the Conference of the Parties had been due in part to those States who had already made their contributions to the Trust Fund of the Secretariat. Recent visits by the Secretariat to a number of countries to seek additional voluntary contributions, particularly for the present meeting, had shown that many States were making arrangements to pay their outstanding contributions, and the Secretariat was grateful for and encouraged by those efforts. Every effort was being made to facilitate the recruitment of staff to the Secretariat. The Food and Agriculture Organization of the United Nations (FAO) had seconded staff to the Secretariat, and he expressed his gratitude to the Director-General for FAO's support of the Convention.

B. Attendance

5. The meeting was attended by representatives of the following States and regional economic international organizations:

Antigua and Barbuda
Argentina
Australia
Austria
Bangladesh
Barbados
Belarus
Belgium
Bhutan
Brazil
Bulgaria
Burkina Faso
Burundi
Cambodia
Cameroon
Canada
Central African Republic
Chile
China
Colombia
Comoros
Cuba
Denmark
Djibouti
Dominican Republic
Ecuador
Eritrea
Ethiopia
European Community
Finland
France
Gambia
Germany
Greece
Guinea (Republic of)
Guyana
India
Indonesia
Italy
Jamaica
Japan
Kiribati
Lao People's Democratic Republic
Lesotho
Luxembourg
Madagascar

Malaysia
Mali
Marshall Islands
Mauritania
Mauritius
Mexico
Mozambique
Myanmar
Nauru (Republic of)
Nepal
Netherlands
New Zealand
Niger
Norway
Papua New Guinea
Peru
Philippines
Portugal
Republic of Korea
Russian Federation
Rwanda
Saint Kitts and Nevis
Saudi Arabia
Seychelles
South Africa
Spain
Sri Lanka
Sweden
Switzerland
Thailand
Togo
Turkey
Uganda
United Kingdom and Northern Ireland
United States of America
Zaire
Zambia

6. The following United Nations bodies and specialized agencies were represented:

United Nations Environment Programme (UNEP)
United Nations Industrial Development Organization (UNIDO)

7. Representatives of the following intergovernmental organizations were present at the meeting:

Organisation for Economic Co-operation and Development (OECD)
South Pacific Regional Environment Programme (SPREP)

8. The following non-governmental organizations were represented:

ACCT
Association of biotechnology Industries in Denmark (FBID)
Australian GeneEthics Network
Biodiversity Action Network
Biotechnology Industry Organization
Biotechnology Working Group
Canadian Broadcasting Corporation (CBC)

Canadian Institute for Environmental Law and Policy
Canadian Institute of Biotechnology
Concordia University
Council for Responsible Genetics
Ecoropa
Environmental Information Management consulting
Forum Environment and Development,Institute for Applied Ecology
Foundation for International Environmental Law and Development (FIELD)
German Working Group on Biodiversity
Green Industry Biotechnology Platform (GIBiP)/Association Internationale des S•ectionneurs (ASSINEL)
Greenpeace International
Japan Bioindustry Association
Kingsbure Coastal Conservancy
London School of Economics
McGill University
Monsanto Company
Montreal International
The Edmonds Institute
The Institute of Agriculture and Trade Policy
Third World Network
Université du Qu•ec à Montr•l (UQUAM)
University of Peradeniya
Vermont Law School
Working Group on Biosafety-Forum Environment and Development
York University

C. Bureau

9. The Working Group noted that during the third meeting of the Conference of the Parties to the Convention on Biological Diversity the following nominations had been made to the Bureau of the Open-ended Ad Hoc Working Group on Biosafety: Mr. Behran Gebre Egziabher Tewolde (Ethiopia), Mr. David Gamble (New Zealand), Mr. Veit Koester (Denmark) and Mr. Sateeaved Seebaluck (Mauritius). In accordance with paragraph 1 (b) of decision III/20 of the Conference of the Parties, the Bureau would remain in office until the fourth meeting of the Conference of the Parties, to be held in May 1998.

10. At the 2nd session of the meeting, on 12 May 1997, the Working Group completed the constitution of its Bureau on the basis of the following nominations:

Mr. Diego Malpede (Argentina)
Mrs. Sandra Wint (Jamaica)
Dr. Ervin Balazs (Hungary)
Dr. Alexander Golikov (Russian Federation)
Dr. Antonio G.M. La Vina (Philippines)
Mr. Bum Soo Kwak (Republic of Korea)

11. Dr. Alexander Golikov (Russian Federation) continued to serve as Rapporteur.

D. Adoption of the agenda

12. At the 1st session of the meeting, on 12 May, the Working Group adopted the following agenda on the basis of the provisional agenda that had been circulated under the symbol UNEP/CBD/BSWG/2/1:

1. Opening of the meeting and adoption of the agenda.

2. Composition of the Bureau in accordance with decision III/20, paragraphs 1 (a) and (b) of the Conference of the Parties to the Convention on Biological Diversity.

3. Elaboration of a protocol on biosafety in accordance with decision II/5 of the Conference of the Parties to the Convention on Biological Diversity.

4. Dates and venue of the third meeting of the Open-ended Ad Hoc Working Group on Biosafety.

5. Adoption of the report.

6. Closure of the meeting.

E. Documentation

13. The Secretary of the Working Group, Mr. Desmond Mahon, introduced the following documents that had been prepared for the meeting: (a) provisional agenda (UNEP/CBD/BSWG/2/1); annotations to the provisional agenda (UNEP/CBD/BSWG/2/1/Add.1); compilation of views of Governments on the contents of the future protocol (UNEP/CBD/BSWG/2/2); background document on existing international agreements related to biosafety: note by the Executive Secretary (UNEP/CBD/BSWG/2/3); potential socio-economic effects of biotechnology: a bibliography (UNEP/CBD/BSWG/2/4); and glossary of terms relevant to a biosafety protocol: results from a preliminary survey by the Secretariat (UNEP/CBD/BSWG/2/5).

14. He explained that those submissions received after the compilation of Governments' views had been circulated informally. It should also be noted that the Secretariat was still pursuing its contacts with the institutions managing the various instruments referred to in document UNEP/CBD/BSWG/2/3 in order to seek their perspectives on how, if at all, their instrument would apply to biosafety.

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

General statements

15. At the 1st session of the meeting, general statements were made under agenda item 3 by the representatives of 16 Governments, one representative of a regional economic integration organization and its member States, and two non-governmental organizations.

16. There was mutual understanding that, at the current meeting, the Working Group should focus on a number of core issues with a view to preparing a first draft of elements for inclusion in the draft protocol. That draft should include both the elements on which there was consensus and those on which there was not. It could then be circulated to Governments with a request to them to submit legal language which could be put before the Group at its next meeting. The drafting of some of the less controversial provisions could be entrusted to the Secretariat. One representative, supported by several others, suggested that those core issues should be: objectives, definitions of living modified organisms, the Advance Informed Agreement procedure, mechanisms for risk assessment and management, capacity-building, financial issues, socio-economic considerations, and liability and compensation. Another representative expressed the view that the first core issue to be addressed should be the procedures in the case of intentional transboundary movements, while another was of the opinion that the primary focus should be on Advance Informed Agreement and information-sharing, which were central to the protocol and closely related. There was also agreement on the need for an instrument that could attract the largest possible participation and was sufficiently flexible to accommodate future technological developments.

17. The view was expressed by a number of representatives that the protocol should be understood as an extension of the Convention and should reflect the provisions of the Convention and other relevant international instruments. Stress was also laid by some representatives on the need for the protocol to be consistent with the World Trade Organization Agreements and to avoid hindering access to and transfer of biotechnology. Any trade measures envisaged should be transparent, non-discriminatory, and not unduly trade-restrictive. It was also stated that the protocol should not duplicate other instruments but should draw on them and use existing institutions as far as possible.

18. One representative, noting the rather low level of attendance of developing countries at the meeting, suggested that the Secretariat should be requested to facilitate broader and more representative participation in future meetings.

19. One representative, speaking on behalf of the African Group, said that the reference to a •orld Biosafety Court" had been included erroneously in the text on liability and compensation submitted to the Secretariat by the African Group (UNEP/CBD/BSWG/2/2, page 68) and should be disregarded.

20. The representative of the Third World Network, speaking on behalf of a number of non-governmental organizations, drew attention to the joint NGO statement circulated by those organizations at the Aarhus meeting and the third meeting of the Conference of the Parties. In that statement, the NGOs had urged the Parties to agree to include in the protocol elements that effectively addressed the precautionary principle, ethical, social and human health risks, public participation, strict liability and emergencies, and had called for a worldwide moratorium on the release of genetically modified organisms until a legally binding protocol had been concluded.

21. The representative of the Green Industry Biotechnology Platform, also speaking on behalf of the Association Internationale des S•ectionneurs (ASSINEL), said that those organizations believed that the scope of the Protocol should be limited to the specifications of Article 19, paragraph 3, of the Convention, should set out procedures based on Advance Informed Agreement, and should apply only to organisms that had been modified using recombinant DNA techniques and were capable of multiplication in the environment. Products of living modified organisms should not be included. There should also be a provision for exceptions based on product characterization.

22. Following the general statements, the Working Group agreed with the proposal of the Chairman that it would first consider the following items in the list produced at its first meeting (UNEP/CBD/BSWG/1/4, annex) and in the following order: objectives; transfer of living modified organisms, including Advance Informed Agreement; competent authority, information-sharing/clearing-house and capacity-building; and risk assessment and management procedures. No attempt would be made to develop definitions until it was clear that they were necessary. All items on the Aarhus list would eventually be covered.

Specific transfer of living modified organisms, including Advanced Informed Agreement

23. The Working Group considered what procedures should be included in the protocol in the case of specific transfer of living modified organisms (LMOs), focusing on whether: (a) transfer would require explicit consent, i.e. a specific reply from the importing country; (b) implicit consent would be acceptable, in the sense that consent would be deemed to have been given if no reply from the importing country was received within the specified time; or (c) both procedures should be included in the protocol.

24. Several representatives were in favour of retaining all three options, to be applied depending on the circumstances. One representative suggested that explicit consent might be required only for LMOs that could have adverse effects on biodiversity and human health. The need for flexibility, to allow countries to adopt procedures as they saw fit, and for transparency, to ensure that procedures were clear to all affected parties, was stressed.

25. One representative, speaking on behalf of a regional economic integration organization and its member States, stated that intentional transboundary movement could be covered by two types of provisions: information supply to the receivers and notification to competent authorities. As for the notifications to competent authorities, the representative explained that for such intentional transboundary movements there were two possible options: Advanced Informed Agreement procedures and Simple Notification procedure (simultaneous notification).

26. A large number of representatives stated that they would require explicit consent. That was in accordance with the precautionary principle in the Convention on Biological Diversity and would take account of the onus which implicit consent would place upon developing countries, their vulnerability to the risks of LMOs, particularly in the tropics, and their lack of adequate assessment facilities.

27. One representative said that the structure of the discussion on the issues should match the sequence of events in the operation of the AIA procedure.

28. One representative said that it would be an unfair burden on the developing countries for them to have to worry that a failure to respond might lead to an unintended implicit consent. Since it seemed that the developed countries favoured implicit consent and the developing countries favoured explicit consent, a multi-tier approach might be worth investigating.

29. Another representative proposed that the protocol should stipulate explicit consent, but that countries should be free to conclude bilateral agreements allowing for implicit consent.

30. In response to a request for clarification from the Chairman, a number of representatives said that after explicit consent had been given to a first shipment of an LMO, responsibility for deciding on subsequent shipments would lie with the authorities of the importing country, and that subsequent shipments might be allowed under the same consent, perhaps with a requirement for simple notification, perhaps with the proviso that such consent could be withdrawn if changed circumstances or new scientific evidence made that necessary. Others took the view that explicit consent had to be repeated for every shipment, with such consent being based, for example, on new experience gained after the first shipment. It might be that such subsequent expressions of consent could be subject to less onerous requirements than the first.

31. A number of representatives said that the requirement of explicit consent for a transfer to proceed should not imply that failure to respond would be a violation of the protocol.

32. One representative said that he had a feeling that having explicit consent alone would give a party an opportunity not to reply to a notification, which was not desirable.

