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OPEN-ENDED AD HOC WORKING
GROUP ON BIOSAFETY
Fourth meeting
Montreal, 5-13 February 1998

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

Introduction

1. The fourth meeting of the Open-ended Ad Hoc Working Group 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 from 5 to 13 February 1998.

I. ORGANIZATIONAL MATTERS

A. Opening of the meeting

2. The meeting was opened by Mr. Veit Koester (Denmark), Chairman of the Open-ended Ad Hoc Working Group, at 10.25 a.m. on Thursday, 5 February 1998. In his opening statement, Mr Koester welcomed all participants and noted that in the two years since the negotiations on the elaboration of a protocol on biosafety had begun, considerable progress had been made. He said that participants had assisted in identifying questions that needed further study and thanked them for their efforts, goodwill and cooperation. He recalled that decision III/20 of the Conference of Parties had established a calendar of work which required the Open-ended Working Group to complete its work by the end of 1998. He closed by stating that the participants shared the same concerns, and he was sure they would meet that deadline and achieve the objectives set out by the Conference of Parties at its second and third meetings.

3. At the opening session of the meeting, the Working Group also heard statements from Mr. Hamdallah Zedan, Chief, Biodiversity Unit, United Nations Environment Programme (UNEP), and Mr. Calestous Juma, Executive Secretary of the Convention on Biological Diversity.

4. Mr. Zedan said that UNEP attached great importance to the negotiations in the Working Group and looked forward to the timely conclusion of a protocol on biosafety. By exercising judicious caution and a spirit of accommodation, the Working Group would ensure that the resultant protocol would, along with other complementary regional and international instruments, offer an effective framework for regional and international cooperation aimed at enhancing the transfer of, and ensuring safety in, biotechnology. Recalling the view expressed by the Conference of the Parties at its third meeting that the UNEP International Technical Guidelines for Safety in Biotechnology constituted a useful complement to the development and implementation of a protocol on biosafety, he said that, in November 1997, the Council of the Global Environment Facility (GEF) had approved a $2,744,000 UNEP/GEF pilot biosafety enabling project. The aim of the project was to provide assistance to developing countries and countries with economies in transition in formulating national biosafety frameworks for the implementation of the Guidelines, in the context of Article 8(g) of the Convention on Biological Diversity, and the future implementation of any agreements on biosafety, such as the protocol under the Convention. Given that it was not yet possible to have a full understanding of the kinds of assistance that countries might need in addressing biosafety issues and the future implementation of biosafety agreements, the usefulness of the project lay in assisting Governments to undertake an initial assessment of the state-of-play in their countries on matters of biosafety, an effort to be accompanied by a global awareness-raising initiative on biotechnology-related biosafety aspects, given the central importance of those issues for the Convention on Biological Diversity and the potential longer-term operational implications for the Global Environment Facility. In implementing the project, UNEP would work closely with, and seek advice from, relevant United Nations bodies, governmental and non-governmental organizations, the biotechnology industry, the Secretariat of the Convention and regional institutions. It would ensure that the Working Group, the Conference of the Parties and the GEF Council were kept informed of the progress made.

5. Mr. Juma welcomed all participants and reiterated that the work of the Working Group represented an important step in the evolution of international environmental law in general and the Convention on Biological Diversity in particular. The negotiations addressed one of the most pressing public policy issues for the next millennium: how to balance the need to share benefits arising from the use of biotechnology with the need to meet environmental and human safety standards. It was the understanding of the Secretariat that the work of the Working Group was guided by the deadline set by the Conference of the Parties, and the draft longer-term programme of work to be submitted to the Conference at its fourth meeting was based on the assumption that that deadline would be met. The timely completion of the work of the Group would also allow for a more informed consideration in the work programme of the Conference of the Parties of a number of issues, such as benefit-sharing, technology transfer, in situ conservation and technical and scientific cooperation. On the question of financial resources, he expressed his gratitude to all those countries that had committed funds in support of the work in hand and, in particular, Austria, Canada, Denmark, Japan, the Netherlands, the Republic of Korea, Sweden, Switzerland and the United Kingdom. Noting that, because of the urgency and significance attached to it by the Conference of the Parties, the meeting had been convened on the basis of pledges and not cash in hand, he stressed that the

Secretariat could not continue to support any activities on the basis of pledges. By doing so for the current meeting, it had in effect curtailed activities in other programme areas, and he would be presenting to the