33. With regard to the LMOs and intended uses to which the procedure should apply, a large number of representatives insisted that it should apply to all LMOs and for all intended uses, because they were not convinced that any transfer or use situation would be completely risk-free. All LMOs resulting from modern biotechnology might have adverse effects. Such an approach would respect the concept of the precautionary principle in the Convention on Biological Diversity, regardless of whether the LMOs were for research and development, use in contained conditions or for wider commercial release. That was particularly relevant for developing countries where assessment capacity was often low. Because of the risk factor, the precaution should also apply to transit movement of LMOs.

34. Other representatives were of the opinion that the AIA procedures should apply to all transboundary movement of living modified organisms resulting from modern biotechnology, except those not likely to have an adverse effect on the conservation and sustainable use of Biological diversity, taking also into account risks to human health. One representative, speaking on behalf of a regional economic integration

organization and its member States, explained that, without prejudice to the scope of the protocol, consent procedures should not apply to transboundary movement of LMOs destined for subsequent contained use and transit of LMOs. Some of the above-mentioned representatives considered that a list should be included in an annex to the protocol to indicate LMO transfers to be excluded from the procedures. That list should be established using carefully-determined criteria to identify microorganisms in low-risk categories. Another representative, however, pointed out that existing classification systems covered only risks to human health, not to the environment.

35. One representative said that there was a need to establish clear criteria to decide on the type of LMOs to which the protocol should apply and suggested that those criteria might include: whether the transfer was to a centre of origin or biological diversity of the unmodified organism; whether the organism was known to be pathogenic, invasive or infective or if there was insufficient knowledge on the organism to determine whether it had any of those characteristics.

36. One representative said the AIA procedure should apply to organisms intended for field testing or first growth in the importing country. It was also important to take into account the experience of the exporting country and whether the LMOs had been refused approval in that country, were awaiting approval or would have required approval if they had been intended for commercialization or growth in the exporting country.

37. Another representative suggested a risk-based trigger mechanism for the AIA procedure based on such criteria as type of intended use, the nature of the introduced characteristic in the organism, the type of the receiving environment, the degree of familiarity with the non-genetically modified species in the receiving environment, and the type of reproductive mechanism of the organism.

38. On the question of whether there should be a distinction between the first transboundary movement and subsequent movements to the same country, unless there were changes in the intended use or in the risk assessment because of new information, many representatives, a number of whom referred to the precautionary principle, expressed the view that the procedures, together with the requirement for explicit consent of the importing country, should apply in all cases. Some of those representatives were of the view that there could be some flexibility in the protocol to allow the importing country to decide on what was required for subsequent movements, if there was no change in the risk assessment or the intended use. In that context, it

was noted that, since adverse effects could take a long time to emerge and it was impossible to predict the complex interactions between an organism and the receiving environment, a system for continuous monitoring both during and after use would be required. Other representatives were of the view that, while explicit consent should be required for the first shipment, subsequent transfers should be able to proceed on the basis of implicit consent following notification. A representative speaking on behalf of a regional economic integration organization and its member States proposed that a single notification as well as a consent given in response to a notification might cover several similar transboundary movements to the same Party of import.

39. Some representatives felt that there was no need for special provisions for LMOs for which commercialization had been prohibited in the exporting country, since the issue was the interaction of the LMO with its receiving environment, which might be very different from that in the country which had produced it. The exporter country would have to supply information to the potential importer country on why the LMO was prohibited in its country of origin.

40. Others felt that if an LMO was prohibited in a country, that country should be absolutely prohibited from exporting it and the producer country would have to supply information to the potential importer country on why the LMO could not be provided to the potential importer. Other delegations agreed that in general there should be such a prohibition, but felt that the protocol should allow for specific derogations from that general rule.

41. One representative, supported by one other, pointed out a related issue, that of LMOs which were prohibited by certain international conventions other that the proposed protocol currently under discussion. The situation would be very complicated if some States were parties to such conventions but not to the protocol.

42. Another was of the opinion that the potential exporter country should certainly share information on why an LMO was banned, but preferred to withhold an opinion on the actual question of whether banned LMOs could be exported.

43. The view was also expressed that there should not be an obligation on the exporter country to volunteer the information, but that there should be a right of the potential importer country to ask for it.

44. After expressions of opinion by several representatives on whether

there should be special provisions for LMOs produced in the country of origin, the Chairman proposed that the question should be deleted and the issue be reconsidered under the aspect of discrimination and non-discrimination.

45. On the question of whether the importing country should have the opportunity to choose between the general procedure and a simplified procedure after receiving notification of a shipment, the Chairman summarized earlier statements as indicating two main opinions: that it was the right of the importing countries to make such decisions, or alternatively that allowing them to do so jeopardized the predictability which other countries had the right to expect.

46. One representative said that the protocol should cover specific and difficult cases but as a general rule each country's national legislature should take the necessary decisions.

47. One representative said that the question as phrased seemed to imply that every shipment would be accompanied by a notification, which might not necessarily be the case.

48. One representative said that each country should be entitled to facilitate the AIA procedure either by replacing it with notification or by exempting certain LMOs from AIA altogether, and to do so bilaterally or unilaterally. Others, referring to the precautionary principle, pointed out that it could not be acceptable for one country unilaterally to take a decision which could harm its neighbours. There was a need for a certain minimum level of information and a certain minimum standard to be specified in the protocol, and countries had the right to assume that their neighbours would not unilaterally derogate from those minima. While agreeing with that general principle, one representative pointed out that the way in which one country impinged on its neighbours differed widely as between, for example, landlocked States and remote islands.

49. The view was also expressed that if a country wished to derogate from the minima, the protocol should state the conditions under which such derogations could be allowed, and the country would have to demonstrate that those conditions did in fact exist.

50. In the interests of making the protocol as flexible as possible, some representatives thought that there should be a general provision permitting unilateral or bilateral deviation from the general procedure, and the use of a simplified procedure or no procedure at all. Another representative said

that there should not, however, be a provision in the protocol where no provision was applicable at all.

51. One representative said that there should be no provision for bilateral or unilateral derogations, while another felt additionally that "simplified procedure", had to be understood as merely a simplifying of the requirements, not as an elimination of the requirement for any agreement at all. The protocol had to define the concept of "simplified" and the conditions under which a simplified procedure would be permitted.

52. There was general consensus on the need for the notification of an intended transfer to contain sufficient information for the importing State to undertake a risk assessment and make an informed decision. One representative, supported by several others, pointed to the need to elaborate an exhaustive list of the types of information to be submitted for inclusion in an annex to the protocol, taking into account existing international standards such as the Safety Considerations for Biotechnology of the Organisation for Economic Co-operation and Development and the UNEP Technical Guidelines for Safety in Biotechnology. One representative suggested that the Secretariat or other competent international organization should prepare a checklist of items for further study. A number of representatives made specific suggestions as to the types of information that should be provided, while other said that they were not yet in a position to do so in a comprehensive manner. One representative expressed the view that the list should be flexible, as the type of information that would be required depended on the nature of the organism and the receiving environment.

53. Among the items suggested for inclusion in the notification were: full description of the characteristics of the organism; affinities with other organisms; nature of the modifications to the organism; date of intended transfer; information on the intended use; type of proposed receiving environment and likely impacts of the organism; type of reproductive mechanism of the LMO; information on prior uses, in particular releases, of the organisms and impacts on the environment; summary of the risk assessment in the country of export; assessment of socio-economic implications; plans for monitoring the organism after introduction; information on packaging and safety measures taken; emergency response measures to be taken in the event of an accidental release; stability of the genes in the organism; bibliography of relevant background documentation; regulations on the safe handling of the organism existing in the country of export; full information on the risk assessment and management procedures for the organism in the country of export; certification from the designated national authority of the exporting that the organism is not prohibited and that the applicant has

complied with all relevant rules and regulations; information on relevant previous notifications and decisions between the importing and exporting countries; and a list of insurance documentation to cover accidental release in transit or in the importing country.

54. Some representatives said that provision should be made for the handling of confidential information that might be required, although one representative cautioned that confidentiality should not be used as a reason for withholding information.

55. Some representatives pointed to the need to allow for an interchange of information between the applicant and the focal point in the receiving country after the initial notification had been received, so that additional information could be sought and obtained if the original submission was deemed inadequate.

56. On the question of whether there should be a prescribed time period for the response on the part of the importing country, a number of representatives said that no mandatory time-limits should be laid down, in view of the uncertainties over the time required to obtain and assess information and to complete all the necessary procedures. The time required could vary from country to country and from organism to organism, as well as being dependent on the completeness of the information provided with the notification. Some of those representatives said that they could consider an indicative time-period for a response or for the acknowledgment of receipt of the notification but could not accept a prescriptive limit after which implicit consent would be assumed.

57. Other representatives believed that time-limits were essential, some of them suggesting that they could vary according to the complexity of the procedures involved or the nature of the organism or intended use in question and that provision could be made for a provisional or interim response. One representative said that limits were necessary to avoid non-tariff barriers to trade and to balance the rights and obligations of importing and exporting countries.

58. One representative said that, since the length of any limits would depend on the volume and type of information submitted and the capacity of the receiving country to digest it, the issue could be deferred until it was clear what information would be required.

59. One representative suggested that there might be provision for a system of cooperative agreements between two parties on a voluntary basis. This

would of course have to be non-discriminatory. There might also be a provision as in the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, whereby any party might at any time signify that it did not want to receive notification of the AIA. In response to this suggestion, another representative said that he did not support any idea of a bilateral procedure because he considered that it would be quite possible that careless action regarding an LMO could affect surrounding third-party countries, something which was highly unlikely during the transport of hazardous wastes, which was covered by the Basel Convention.

60. On the question of whether there should be one or more types of simplified procedure in cases for which the general procedure did not apply, one representative, recalling that at this point he envisaged only the single general procedure, emphasized that procedure should be as simple as possible and completely standardized. Subsequent actions could then be treated on a case-by-case basis.

61. The need for flexibility to allow the importing country, after a first import, to determine whether the same conditions prevailed for further imports, was mentioned. Another speaker cautioned that a shipment-by-shipment notification scheme was likely to cause many bureaucratic problems and might well serve as a disincentive to trade in many beneficial products.

62. Turning to the modalities of the procedure, the Group first considered the questions of: (a) who should trigger the procedure (i.e. make the first application), the non-government entity or the Government; (b) whether the procedure should be triggered in the exporting or the importing country; and (c) vis-à-vis whom.

63. All representatives who took the floor favoured notification to the national competent authority in the importing country. On the question of who should trigger the procedure, the viewpoint of several representatives was that the exporter, be it a company, institution, government agency or individual, should trigger the procedure and notify the focal point, normally a national competent authority, in the importing country.

64. Others were of the view that, as States would be parties to the protocol, it should be the exporting State that should trigger the procedure, notifying the importing State, normally in the form of the national competent authority.

65. One representative said that the responsibility for triggering the

procedure lay with the receiving entity and that requests were acceptable only from within the importing country so that there could be no ambiguity as to who was using the LMO after import.

66. On the question of the kind of review mechanism which should be put in place for re-examining a decision made by the importing country, many representatives felt that the importing country had an evident right to modify a consent already given, for example if new information about the impact of the LMO on the importer or on another country should come to light. The notifiers would have to be informed promptly of such a change to a consent, as well as of the reasons for it. It would also be advisable for the importing country to communicate the new information to other importing countries.

67. It was said that review of a consent decision was a matter for the importing country alone and, in consequence, an independent review body should not be set up. It was also suggested that Article 27 of the Convention on Biological Diversity might be incorporated into the protocol.

68. In the event than an exporter asked for a review of an importing country's decision, one representative suggested that the review should be done jointly by both sides.

69. Another view was that interested parties in the countries adjacent to an importing country should be given the right of consultation with that country, and that disputes might be submitted to a expert panel, the establishment of which might be incorporated into the protocol. The representative of a non-governmental organization agreed that adjacent countries should have access to the appeal process and also said that the citizens of the importing country should be involved in the decision-making process.

70. One representative said that in his country, the review mechanism was incorporated into law. A consent decision could be reversed only by a legal appeal, not by an administrative procedure.

71. At the 5th session of the meeting, on 14 May, the Chairman introduced a conference room paper containing the Chair's summary of draft elements presented by delegates during the discussion on the item. The Chairman emphasized that the paper should not be considered a negotiated document and he was in no way attempting to set up a prescriptive framework for negotiations. The paper should be understood and read in close conjunction with the report of the meeting and government submissions. Delegations were

of course free to add elements, and elements could be deleted, provided there was general agreement to do so. The purpose of the document was to assist Governments by identifying issues relevant for further formulation of positions and submission of proposed text for future negotiations.

72. The Chairman's summary of draft elements was reviewed by the Working Group at the 6th and 7th sessions of the meeting, on 14 May. the Working Group agreed that the elements, as revised by members of the Working Group, should be included in the Chairman's summary of elements as contained in annex II to the present report.

Competent authority/focal point

73. The Working Group considered the question of competent authority/focal point at the 4th session of the meeting, on 13 May.

74. In the discussion on the item, Many representatives felt that the protocol should specifically require parties to designate competent authorities or focal points or both. One representative said that the focal points could be informal and established at any time, while the national competent authority should be established formally.

75. While several representatives felt that there could be more than a single competent authority, a number took the view that there should be only one focal point per country. One representative said that it would be preferable if the focal point were one of the competent authorities (if there were several), while another said that a country should be able to designate more than one focal point, if the second one was regional.

76. Two representatives suggested that the distinction between competent authority and focal point should be abandoned. What was needed was a point or points of contact for notifications, information-sharing, and so on.

77. Many representatives thought that the idea of regional focal points should be explored, with one representative saying that regional focal points should be based on commonality of environmental conditions in the region and another wondering if one of the criteria of commonality might be vulnerability. Some representatives said that they were not sure if there should be regional focal points at all.

78. It was felt that in order to preserve flexibility in the protocol,the responsibilities and tasks of the competent authorities and focal points should be left to the individual countries, rather than being specifically

fixed in the protocol. Specific tasks suggested were: providing information, for example through a database; ensuring that notifiers complied with the importing country's requirements; acting as an early warning system, or as the recipient for urgent notification of adverse environmental events; and taking legal action, for example in customs matters.

79. Many representatives felt that the competent authorities and/or focal points should be established as soon as possible, but a number of them pointed out that in certain countries that would require financial and technical assistance. Some said that the bodies should be established before the entry into force of the protocol in the country concerned while others said that it should be within 90 days of ratification, with changes being communicated to the clearing-house mechanism within 30 days.

Information-sharing/capacity-building/public awareness/participation

80. At the 5th session of the meeting, on 14 May, the Working Group took up the question of information-sharing/capacity-building/public awareness/ participation.

81. There was general agreement that there should be a provision in the protocol for sharing of information between parties on actions undertaken under the protocol. It was observed that this was in fact an obligation in view of Article 17 and Article 19, paragraph 4, of the Convention on Biological Diversity, which called for information-sharing on biosafety regulations and national legislation.

82. A number of representatives expressed the view that information-sharing, an essential component of technology transfer, would play a fundamentally important role in the future protocol. Several of them stressed that the general sharing of information, which was voluntary, was additional to and different from the mandatory provision of information for the AIA procedure. The voluntary provision of information should not be a pretext for countries not to comply with AIA.

83. Several representatives stressed that the range of publicly available information to be shared should be as broad as possible, relating not only to transboundary movements but also to other information on LMOs, such as past approvals, prohibitions, development of new LMOs, releases into the environment and so on. Additionally, the secretariat of the protocol might also play a role, for example, in comparing national regulations and changes to them. Statistics should be provided to the secretariat, for example by the exporting countries, for onward distribution.

84. Elements suggested for inclusion in the information-sharing process were: data on national competent authorities and/or focal points; texts of consents given in response to notifications of intentional transboundary movement and the summary of the risk assessment included in the notification; unintentional transboundary movements likely to have adverse effects in another party on the conservation and sustainable use of biological diversity, taking also into account human health; products consisting of or containing LMOs which had received consent by a Party or Parties for placement on the market; decisions on safeguards; relevant information on national laws, regulations and guidelines; decisions on denials.

85. It was suggested by some representatives that States should report annually to the Conference of Parties through the Secretariat on such matters as amounts and categories of transborder movements of LMOs; information on measures adopted by them in implementation of the Convention; statistics on incidents affecting human health and the environment; accidental or unintended movements; and any other relevant information.

86. Several representatives said that the information should not necessarily be restricted to the parties to the protocol, but should also be available to all interested countries, organizations and the general public. That would facilitate informed decision-making, but at the same time there was a need for confidentiality to be respected, which might be achieved by having differing levels of access to the information.

87. On the question of how the information should be shared, several representatives felt that this should be based on existing mechanisms, rather than on something new. Others said that it might be the clearing-house mechanism already provided for in the Convention on Biological Diversity, open to the participation both of parties and of non-parties. Some representatives thought that the information exchange might also pass between focal points and competent authorities, others suggested a decentralized logical database with one or more central nodes, while others saw the information as being shared through the intermediary of whatever national bodies approved LMO introductions, or through scientific research institutes.

88. A group of countries requested the Secretariat to investigate the possibility of using the existing international information-sharing mechanism, the BIOBIN-UNEP Register (OECD/UNIDO/UNEP), as a core information-sharing mechanism within the framework of the protocol and submit a working paper on the subject to the Working Group at its next meeting.

89. On the question of who should generate the information, representatives said that it was not necessary to be specific in the protocol: information might be generated by the importer, the exporter or the user.

90. Some representatives thought that there should be a common format for certain information, such as that on decisions already made, in order to ensure comparability. These should also be a standard way to name LMOs in order to mask any actual names that were considered to be confidential. Other representatives felt that standardization could not be absolute, owing to variations in LMO and situations.

91. One representative, speaking on behalf of a regional economic integration organization and its member States, suggested that the Secretariat should submit a proposal for a standard format to the Conference of the Parties, while another suggested that a technical subcommittee should be set up to develop the format.

92. In the light of a clarification from the Chairman that there would need to be a definition of confidentiality, no representatives expressed opposition to the making of special provisions for information considered to be confidential. It was suggested that confidential information was likely to be the gene donor and the specification of the LMO, or the data needed for risk assessment. Some representatives supported confidentiality provisions as long as they were not used to undermine the making of an informed decision by the competent authority of the importing country, while another said that the protocol should stipulate that the importer had to protect such information.

93. One representative suggested that the Secretariat should draw up a paper on relevant issues for future discussion.

94. When discussing what additional functions the information-sharing mechanism might have, several representatives pointed out that, while the provision of names of organizations which could give advice was very feasible, it should not be the role of that mechanism actually to provide advice.

95. Several representatives supported the idea that the information-sharing mechanism should be linked to or draw on databases of existing organizations, while agreeing that such a linkage should not be explicitly stipulated in the protocol.

96. One representative said that it would be helpful for the Working Group

to have a better understanding of the way in which transfers of LMOs were currently taking place and the volume of those transfers, particularly those involving commodities. He therefore suggested that the Secretariat should be requested to prepare a report on relevant commodity-related issues for submission to the Working Group at its fourth meeting. In response to that suggestion, the Working Group agreed, on the proposal of the Chairman, to establish a small subgroup, to be chaired by Mr. David Gamble (New Zealand), to prepare precise terms of reference to guide the Secretariat in the preparation of the proposed report.

97. Many representatives agreed that the primary aim of capacity-building was to enhance countries' abilities to perform risk assessment and risk management. That aim would be much facilitated by information-sharing and by the clearing-house mechanism, and there were, indeed, many mechanisms already in existence through which capacity-building could be achieved.

98. One representative said that the primary aim of capacity-building was to enhance countries' ability to apply the provisions of the protocol. It was important to ensure, by means such as training, that each country had equivalent capacities, otherwise some might miss important opportunities or suffer grave consequences. One representative said that the primary aim of capacity-building was to ensure the development and implementation of national biosafety mechanisms which are harmonized with existing mechanisms.

99. A number of representatives stressed the importance of capacity-building, which was already reflected in decisions III/5 and III/20 of the Conference of the Parties to the Convention, which categorically stated that GEF funds be made available to developing countries for capacity-building. They requested the Secretariat to implement those decisions urgently.

100. It was said that the stipulations in the protocol on capacity-building should be couched in fairly general terms, as what was needed would vary from case to case.

101. There was support for the idea of capacity-building at regional level, but several representatives warned that that should not be at the expense of the national level.

102. One representative urged that financial assistance should be provided urgently so that capacity-building could be effective, while another said that, although everyone appeared to be in favour of capacity-building, the underlying message seemed to be that existing material resources would have to be spread thinner rather than new ones being provided.

103. The representative of a non-governmental organization pointed out that there was considerable expertise in risk assessment and management in the insurance sector.

104. The meeting also considered public awareness. Some representatives felt that since there was a whole Article in the Convention on Biological Diversity devoted to public awareness, there should be a similar one in the protocol. Others took the view that Article 13 of the Convention was broad enough to make a corresponding item in the protocol superfluous.

105. One representative felt that the mechanism was likely to be multi-facetted, and to include the clearing-house as well as regional and national systems, while another urged that the precise form of the mechanism should be left to individual countries.

106. Other representatives welcomed the release of information to the public, but cautioned that confidentiality would have to be respected. The representative of a non-governmental organization, recalling the catastrophe at Bhopal, said that the right of citizens to know what was happening to them took primacy over companies' rights to confidentiality.

107. It was felt that the responsibility for public awareness would be at national government level, with one delegation extending it to non-governmental organizations, and another placing it with the national competent authority. Some felt that, while promotion of public awareness was a domestic issue, consultation with other countries could well be helpful, whereas another said that promotion should be stipulated in the protocol.

108. The Chairman said that it was sometimes difficult to distinguish between public awareness and public participation, but that the latter should be understood as the right of the public to participate in decision-making processes.

109. The representative of a non-governmental organization expressed the view that public participation was actually the more important of the two. The public should have a right to influence anything affecting it.

110. Several representatives supported the inclusion in the protocol of a paragraph on public participation, hoping that it would encourage the participation of local communities and/or non-governmental organizations. Some representatives felt that the level of public participation should be defined by individual countries, but that the guidance of the Conference of

Parties might be sought at the international level.

111. One representative thought that public participation should be encouraged in the protocol but not specifically mandated, while another felt that it was so important that it should be specifically mandated. On the other hand, the items to be addressed by public participation, and the level at which it should occur, were national matters to be decided on a case-by-case basis and could not be covered in the protocol. One representative said that the level of public participation should be defined by a country's legal framework, while another said that it should be defined by its competent authority. Two others felt that the involvement of the public in matters such as environmental impact assessments was of crucial importance, while one representative said that public debate had proved to be essential to the acceptance of modified organisms. The representative of a non-governmental organization concurred that grass-roots participation was essential.

112. Some representatives thought that public awareness and public participation should be combined, as they were in Article 13 of the Convention on Biological Diversity.

113. The Chairman's summaries of draft elements relating to information-sharing/capacity-building/public awareness/participation were reviewed by the Working Group at the 9th and 10th session of the meeting, on 15 and 16 May. The Working Group agreed that the elements, as revised by members of the Working Group, should be included in the Chairman's summary-of-elements presentation, which is contained in annex II to the present report.

Risk assessment

114. The Working Group took up the question of risk assessment at its 7th•ession, on 14 May.

115. Most representatives who took the floor fully agreed that the protocol should contain provisions on risk assessment. Some others said that such provisions could be useful, one of them stating that a definitive opinion on the question would depend on the actual content of the provisions.

116. A number of representatives considered that the purpose of risk assessment was to provide a basis for decision-making either on transboundary movements of living modified organisms or for all purposes, one of them stating that risk assessment was an essential part of the Advance Informed

Agreement procedure. Another representative said that the purpose was to provide a basis for the safe transfer, handling and management of living modified organisms, while other views expressed were that it was a means of ensuring a minimum level of harmonization in decision-making, an important element for information-sharing, and a means of fulfilling the objectives of the protocol. One representative said that the risk assessment might not be the only basis upon which countries might make decisions concerning any transfer of LMOs. The risk assessment must also be relevant to the affected country and should address its environment and the socio-economic impacts on that country.

117. A number of representatives said that the provisions should consist of general principles placed in the body of the protocol, some of them stating that detailed provisions could be placed in an annex to the protocol. Another representative believed that the provisions should consist of both general principles and minimum standards, again with the details placed in an annex. Two others said that they should consist of minimum standards, leaving it to national Governments to decide on the specific legislation. Other representatives said that they should consist of all three: general principles, detailed provisions and minimum standards. One representative said that the provisions should be annexed to the protocol and not appear as an article.

118. Several representatives said that the provisions should be legally binding. Others said that they should be guidelines and one other said that they should serve as reference points. One representative reserved his opinion on the proposed legal status of the provisions in view the uncertainties surrounding the implications for countries that lacked capacity.

119. Some representatives were of the opinion that the basis of risk assessment should be up-to-date scientific knowledge. Others said it should be based on information obtained from the exporter, while another representative said that the basis should be information on the relevant organism and the receiving environment, adding that it was up to the exporter to provide the best possible risk assessment. A number of representatives stressed that it was also important to take into account of other factors during the assessment. Those included the intended use of the LMOs, doubts that might have already arisen concerning their use, socio-economic impact, and the need to weigh private benefits against possible adverse effects on human health and the receiving environment. One representative said that the risk assessment should not only be based on scientific data but also on possible socio-economic impacts to the affected country.

120. All representatives who spoke on the subject considered that the UNEP Technical Guidelines could be a useful source for the elaboration of provisions on risk assessment. Some representatives also referred to the national submissions before the Working Group as being another useful source.

121. Several representatives said that the responsibility for the risk assessment lay with the designated competent authority of the importing country, or any institution nominated by it. One representative said that the process could be facilitated by third parties with the capacity or by establishing regional centres of excellence. Some representatives considered that in the first instance both the State of export and the State of import had responsibility; it was then up to the State of import to analyse the assessment and take decisions based on the material received. Two others suggested that the exporting company or country had the first responsibility for the risk assessment, with the final decision being that of the competent authority in the importing country. Several representatives said that the responsibility for the risk assessment rested with the national competent authority of the exporting country. One representative said that the final responsibility for the risk assessment should rest with the exporting Party. One representative stated that the responsibility for risk assessment, including the financial responsibility lay with the competent authority of the exporting country.

122. The Chairman's summary of draft elements relating to risk assessment was reviewed by the Working Group at the 10th session of the meeting, on 16 May. The Working Group agreed that the elements, as revised by members of the Working Group, should be included in the Chairman's summary of elements, which is contained in annex II to the present report.

Risk management

123. The Working Group took up the question of risk management at its 8th meeting, on 15 May 1997.

124. Many representatives agreed on the need for provisions for risk management in the protocol. Such a provision was described as a valuable tool for making decisions on allowing or forbidding transboundary movement of LMOs and for controlling the related risks, and as affirming the sovereign right of a State to take the risk management measures which it considered appropriate when importing an LMO. It was also stated by some representatives that risk-management provisions would help discharge of responsibility and liability.

125. One representative said that such a provision was needed because there was a direct relationship between risk-management and AIA. Another said that allowance had to be made for the technical capacity for implementation in some countries.

126. One representative said that the provision should specifically create an obligation on the applicant to formulate risk-management strategies and measures that could be used by the importing country. Article 8 (g) of the Convention on Biological Diversity should not be taken as precluding that obligation, but there was no need to repeat the provisions of Article 8 (g) in the protocol. That view was supported by another representative.

127. Several representatives thought that Article 8 (g) was very relevant, and reinforced the need for a provision on risk management in the protocol. One representative described in Article 8 (g) as the international basis for handling transboundary movement risks, and pointed out that it was already legally binding. The representative of a non-governmental organization pointed out the additional relevance of Articles 8 (j) and 8 (k) of the Convention.

128. Many representatives agreed that the purpose of risk management was to provide the basis for decisions on transboundary movement. One representative said that it was to provide a basis to manage the likely effects of transboundary movement.

129. One representative thought that its purpose also encompassed information-sharing, since risk-management measures taken by a country were of interest to other countries also. Another representative suggested that an additional purpose was to provide a basis for liability and compensation matters.

130. Views were evenly divided on whether the provisions on risk management should be general principles, detailed provisions or minimum standards.

131. Some representatives thought that the provisions should be legally binding, while others took the opposing view.

132. Some representatives thought that the provision should be contained in an article in the protocol itself, while others that only general principles should be in the protocol itself with detailed guidelines in an annex. One representative said that the provisions might be in the protocol itself or in an annex, but that in either case they should be legally binding.

133. While some representatives thought that the sources should include the UNEP Guidelines, they also recommended that use should be made of any and all sources, such as government legislation, which could help the international community make a well-founded decision on risk-management matters.

134. The representative of a non-governmental organization pointed out that risks could best be managed by incentives such as were inherent in the liability and compensation regime.

135. Some representatives raised the question of who should be responsible for risk management. One representative thought it should be the competent authority of the importing country, while another said that the exporting and the importing countries shared the responsibility jointly.

136. The Chairman's summary of draft elements relating to risk-management was reviewed by the Working Group at the 10th session of the meeting, on 16 May. The Working Group agreed that the elements, as revised by members of the Working Group, should be included in the Chairman's summary of elements, which is contained in annex II to the present report.

Unintentional transboundary movement of LMOs (including accidents and emergency cases)

137. The Working Group took up the question of unintentional transboundary movement of LMOs at its 8th session, on 15 May 1997, in conjunction with its discussion on handling, transport, packaging, and transit requirements for transboundary movements of LMOs.

138. A number of representatives said that the issue of unintentional transboundary movements of LMOs should be covered by the protocol, one, however, cautioning that the concept of unintentional transboundary movement was a new one and could give rise to difficulties in determining its exact scope. Other representatives said that accidental movement was already covered in Article 14, paragraph (d), of the Convention and there was no need for the protocol to include a provision on unintentional transboundary movement, especially in view of the doubts as to whether such a provision could be implemented.

139. One representative stressed the need for capacity-building in the developing countries to guard against the risks of unintentional transboundary movements.

140. One representative called for two different procedures to be included, one for cases where the movement was the result of an accident or natural disasters and the other for cases of illegal activities. In the first case, the procedure would be triggered by the country in which the accident or natural disaster took place, while in the second case it would be triggered by the State suffering damage.

141. A number of representatives said that the procedure should be triggered by the first country detecting the unintentional movement.

142. Several representatives said that information on unintentional movements should be shared with other parties, particularly those in the immediate vicinity of an affected country and those where the LMO in question was originally developed.

143. The representative of a non-governmental organization pointed out that, in addition to the transboundary movement of the LMOs themselves, there could also be transboundary movements of their effects, such as impacts on agriculture.

144. The Chairman's summary of draft elements relating to unintentional transboundary movements of LMOs was reviewed by the Working Group at the 10th session of the meeting, on 16 May. The Working Group agreed that the elements, as revised by members of the Working Group, should be included in the Chairman's summary of elements, which is contained in annex II to the present report.

Handling, transport, packaging, and transit requirements for transboundary movements of LMOs

145. Many representatives said that handling, transport, packaging and transit requirements for transboundary movement in LMOs should be covered by the protocol. Some of those representatives stressed the importance of laying down strict requirements in order to prevent avoidable accidents and adverse effects, including effects in transit and other non-LMO-receiving States. One of those representatives suggested that the LMOs should be accompanied by a movement document for the start of transboundary movement to the point of use or release, but that the actual wording in the protocol should be of a general nature, with more detailed provisions to be developed by the Parties taking into account existing rules on the transport of dangerous goods. Another representative said that the detailed requirements could be spelt out in an annex to the protocol. Another representative said that the requirements should apply to both the importer and the exporter, the

responsibility of the former being to ensure that adequate facilities were on hand for handling the organisms on arrival. Another representative spoke of the need to include provisions on labelling under the same rubrique.

146. Another representative said that the requirements of the protocol should be as rigorous as those imposed in national legislation and that the precautionary principle should be applied to ensure the highest possible degree of safety. Another representative, however, said that the protocol provisions should not be prescriptive but should rather be aimed at encouraging all parties to observe appropriate safety considerations through the inclusion of the necessary arrangements in national legislation.

147. Other representatives stressed the importance of obtaining the consent of transit States before the movement started and to that end providing those States, whether or not a party to the protocol, with all the information available to the importing State. One representative said that greater thought should be given to the concept of transit, which might be dealt with more comprehensively in the protocol. The same representative noted that transit issues on LMOs may not be adequately covered in existing international instruments, while transport, packaging and handling were to some extent.

148. Some representatives noted that LMOs were not adequately covered by existing international agreements — the United Nations Recommendations on the Transport of Dangerous Goods, for example, covered only infectious organisms, while the World Health Organization Labour Safety Manual concerns only health-related effects. Another representative said that, while it was clear that not all issues regarding the carriage of LMOs were covered in existing international instruments, the United Nations Recommendations on the Transport of Dangerous Goods were the appropriate framework for coherent and non-duplicative action. Having suggested that the issue of LMOs be referred to the United Nations Committee of Experts on the Transport of Dangerous Goods, the representative said that the protocol should refer to the need for safe transport, and a specific request should be made to the relevant bodies as soon as possible. Another representative agreed that the recommendations of the Committee of Experts should be taken into account.

149. The Chairman's summary of draft elements relating to handling, transfer, packaging, and transit requirements for transboundary movements of LMOs was reviewed by the Working Group at the 10th session of the meeting, on 16 May. The Working Group agreed that the elements, as revised by members of the Working Group, should be included in the Chairman's summary of elements, which is contained in annex II to the present report.

Monitoring and compliance

150. At its 9th session, on 15 May, the Working Group took up the question of monitoring and compliance.

151. Addressing the element of monitoring, all representatives who took the floor agreed that there was a need for individual parties to report on the implementation of their commitments, one representative observing that that might be done on an annual basis and as concisely as possible.

152. Regarding what matters the reports should address, in addition to the operation of the AIA and notification procedures and adoption of national regulations, one representative suggested information on regulations, laws and institutions, the burden of the task on human resources, information on problems encountered and how they were overcome, public-awareness programmes and other relevant information.

153. On the question of how the reports should be processed, most representatives who took the floor favoured their referral to the Conference of Parties of the Convention on Biological Diversity, perhaps through the clearing-house mechanism.

154. Two representatives expressed the view that the procedure should not only cover monitoring of implementation of the protocol, but also monitoring of the behaviour of the LMO.

155. Regarding compliance, there was general agreement that the provisions of the protocol would be sufficiently normative in character to justify establishing a procedure for reviewing the implementation of commitments by individual parties. It was observed that Article 26 of the Convention on Biological Diversity was the basis for the compliance mechanism. One representative was of the view that since the protocol would establish its own compliance procedure, the procedures under other international legal instruments should not apply.

156. It was suggested that the type of procedure to be developed should be cooperative, conciliatory, advisory, rather than supervisory, and transparent rather than private, though with provision to protect confidential information from general circulation. It was generally agreed that the procedure should be non-judicial rather than judicial, one representative suggesting that judicial procedures should be limited to blatant cases of non-compliance, and another said that there should be a sufficient range

available to cover situations requiring judicial action when necessary.

157. There was no general consensus on how the process should be triggered, one representative suggesting that it was too early to decide at the present time.

158. There was general agreement that the process should operate through a standing body established by the Conference of Parties of the Convention on Biological Diversity, one representative mentioning that geographical distribution should be taken into account. Another representative considered that it was too early to decide on that element.

159. The objective of the compliance process was generally seen as friendly settlement of differences and therefore a means to prevent disputes and also provision of practical guidance to parties in difficulty. There was also some support for the objective of obtaining formal findings of non-compliance.

160. The Chairman's summary of draft elements relating to monitoring and compliance was reviewed by the Working Group at the 10th session of the meeting, on 16 May. The Working Group agreed that the elements, as revised by members of the Working Group, should be included in the Chairman's summary of elements, which is contained in annex II to the present report.

Definitions

161. At its 4th session, on 13 May 1997, the Working Group agreed to the establishment of an open-ended contact group, to meet simultaneously with the plenary, with the mandate to review what was available in the field of definitions and to recommend what could be done with the material on hand. Neither the contact group nor the plenary would attempt any definitions at the present meeting, but would recommend preparation of an appropriate consolidated document for presentation to the Working Group's third meeting. The contact group was co-chaired by Dr. Gert Willemse, nominated by the Group of 77, and Dr. Helen Marquard nominated by the other delegations.

162. At the 7th session of the meeting, Dr. Willemse, co-Chairman of the contact group, reported that the group recommended that the material on definition that had thus far been submitted by Governments should be listed alphabetically by the Secretariat in order to have the material in a systematic form. The group stressed that the terms appearing on the list would not necessarily mean that they would need to be defined in the protocol and that any definitions would need to be developed to reflect their use in

the protocol and the context in which they appear. The group also observed that the current list was neither complete nor exhaustive and that States that had not yet provided terms for definition could do so as the process developed.

163. The group discussed the possibility and/or need for identifying "Key terms" within this list but concluded that: (a) these terms did not necessarily require definitions; (b) if they were to be defined, they would require broader input; and (c) the task went beyond the group's mandate.

164. The Working Group, while taking note of the report of the contact group, agreed that the task of preparing the proposed alphabetical list should be included in the work programme of the Secretariat in preparation for the Working Group's next meeting.

III. FUTURE WORK OF THE WORKING GROUP

Review of items addressed by country submissions

165. At the 9th session, the Working Group considered the Chairman's review of items which had been addressed by country submissions, to determine what should be done to prepare for the next meeting.

166. It was noted that nothing had been done on the items "Title", "Preamble", "Scope of the protocol" and agreed that nothing should be. prepared in this respect for the next meeting. The same applied to the item "Objectives" and the same decision was taken with regard to this item.

167. Regarding "Definitions", the meeting recalled that it had already decided on the Secretariat action in that regard.

168. Regarding the items "AIA including scope of/criteria for use of AIA as well as notification procedures", "risk assessment and management including minimum national standards", "unintentional transboundary movements (including accidents and emergency cases)", "handling, transportation, packaging and transit requirements", "competent authority(s)/focal point(s)", and the three closely related items of "information-sharing and clearing house", "capacity building", "public awareness/public participation", the Working Group agreed that Governments should be invited to propose by 1 August 1997 legal texts (draft article or articles) dealing with those subjects for discussion at the next meeting. Governments that had already submitted legal texts would be requested to submit them again, reviewing

their earlier submission if they considered it necessary. Related annexes should also be submitted or resubmitted in accordance with this procedure. These draft articles and related annexes would replace any submissions concerning the items referred to. The existing submissions would therefore be considered to be obsolete.

169. Following remarks from several representatives, the Chairman said that draft articles could also be submitted by Governments on the issues of liability and compensation on the one hand, and of socio-economic considerations on the other, even though those items had not been discussed at the current meeting.

170. In response to a question from one representative, the Chairman clarified that submissions which appeared in neither category, because they had been received very late, should be introduced at the next meeting, urging representatives to do so in relation to other items on that meeting's agenda.

171. The meeting agreed that the Secretariat should develop draft articles on the items "financial issues" and "institutional framework", including different options if appropriate.

172. The Secretariat should also develop draft articles on "jurisdictional scope", "relationship with other international agreements", and "settlement of disputes", including different options if appropriate.

173. Furthermore, the Secretariat should develop draft articles on the items "final clauses", including the item "review". Those draft articles could also provide options as appropriate.

174. While the Working Group had considered the items of "monitoring and compliance", it was agreed that it was premature to draft any articles on this item for the next meeting. "Illegal traffic" was somewhat related to "monitoring and compliance" and should therefore be regarded in the same manner.

175. The Working Group also agreed that it was premature to prepare the items of "non-discrimination" and "non-parties".

176. The item "general obligations and/or principles" would be retained but would be addressed only at a later stage.

177. The items "socio-economic considerations" and "liability and compensation" should be discussed at the next meeting on the basis of the legal texts submitted by Governments before 1 August 1997, as well as the

present report and draft elements contained in annex II below.

178. The Chairman stated that any government submissions relating to elements that had not been discussed at the current meeting would be retained for discussion at the next.

179. In response to a question from another representative, the Chairman clarified that the invitation to Governments to submit draft articles did not imply that any particular item would, in fact, appear as an article in the protocol.

180. One representative, speaking on behalf of the Group of 77 and China, said that countries were of the opinion the liability and compensation should be a priority item on the agenda of the next meeting of the Working Group. One representative, speaking on behalf of a regional economic integration organization and its member States, was of the opinion that a priority item on the agenda of the next meeting should be those items for which element papers had been developed.

181. The Chairman announced that the deadline for Governments to submit proposals to the Secretariat would be 1 August 1997. Any submissions received after that date would not be included in the compilation to be prepared by the Secretariat.

Future studies

182. At the 5th session of the meeting, on 14 May, one representative said that it would be helpful for the Working Group to have a better understanding of the way in which transfers of LMOs were currently taking place and the volume of those transfers, particularly those involving commodities. He therefore suggested that the Secretariat should be requested to prepare a report on relevant commodity-related issues for submission to the Working Group at its fourth meeting. In response to that suggestion, the Working Group agreed, on the proposal of the Chairman, to establish a small contact group, to be chaired by Mr. David Gamble (New Zealand), to prepare precise terms of reference to guide the Secretariat in the preparation of the proposed report.

183. At the same session, one representative, speaking on behalf of the Group of 77 and China said that it would be useful for the Working Group to have a better understanding of the socio-economic impacts of the transfer of LMOs and, to that end, proposed that the Secretariat be requested to prepare a series of five studies on: (a) socio-economic implications of

biotechnology and how they can be approached by a biosafety protocol; (b)•he impact of LMOs on agrobiodiversity and how a protocol can respond to such an impact; (c) the impact of LMOs on fisheries and aquatic life and how the protocol can manage such risks; (d) the impact of biotechnology on indigenous and farming communities who are regarded by the Convention on Biological Diversity as central to the conservation and sustainable use of biological diversity.

184. At the 7th session of the meeting, on 14 May, the Chairman of the contact group reported that the group had observed that a study on relevant commodity-related issues would be helpful to define the range of such LMO commodity transactions. Data should be available from various sources, such as Governments and institutions, for example OECD, including statistical information on trade flows, as well as more qualitative information on the numbers and types of transactions already taking place. The study could cover, inter alia, information on the range of LMOs moving both into field trials and for commercial applications. The suggested focus should be on the agricultural sector, where the greatest volume and range could be found. The study could also cover movements as LMOs became substituted in commodity flows over time. The contact group therefore recommended that, in the light of issues related to the development of procedures under the protocol related to transboundary movement of LMOs that eventually would become commodities, particularly the growth and diversification of trade in LMOs, the Working Group should request the Secretariat to prepare for submission at the October meeting a study on current and potential movements of LMOs that eventually would become commodities, in particular in the agricultural sector including transactions involving field testing and commercial movements, and should ask Governments and other institutions to submit information relevant to this study.

185. At the 9th session of the meeting, on 15 May 1997, the sponsor of the proposal announced that, in view of the burden the commodity-related and other studies would impose on the Secretariat, his delegation was modifying its proposal and would instead try to arrange an informal discussion on the subject at or before the fourth meeting of the Working Group, in October 1997. He expressed the hope that such a discussion would allow much useful information to be provided, and he believed that a similar discussion on socio-economic matters would also be beneficial.

186. At the 9th session, the sponsor withdrew his proposal for a study on criteria for confidential information (see para. 93 above). The work programme envisaged for the Secretariat before the next session was large, and too many additional studies would be overwhelming.

187. Also at the 9th session, one representative, speaking on behalf of a regional group, proposed that a study should be undertaken on the possibility of meeting complementary use of existing international, UNEP, UNIDO and OECD information-sharing systems as a basis for information-sharing mechanisms under the Protocol and to present the study at the next meeting of the Working Group. The meeting accepted the proposal.

188. At the 9th meeting of the session, on 15 May, one representative, speaking on behalf of the Group of 77 and China, requested that in the light of the importance of socio-economic considerations, the Secretariat should be mandated to carry out a study into such issues, and should be requested to present its findings at the next meeting.

189. One representative wondered how it would be possible to submit draft articles on socio-economic issues, as authorized by the Chairman, in advance of the results of the study called for by the Group of 77 and China.

190. At the 10th session, on 16 May, the representative of the Group of 77 and China, said that, having realized the heavy load being placed on the Secretariat of the CBD and in the spirit of give and take, the Group of 77 and China have decided reluctantly to withdraw the request for the five studies. However, the Group of 77 and China were requesting the Secretariat it have made earlier in the meeting to facilitate an informal round-table discussion on socio-economic considerations during the third meeting of Working Group, in Montreal in October 1997. The round-table discussion should be in the agenda of the meeting and should allow for translation.

IV. DATES AND VENUE OF THE THIRD MEETING OF THE OPEN-ENDED AD HOC WORKING GROUP

191. At the 10th session of the meeting, on 16 May, the Working Group agreed that its third meeting would be held in Montreal from 13 to 17 October 1997.

192. It further agreed provisionally that its fourth meeting would be held in the last week of February 1998.

V. OTHER MATTERS

193. At the 10th meeting of the session, on 16 May, the representative of the Group of 77 and China drew attention to the fact that less than 60 developing countries were represented at the current meeting. That meant

that more than half of the members of the group had not been able to attend. The Group of 77 and China were extremely concerned at the low level of participation by developing countries in a process that was expected to have a critical impact on such countries, and reiterated their request to the Secretariat to exert all effort to obtain funding for maximal participation in subsequent meeting. The Group of 77 and China again appealed to its partners in the process to do their part in facilitating universal participation.

194. At the same meeting, one representative speaking on behalf of the European Community and its member States, said that the Community and its members were working to meet that concern. The European Community and its member States had already provided significant financial contributions, with a view to facilitating in any case the participation in the present meeting of small island developing States and of the least developed countries. They were willing to complement those contributions in particular in view of the October meeting. Moreover, they were also considering how to extend that support to a broader range of countries. The Community and its member States called upon all contributors to make their contributions available in the speediest way, and if possible at least two months in advance of the meeting they were supporting.

195. Also at the 10th session, one representative, speaking on behalf of the Group of 77 and China expressed her gratitude to the Secretariat for its efforts in the past to afford countries and groupings every opportunity to prepare in an adequate and timely manner for meetings of the Ad Hoc Working Group. In view of the logistical difficulties resulting from geographical distribution, however, the Group of 77 and China experienced the need to be afforded an opportunity to conduct a preparatory meeting prior to the next meeting of the Working Group. She therefore called upon the Secretariat to provide and include in the programme for the next meeting of the Working Group, preferably on 12 October 1997, a day for a regional group meeting. She also trusted that the Secretariat would be able to ensure sufficient means to enable maximum participation at the meeting.

VI. ADOPTION OF THE REPORT

196. The Working Group adopted the present report at the 10th session of the meeting, on 16 May 1997, on the basis of the draft report circulated under the symbol UNEP/CBD/BSWG/2/L.1 and Add. 1-3.

VII. CLOSURE OF THE MEETING

197. The Chairman declared the meeting closed at 1.30 p.m. on Friday, 16•ay 1997.

Annex I

CHAIRMAN• REVIEW OF ITEMS WHICH HAVE BEEN ADDRESSED BY COUNTRY SUBMISSIONS

A. Title

Preamble

Definitions

B. Objectives

Scope of Protocol

C. AIA including scope of/criteria for use of AIA + notification procedures (including bilateral/multilateral agreements) (CBD)*

Risk assessment (+ management) including mechanisms and minimum national standards (CBD)

Unintentional transboundary movements (including accidental and emergency cases)

Handling, transportation., packaging and transit requirements
Competent authority(ies)/focal point(s)

D. Information-sharing and clearing-house (Confidentiality) (CBD)

Capacity-building (CBD)

Public awareness/public participation (CBD)

E. Financial issues (CBD)

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* Reference to CBD at the end of an item indicates that there are articles within the Convention dealing with the subject, or some aspects of the subject.

Institutional framework (CBD)

F. Monitoring and compliance

Illegal traffic

G. Non-parties

Non-discrimination

H. General obligations (and/or principles)

I. Socio-economic considerations

Liability and compensation (CBD)

J. Jurisdictional scope (CBD)

Relationship with other international agreements (CBD)

Settlement of disputes (CBD)

Review

K. Final clauses (CBD)

L. Annexes

Annex II

CHAIRMAN'S SUMMARY OF ELEMENTS PRESENTED

Introduction

On the basis of his review of items which had been addressed by submissions of participants, the Chairman tabled conference room papers or aide-m•oires raising specific questions on which the views of the delegates were sought. These views were compiled by the Chairman, and representatives were given an opportunity to add elements that had been proposed or to suggest modifications. It was decided to annex to the revised Chairman's summary of draft elements to the report. It was agreed that these revised summaries should not be treated as negotiated documents and that they in no way created prescriptive framework for negotiations.

ITEM A: PROCEDURES IN THE CASE OF SPECIFIC TRANSFER OF LMOs

TOPIC: Modalities of the procedure(s)

Elements

NOTIFICATION

1. The exporter (undefined) triggers the procedure and notifies the national competent authority in the importing country/national focal points.

2. The exporter, be it a government body, a company, university, or an agent of the exporter in the importing country, may apply to transfer LMOs. Notification is submitted to the national competent authority/national focal points.

3. The Government of the exporting country is responsible for triggering the procedure and notifying the national competent authority/national focal points in the importing country.

4. The Protocol may require that the procedure be triggered by a Government, however, it does not preclude the right of private enterprises to apply to the national competent authority/national focal points of the exporting country.

5. The procedure may be initiated by either the importer or the exporter,

whichever the case may be. However, notification is submitted to the national competent authority/national focal points in the importing country.

6. Intentional transboundary movement could be covered by two types of provision: information supply to the receivers and notification to the competent authorities.

7. There are two possible options for the notifications: Advanced Informed Agreement procedure and simple notification procedure (simultaneous notification).

INFORMATION THAT MAY BE REQUIRED

8. The State of export shall supply or shall require, or the State of import shall require, the exporter to supply through the channel of the competent authority of the State of export the following information to the competent authority of the State of import, prior to the first intended transfer of LMOs:

9. The State of export shall supply or shall require the exporter to supply the following information to the competent authority of the State of import, prior to the first intended transfer of LMOs:

(a) Name and address of agency/body/person intending/proposing to transfer, etc.;

(b) Name and address of intended user;

(c) Origin, name and taxonomic status of recipient and donor organisms;

(d) Full description of all traits introduced or modified and characteristics of the organism, including prescribed and desired ecological and other parameters;

(e) Purpose of the genetic modification;

(f) Process of genetic modification being applied to recipient and donor organisms;

(g) The results of a risk assessment carried out by the exporting country, including a summary of risks to human health and the environment, including the environment of the affected country and the risk management

measures applicable in respect of the affected country;

(h) Results of testing under real conditions, with growing plants and living soil organisms, in different soil types and under different water conditions, prior to the release of the LMO;

(i) A copy of the risk assessment and risk management report undertaken by the country/person in respect of the affected country;

(j) Intended dates of transfer/movement/release/activity;

(k) Number of organisms to be transferred or volume of culture and physical state;

(l) Any relevant requirements to ensure safe handling, storage, subsequent transport and use;

(m) Methods for safe disposal and suitable procedures in case of accidents;

(n) Intended use of the transfer, etc., and intended use of the organism, including possible products derived therefrom, including ecological conditions and socio-economic impacts;

(o) Intended location of the release or activity;

(p) Information on relevant previous releases and the impacts on the environment and human health of such releases;

(q) Information on experimentation, field trials, status at the home of origin of the LMOs;

(r) Information on the relevant regulation concerning safe transfer, handling and use of the LMO in the country/person intending/proposing to transfer, etc.;

(s) Information on the use of the LMO that has been prohibited in another country;

(t) Conditions of real containment in the case of contained use, such as closed laboratories, inactivation of waste water, sludge, used air etc.;

(u) The applicable laws, procedures and guidelines of the country

intending the transfer, etc., of the LMO;

(v) Reception and response by the people and stakeholders in biodiversity conservation in the country of origin, the country where field test conducted, and the country where released;

(w) Any differences in the environment of the exporting country and the environment into which the organism is intended to be released;

(x) In the case of a simple notification procedure, parties should also be free to decide that such notifications do not need to pass through a (public sector) competent authority/focal point, but that the relevant institution could be, for example, the (private) company receiving the LMO, with or without informing the competent authority;

(y) The necessary confidentiality should be ensured;

(z) Look to the UNEP International Technical Guidelines for Safety in Biotechnology and other potentially relevant existing guidelines for guidance on the type of information to be provided;

(aa) Information on relevant previous notifications and decisions.

PERIOD OF TIME

10. There should be a time-limit for a response by importing country depending on the type of procedure that is to be applied.

11. There should be no time-limit for a response by the importing country.

12. The competent authority in the State of import shall be obliged to respond to the State of export within 90 days. A response may consist of either:

(a) Explicit consent to import;

(b) Not consent to (or prohibit) import; or

(c) Consent to import only under specified conditions;

or

(d) An interim response, that may contain a statement consenting to import with or without specified conditions or prohibiting import during the interim period, which may include, for example, a statement that a final decision is under consideration and/or a request for further information.

13. A importing country• failure to respond within prescribed time must not be interpreted as implied consent.

14. Account should be taken of importing countries capacity to digest information provided and ability to respond within prescribed time.

15. In cases where the State of import considers that the documentation provided by the State of export is not sufficient in order to determine the adverse effects of an LMO, the burden of proof lies with the State of export.

16. If at any time before, during or after the transboundary transfer, the State of export/import becomes aware of relevant new information on the LMO in question, which could have significant consequences for the associated risks, the competent authorities of the States concerned shall be informed within 30 days and the terms of the Advance Informed Agreement may be changed accordingly.

17. The importing countries should acknowledge promptly receipt of a notification from the exporter to transfer LMOs.

18. Time periods may be prolonged if the competent authority is waiting for further information it has requested.

REVIEW

19. A review may be initiated by the importing country in case sufficient scientific information becomes available to warrant such an action. Such a review could be undertaken unilaterally by the importing country or jointly with the exporting country.

20. A Government should have the option to review a decision whether its initial response was either positive or negative.

21. Interested parties and neighbouring countries sharing a unitary ecosystems with the importing country [has] [should be given] the right of consultation with the importing country.

22. The Protocol may include an expert panel to assist countries in their

review mechanisms.

TOPIC: For which cases should the procedure(s) apply

Elements

NO EXCEPTIONS/DEVIATIONS

23. Explicit consent shall apply to all LMOs including, but not limited to, those LMOs which have been deregulated in the country, those intended for research, field trial, as well as those to be kept in containment/contained use and in transit.

24. Explicit consent shall apply to transboundary movement of all LMOs. These procedures apply to initial and subsequent shipments of LMOs and no distinction in procedure shall be allowed for the different types/kinds of intended use of LMOs.

25. All initial exports of a specific LMO shall be subject to the AIA procedure requiring explicit consent from the State of import.

EXCEPTIONS/DEVIATIONS

26. A notification procedure shall be applied for subsequent exports, requiring implicit consent from the State of import.

27. Simpler AIA procedures shall apply to LMOs that do not reproduce and/or do not integrate in the natural environment

28. AIA procedures shall not apply to the transboundary movement of low-risk LMOs.

29. Without prejudice to the overall scope of the protocol, the consent procedure should not apply to transboundary movement of LMOs destined for subsequent contained use and transit of LMOs.

30. Exemptions for certain categories of LMOs for certain products consisting of or containing LMOs (possibly medicinal products could be considered in this respect).

31. Contracting Parties shall have the right to exempt certain LMOs for

which there is established evidence that there is no associated risk with their release and use. This can be done within a bilateral agreement, multilateral or regional agreements or a unilateral declaration.

32. Contracting Parties may wish to apply different and more simplified procedures shall apply to LMOs intended for research and development (R•nd•) purposes.

33. LMOs appearing on a negative list shall require an explicit consent, while implicit consent shall apply to LMOs appearing on a positive list. These lists must be thoroughly crafted based on scientific evidence and shall be revised periodically to allow the deletion and/or addition of LMOs.

34. The creation of negative and positive lists for the classification of LMOs may either be included as part of the core text or the annex of the protocol.

35. AIA procedures shall not apply to the transboundary movement of LMOs that have no adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

36. There shall be no exceptions to the AIA procedure for any transboundary movements of LMOs.

37. There must be a basic minimum standard of procedure and information from which Parties must not derogate from after receiving notification of shipment. The Protocol should allow maximum flexibility which permits unilateral or bilateral deviation from general procedure.

38. The protocol should not contain provision that allows for unilateral or bilateral deviation from general and/or simplified procedure.

SPECIFIC CASES

39. LMOs banned in exporting/producer country may have different effects in importing country and therefore should not be generally banned.

40. There must be full and frank disclosure of information about LMOs which have been banned in exporting countries.

41. Transfer of LMOs banned by other international conventions/agreements must be covered by the Protocol, as Parties to those agreements may not be

Parties to the Convention on Biological Diversity.

42. Transfer of LMOs covered by other agreements should be governed by those agreements.

43. There should not been an obligation on exporting countries to supply information about LMOs that are banned in their countries but if importing countries request such information, they have a right to obtain it.

44. Consideration should be given to LMOs for which approval has not been sought, or the approval process has not been completed in the exporting country.

45. The AIA procedure should cover:

(a) LMOs that are intended for field testing in the country of import;

(b) LMOs that are intended for first growth in the country of import.

46. Criteria to determine whether LMOS would be subject to AIA that could be considered are:

(a) Importation to a centre of origin or diversity of the unmodified organisms;

(b) If the LMO is known to be pathogenic, infective, invasive, and cases where there is insufficient knowledge to determine if the LMO is in any of those categories.

TOPIC: Simplified procedure

Elements

47. The Protocol shall allow a single, explicit, and standardized procedure for all transboundary movement of LMOs.

48. The AIA procedure shall cover:

(a) LMOs that have been refused approval in the exporting country because of potential negative impacts on biological diversity;

(b) LMOs for which approval is being sought in the exporting country but for which approval has not yet been granted;

(c) LMOs for which approval would have required in the exporting but for which approval has not been sought in the exporting country because the LMO was not intended for commercialization or growth in the exporting country.

49. The Protocol may permit countries to eliminate application of AIA procedures should they so wish. This, however, should be voluntary and non-discriminatory.

50. The Protocol should allow the importing country to choose whether explicit consent is applicable, or a notification process suffices, particularly for subsequent shipments of LMOs.

TOPIC: Consent

Elements

51. The protocol should contain a general provision pertaining to voluntary cooperation agreements that would provide that parties may agree to eliminate the need to apply AIA procedures with regard to imports and exports between them.

52. The protocol should contain a general provision that provides that any party may indicate that it does not wish the AIA procedure to apply to it as an importing party.

53. Following any advance notification, the importing country• competent authority must respond within a specified time, after which consent would be deemed to have been given.

54. Following any advance notification, the importing country• competent authority must respond within a specified time. Delay in responding should not be deemed as a violation of the protocol, nor should it be considered a positive response.

55. It has to be further examined in which cases and under what circumstances explicit and implicit consent is required.

56. All initial transboundary movement of LMOs covered by the Protocol

shall be subject to the AIA procedure.

57. Explicit consent is a requirement for shipments of all LMOs.

58. Explicit consent is a requirement for initial shipment of all LMOs. For subsequent shipments of the same LMOs, implicit consent may apply.

59. Explicit consent is a requirement for shipments of LMOs. The importing country must respond within a specific time.

60. Explicit consent is a requirement for shipments of LMOs. Delay in responding to requests/applications should not be deemed as a violation of the protocol, nor should it be considered a positive response.

61. Explicit consent is a requirement for shipments of LMOs. Lack of response within a specific/specified time should not be deemed as an implicit consent.

62. To avoid superfluous notifications, it should be provided that a single notification as well as a consent given in response to a notification may cover several similar transboundary movements to the same party of import.

63. Implicit consent should apply to low-risk LMOs.

64. Expedient and simpler explicit consent procedures should apply to the transfer of low-risk LMOs.

65. Expedient and simpler explicit consent procedures should apply to transfer of subsequent shipments of LMOs.

66. Explicit consent should be reflected in the Protocol. However, countries may enter into bilateral agreements allowing for implicit consent.

67. Explicit consent should be a requirement for initial shipment of LMOs. Subsequent shipments of LMOs may be allowed under the same consent with simpler notification requirements. Such consent may be withdrawn if new scientific evidence or change circumstances make it necessary.

68. Certain LMOs may be exempt from provisions of the AIA by importing countries either by means of bilateral, multilateral or regional arrangements, if it has been established that such LMOs are of low risk or in the case of mutually agreed terms, for example, mutually recognized risk-assessment procedures.

69. The procedure whether explicit or implicit must be consistent with the provisions of the World Trade Organization.

70. A positive or negative list of LMOs approach should be adopted in determining coverage of LMOs under AIA.

71. Following any advance notification, the importing country• competent authority would determine the appropriate procedure based on national requirements.

72. Explicit consent procedures shall apply to LMOs intended for commercial use.

73. AIA procedures may be replaced by simple notification procedures for LMOs intended for research purposes.

74. Explicit consent shall apply to initial shipments of LMOs. Implicit consent shall apply to transboundary movement of subsequent shipments of LMOs unless there are changes in their intended use or risk-assessment tests revealed additional information which was not available at the time of granting the initial consent.

75. While explicit consent applies to all shipments of all types of LMOs, the national competent authorities may wish to exempt certain LMOs from this procedure based on national requirements.

76. LMOs which have been prohibited in exporting country must not be exporting without providing all relevant information of such prohibition should/must be made available to importing State and/or through a clearing-house mechanism (CHM).

77. There is no need for a simplified procedure.

ITEM B: COMPETENT AUTHORITY(S)/FOCAL POINT(S)

TOPIC: Modalities for competent authority(s)/focal point(s)

Elements

NOMINATION

1. Countries may wish to designate one or more focal point and/or national competent authority.

2. Countries designate one national competent authority and/or focal point.

3. The Secretariat should be informed about the designation of competent authority and/or focal points.

4. Regional focal points is optional depending on definition of •egion".
5. An international network of focal points is preferable and more effective than regional focal points.

6. Regional focal point is optional.

7. Regional focal points may be based on commonality of the environment in a particular region.

8. There should preferably be one focal point per country, acting as a contact point.

TIME OF DESIGNATION

9. Designated national competent authority/focal point should be nominated as soon as possible.

10. Designated national competent authority/focal point should be nominated prior to entry into force of the Protocol for that Party.

11. Designated national competent authority/focal point should be nominated within ninety days from date of ratification of the Protocol.

12. Designated national competent authority/focal point should be nominated depending on the capacity of the respective country.

13. The designation of the Authority in Charge (in contrast to focal point and/or competent authority) shall take place as soon as possible.

RESPONSIBILITIES OF COMPETENT AUTHORITY(S)/FOCAL POINT(S)

14. Each country shall have the right to define the responsibilities of its designated national competent authority(s)/focal point(s) based on its national circumstances and requirements.

15. Responsibilities of the designated national competent authority(s)/focal point(s) shall include but are not limited to the following:

(a) To receive notifications;

(b) To transmit information to other Parties and/or Secretariat and notifiers;

(c) To evaluate risk assessment;

(d) To take decisions about notifications under AIA;

(e) To transmit decisions on AIA to notify for competent authorities, enforcement;

(f) To serve as the focal point for handling inquiries and proposals regarding any intended transfer/transboundary movement/release which affects its country or any activity undertaken within its national boundaries of LMOs;

(g) To establish and impose such conditions as it deems appropriate regarding the transfer in order to protect its environment and human health;

(h) To undertake its own risk assessment and give its own risk management decisions;

(i) To be informed immediately in the event of an adverse effect of the transfer of the LMOs which could affect it.

16. For a national competent authority which lacks capacity to undertake fully its responsibilities related to the Protocol, financial and technical assistance are essential to upgrade its infrastructure and human resource to deal with the issues at hand.

ITEM C: INFORMATION-SHARING

INFORMATION-SHARING

General

1. The protocol should provide a clause for information-sharing.

2. The concept of information-sharing is separate from, and in addition to, the requirement for providing information under AIA procedures.

3. In accordance with Article 17 of the Convention on Biological Diversity, parties are obliged to exchange information relevant to the conservation and sustainable use of biological diversity. Such an information-sharing should preferably operate through a database and also Internet.

Between parties

4. Information-sharing should draw from/use/be linked to existing international information systems.

5. The protocol may call for the establishment of an international scientific body to register and compile information related to LMOs.

6. Information related to LMOs should not be restricted to parties, but should be accessible to the general public to the maximum extent possible including qualities of different types of LMOs, safety and risk assessment results.

7. Exchange of information should be implemented through the national focal point(s)/national competent authority(s).

8. Examples of relevant information that could be shared includes the following:

(a) Information relevant to proper risk assessment and risk management;

(b) Information on accidental/unintentional movement of LMOs that have adverse impact on the environment/human health;

(c) Information on LMOs and/or products containing or consisting of LMOs released on the market;

(d) Information on national legislation in countries;

(e) Information regarding transboundary movement of LMOs;

(f) The amount of LMOs exported, category, characteristics, states of import, etc.;

(g) Information on the measures adopted by parties in implementation, including laws and regulations;

(h) Information on available statistics on the effects on human health and the environment;

(i) Information on decisions taken by countries in relation to movement of LMOs;

(j) Information on code(s) of practice and guidelines related to the transboundary movement of LMOs;

(k) Information on the implementation of the AIA including simplified procedures and bilateral, multilateral and regional agreements;

(l) Information on domestic release of LMOs;

(m) Information on prohibited, approved and newly developed LMOs;

(n) Information on monitoring post-commercial release of LMOs;

(o) List of experts and training workshops/programmes;

(p) List of advisory bodies.

9. The protocol should address the need to validate the information provided, as well as any changes/updates made to it.

Clearing-house

10. The Protocol should call for the establishment of a special clearing-house mechanism to be used for information-sharing purposes related to LMOs.

11. Parties shall provide information to the CBD Secretariat/clearing-house mechanism/central international database to be shared by other Parties/general public.

12. The protocol should preferably not call for the formation of a new clearing-house mechanism, but rather to the extent possible use the existing CBD clearing-house mechanism, depending on its function.

13. The protocol shall provide a clause for the establishment of a separate entity to handle and disseminate information relevant to LMOs to parties/the general public.

14. The central database should only provide information related to LMOs.

15. The clearing-house should not have an advisory role.

16. The central database should be designed to allow the general public accessibility to information as appropriate. However, input of data is restricted to certain entities.

17. Information-sharing mechanism should be flexible to accommodate present and future needs.

18. A distinction should be drawn to the difference between a clearing-house mechanism and a central database system.

19. Information may be generated by parties, research centres, media, exporters, importers, suppliers, enterprises, users of LMOs, NGOs and local community. Information should be channelled through the national competent authority(s)/national focal point(s).

Confidentiality

20. Information-sharing provisions should allow for the protection of confidential data and proprietary rights relative to information-sharing.

21. Confidentiality provisions should not be excessive or broad so as to hinder information-sharing amongst parties/undermine the ability of the national competent authority(s) to take informed decisions.

22. The protocol needs to clearly define "confidentiality".

23. Confidentiality provisions should be seen in the context of the need to disclose information to the public, as appropriate.

Common format

24. A standardized format/template should be created for the input of information to facilitate comparability.

25. A common format should be developed for entry of data, however, the format should be flexible to accommodate the difference in countries, types of LMOs, nature of information, etc.

26. The common format for data input should be so designed to observe confidentiality of information, whenever applicable.

27. A common format for data input shall be designed by a technical committee.

ITEM D: CAPACITY-BUILDING

1. The aim of capacity-building includes:

(a) Strengthening the capabilities of all to implement the protocol;

(b) Facilitating the elaboration of national legislation related to biosafety;

(c) Permitting the competent authority to make informed decisions on risk assessment;

(d) Promoting the establishment of appropriate institutional mechanisms within all Parties to ensure compliance with biosafety regulations.

2. The capacity-building mechanism should, among other activities, provide advice and names of organizations that could provide advice.

3. Information required for capacity-building shall be contained within a central database. Such a database should be easily accessible and training would be provided to facilitate interpretation and use of the information in the database.

4. Capacity-building could operate at both the regional and national level. However, capacity-building at the regional level should not be to the exclusion or detriment of capacity-building at the national level.

5. As most developing countries are engaged in a process of capacity-building for the management of safety in biotechnology and, in many cases, are initiating such a process, it is important that the protocol should take this aspect into account and urge these countries and international organizations with relevant experience to lend support and cooperation for its development and strengthening, to allow proper risk assessment and management. Decisions III/5 and III/20 of the Conference of the Parties to the Convention on Biological Diversity categorically state that GEF funds should be made available to developing countries for capacity-building.

6. Capacity-building in the form of information exchange, the institutional framework for biosafety, training, education and institutional capacities, are essential for the effective functioning of the Protocol. Required activities for capacity-building are properly addressed in the general framework of the Convention on Biological Diversity and through programmes and activities under international organizations such as UNEP and UNIDO, and therefore, the protocol should refer to the need for and importance of capacity-building but should not contain specific provisions for this purpose.

7. Each Party shall strengthen and/or develop human resources and institutional capacities in order to facilitate an effective implementation of the protocol. Such capacity-building shall aim to ensure:

(a) That Parties develop and strengthen their capacities to implement this Protocol;

(b) That national legislation related to biosafety is developed;

(c) That States involved in the transfer, handling and use of LMOs are aware of any associated risks and have the means to assess and manage the risks;

(d) That States are able to achieve safety when certain LMOs are transferred into and/or to be used in their territories.

8. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and biosafety.

9. The Secretariat, in collaboration with the Biosafety Clearing-House, shall develop and implement regional and global capacity-building programmes based on the identified needs of the concerned Parties. The Secretariat and

the Biosafety Clearing-House shall, in particular, assist developing countries in their efforts to identify and plan their capacity-building requirements and secure funds for the implementation of their capacity-building programmes.

10. Regional or subregional centres for training and capacity-building regarding the safe management of living modified organisms or products thereof should be established, according to the specific needs of different regions and subregions.

11. Capacity-building should be mentioned in the preamble to the protocol and should be included in the protocol. This element should refer to capacity-building for purposes of enabling risk assessment.

ITEM E: PUBLIC AWARENESS/PUBLIC PARTICIPATION

PUBLIC AWARENESS

1. The protocol must address public awareness.

2. The protocol should not contain provisions for public awareness since this is already covered by Article 13 of the Convention on Biological Diversity which is broad and flexible enough to accommodate the various and different circumstances and needs of countries.

3. Parties shall ensure that adequate information on the safe transfer, handling and use of LMOs is provided to the public.

4. Not only the national competent authority(s)/focal point(s) but also the private sector and NGOs shall be responsible for undertaking/implementing public awareness mechanism(s).

5. The protocol should not specify mechanisms for public awareness. They should be decided at a national level.

6. Parties shall promote and facilitate, at the national and regional level, as appropriate, and in accordance with national laws and regulations, and within their respective capacities, the development and implementation of educational and public awareness programmes on safety in biotechnology.

7. The institutional framework of the protocol shall be responsible for public awareness.

8. Public awareness mechanisms could include: formal education, information-sharing, workshops, clearing-house, media, consultations with interested parties, public debate.

9. In designing public-awareness mechanisms, confidentiality provisions should be respected.

PUBLIC PARTICIPATION

1. A public hearing may be carried out in cases where an AIA is required.

2. The protocol should include a provision on public participation.

3. Public participation and public awareness are closely linked and therefore, should be reflected in one provision.

4. Under the protocol, public participation should be encouraged but not mandated.

5. Public participation could address compliance with protocol provisions/labelling and packaging of goods, etc.

6. Public participation should include participation of NGOs, ordinary citizens, consumer protection groups and stakeholders.

7. The level of public participation should be decided at a national level.

8. Article 14, paragraph 1, of the Convention on Biological Diversity already addresses public participation in the context of environmental impact assessment procedures.

ITEM F: RISK ASSESSMENT AND RISK MANAGEMENT (INCLUDING MINIMUM NATIONAL STANDARDS)

RISK ASSESSMENT

Provisions

1. The protocol should include a provision on risk assessment.

2. Suitable mechanisms for risk assessment and risk management will be an important element underpinning the effective functioning of any AIA procedure under the protocol. However, it does not automatically follow that the mechanisms themselves should form part of the protocol.

3. In order to ensure that risk assessment undertaken under the protocol is based on scientific grounds, it will be appropriate to include a general article on the principles for risk assessment in the protocol.

4. The protocol should include provisions requiring exporting parties to cooperate in facilitating the exchange of scientific knowledge/information.

5. In order to ensure a minimal degree of harmonization, it may be necessary to include in the protocol the basic principles of risk assessment and management.

6. Provisions on risk assessment should provide general principles. Parties shall formulate and implement detailed risk assessment procedures in accordance with their national legislation and needs.

7. Provisions on risk assessment should provide minimum standards and/or minimum protection levels.

8. The protocol shall include an article outlining general provisions on risk assessment. Detailed provisions shall be subject of an article or part of an annex to the protocol.

9. Standardized criteria and procedures for risk assessment should be considered.

10. Procedures for risk assessment for imported LMOs in a contracting party to the protocol should not be different from those for domestic LMOs. Moreover, imported LMOs should not be treated in a disadvantageous way compared to homologous domestic LMOs.

11. The risk assessment must be relevant to the affected country and should address the environment of the affected country and the socio-economic impacts on that country.

<u>Responsibility</u>

12. The importing country may lack the technical capacity to evaluate the quality of the data provided by the exporting party and draw scientifically valid conclusions. Therefore, the protocol should mention measures to assist these countries financially and technically.

13. The protocol could include a provision that exporting parties consider assisting in other ways the process of risk assessment in the importing party to help reach informed judgements as to the suitability and safety of an LMO, in terms of possible adverse effects on biodiversity, for import by another party. However, this should not be mandatory.

14. The exporting party shall provide risk assessment to the national competent authority(s) of the importing party. The latter shall evaluate and analyse the submitted data. The exporting party is responsible for the reliability of the information provided. If it deems necessary, and in accordance with national legislation, the importing party may wish to conduct its own risk assessment measures.

15. The State of export and the State of import shall ensure that risk assessments in accordance with the provisions of this protocol are carried out prior to the transfer, handling and use of living modified organisms with regard to the risks or possible adverse impacts on human health and/or the environment in their respective territories.

16. Protocol provisions on risk assessment shall allow for public participation particularly from farmers and local communities/indigenous people since they may possess the requisite knowledge more fully than any other source.

17. The financial responsibility of risk assessment shall lie with the exporting party.

18. Any person or country who intends to undertake the transfer may undertake the risk assessment. However, the responsibility for the risk assessment must be with the national competent authority(s) of the exporting country. The exporter should provide information relevant for such risk assessment as appropriate.

19. Primary responsibility for risk assessment rests with the competent national authority of the importing country.

Legal status

20. As appropriate risk-assessment and risk-management mechanisms will vary from country to country, taking into account differences in the receiving environment, they should not form part of an international legally binding instrument.

21. The protocol shall include an article outlining detailed provisions on risk assessment to ensure minimum protection for developing countries.

22. Provisions on risk assessment should only be reflected as an article in the protocol.

23. The provisions on risk assessment included in the protocol shall be legally binding/shall not be legally binding.

24. The provisions on risk assessment included in the protocol shall be treated as guidelines for contracting parties.

Aim/basis

25. Risk-assessment measures outlined in the protocol shall provide the basis for decisions regarding the transboundary movement of LMOs.

26. Risk-assessment measures may not be the only basis for decisions regarding any transfer of LMOs.

27. Decisions under the Protocol, in regard to adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, shall be based on up-to-date scientific data and experience and take account of:

(a) Socio-economic impact;

(b) Characteristics of the LMOs, including any introduced sequences or modified traits;

(c) The intended use of LMOs;

(d) The potential recipient/parental or host organism;

(e) The genetic modification of LMOs;

(f) Risk/benefit analysis of the LMOs;

(g) Horizontal gene transfer - the ability of genes introduced into LMOs to jump across species, geographical and national boundaries;

(h) The characteristics of the potential receiving environment.

(i) The interaction between these.

28. The basis for risk assessment should not be only on scientific data but also on possible socio-economic impacts.

29. States shall establish, designate or strengthen national and/or regional authorities to implement adequate risk assessments.

30. A complete risk assessment shall be carried out prior to the transfer of an LMO for the first time into a new country.

31. The purpose of including provisions on risk assessment is to provide basis for decisions related to the transboundary movement of LMOs, including decisions related to socio-economic and ethical impact of such a movement.

32. While the UNEP International Technical Guidelines on Safety in Biotechnology are an adequate source for information regarding risk assessment, other available relevant information sources shall also be used.

RISK MANAGEMENT

Provisions

33. Risk management strategies and measures must be incorporated in the protocol to provide the basis for decisions on the transboundary movement of LMOs/safe handling and use of LMOs/liability and compensation/likely effects of the outcome of the movement of LMOs.

34. Risk management is covered by Article 8(g) of the Convention; therefore, there is no need to include a separate provision on this matter in the protocol.

35. Because of its relevancy, Article 8(g) of the Convention should be cross-referenced in the protocol.

36. The protocol should not include a provision on risk management. This should be decided at the national level.

37. Risk-management measures included in the protocol shall reflect minimum standards required for the risk management of LMOs.

Legal status

38. Risk-management provisions mentioned in the protocol shall be legally

binding.

39. Risk-management provisions mentioned in the protocol shall not be legally binding since it is already encompassed in Article 8(g) of the Convention, which is legally binding.

40. Risk management provisions mentioned in the protocol shall not be legally binding. However, a legal framework has to be established to ensure consistency and transparency.

41. The protocol shall include general principles on risk management. Detailed management measures shall be left to national authorities. However, the protocol shall reaffirm the sovereignty rights of parties to determine their respective risk-management measures.

Responsibility/trigger

42. National competent authority(s)/Focal point(s) shall be responsible for undertaking risk-management procedures.

43. The procedure of risk assessment may be triggered by any party (importing/exporting/third party) in cases of an unintentional release of LMOs. Notification shall be submitted to the national competent authority(s)/focal point(s) of the affected country.

Basis

44. UNEP Guidelines and other available resources shall be used for the elaboration of provisions on risk management in the protocol.

ITEM G: UNINTENTIONAL TRANSBOUNDARY MOVEMENT OF LMOs (INCLUDING ACCIDENTAL AND EMERGENCY CASES)

1. In the event of an unintentional transboundary movement of LMOs and/or accident, the user shall be required to inform immediately the competent authorities of the State(s) concerned. The information shall include, inter alia, the circumstances of the accident, the identity and numbers or quantities of the living modified organisms released, other facts necessary to assess the effects of the accident on human and animal health, the environment, and biological diversity, and the emergency measures taken or needed to be taken together with any available information regarding the handling of the organisms and information related to risk assessment and risk management.

2. Article 14 of the Convention shall apply to the emergency procedure with respect to the implementation of the Protocol.

3. Whenever it comes to a State's knowledge that an accident has occurred during the transboundary movement of LMOs, or in the case of an accident/unintended movement within their territories which may have transboundary effects likely to present risks to human health and/or the

environment in other States, the State shall immediately inform all affected States.

4. The Protocol should include provisions which require States to have appropriate procedures for environmental impact assessments of planned activities within their territories that are likely to have significant adverse effects on human health and/or the environment within their own territories, where such activities could have transboundary effects on other States.

5. The affected State(s) may ask for consultations with other concerned States.

6. Landlocked/neighbouring countries shall also be consulted and informed of an unintentional release, as LMOs do not recognize national boundaries.

7. There needs to be a clear and distinct procedure to deal with unintentional transboundary movement associated with natural movement and accidental releases.

8. Information on unintentional releases of LMOs shall be deposited with the clearing-house mechanism.

9. The Protocol should include provision for unintentional transboundary movement of LMOs which are likely to have significant adverse effect on the conservation of biological diversity, taking also into account human health.

10. Article 14 of the Convention on Biological Diversity, which addresses impact assessment and minimizing adverse impacts, shall provide the legal basis for provisions related to the unintentional transboundary movements of LMOs.

11. Any procedures for unintentional transboundary movement should be triggered by the State which first becomes aware of the release.

12. As regards unintentional transboundary movement, the primary concern of Parties should be the speediness and effectiveness of the transmission to the affected Party of the relevant information.

13. Any directly involved third parties, such as the entity that originally developed the LMO, should also be immediately informed of unintentional transboundary movements.

ITEM H: MONITORING AND COMPLIANCE

MONITORING

1. There should be a process for monitoring implementation of the protocol.

2. Parties shall report annually to the Secretariat and the Biosafety

Clearing-House on the steps taken to implement the protocol.

3. Parties shall ensure that monitoring of activities and products involving living modified organisms is undertaken at regular intervals by the user and the same is reported to the competent authority.

4. Reports on monitoring and compliance should be submitted to the Conference of the Parties and/or Secretariat and scrutinized/not scrutinized by an expert committee.

5. The monitoring process should be simple, cooperative and transparent and should be guided by the need for all parties to cooperate in good faith and participate fully, be non-judicial, advisory or supervisory.

6. Individual Parties should report on the implementation of their commitments on an annual basis and as concisely as possible.

7. In addition to the AIA and notification procedures and adoption of national regulations, laws and institutions, the burden of the task on human resources, information on problems encountered and how they were overcome, public-awareness programmes and other relevant information should be addressed in an annual report on the implementation of the protocol.

8. The procedure should not only cover monitoring of implementation of the protocol, but also monitoring of the behaviour of the LMO.

9. The application of Article 26 of the Convention on Biological Diversity and/or decision II/17 of the Conference of the Parties should be explored before adding new requirements.

COMPLIANCE

10. There should be a process for monitoring implementation (compliance) of commitments by parties.

11. The Protocol should be designed in a manner that will best yield compliance within it.
12. Judicial process should be reserved for those parties who refuse to and blatantly disregard the provisions of the protocol.

13. The process for compliance can be triggered by individual parties or the Secretariat.

14. The process for reviewing compliance should operate through a standing body established by the Conference of the Parties.

15. The process for reviewing compliance should operate through an ad hoc body established by the Conference of the Parties.

16. Any party which has reason to believe that another party is acting or has acted in breach of its obligations under the protocol shall inform the

Secretariat thereof, and in such an event, shall also inform directly or through the Secretariat, the party against whom allegations are made. All relevant information shall be submitted by the Secretariat to the parties.

17. Compliance procedures might be developed in addition to the settlement-of-disputes procedures.

18. Article 26 of the Convention on Biological Diversity should form the basis for the compliance mechanism.

19. The procedure should be cooperative, conciliatory, advisory rather than supervisory and transparent rather than private, though with a provision to protect confidentiality.

20. It is too early to decide at this early stage how the process for reviewing compliance should be triggered.

21. The compliance process should operate through a standing body established by the Conference of the Parties, geographical distribution should be taken into account. It may, however, be too early to decide on this element.

22. The objective of the compliance process should be a friendly settlement of differences and therefore a means to prevent disputes and also provision of practical guidance to parties in difficulty.

23. There should be an aim of obtaining formal findings of non-compliance.

24. There should be a recognition that some Parties have limited resources and so the information requested should not be onerous.

25. With respect to compliance, the procedure(s) of other international legal instruments should not apply.

26. Since the protocol will establish its own procedures, the procedure(s) of other international legal instruments should not apply.

27. The provisions of the protocol should be sufficiently normative in character to justify establishing a procedure for review the implementation of commitments by individual parties.

ITEM I: HANDLING, TRANSPORT/PACKAGING/AND TRANSIT REQUIREMENTS FOR TRANSBOUNDARY MOVEMENT OF LMOs

1. In order to maintain safety levels during transport and transit, LMOs should be packed and labelled adequately.

2. In order to maintain safety during transport, existing international United Nations recommendations and agreements on transport should be applied.

3. The need for safe transport and possibly transit should be reflected in the protocol.

4. International instruments do not adequately cover this issue, therefore it must be reflected in the protocol.

5. Parties shall require labelling of living modified organisms intended for food purposes. Other living modified organisms shall be labelled if necessary with regard to environmental, health or ethical concerns.

6. The protocol shall contain a provision that outlines general principles on labeling, packaging and transport.

7. A precautionary approach should be adopted.

8. Although interrelated, handling/transport/and packaging should be treated separately from issues on transit. Further elaboration on transit matters should be provided for in the protocol.
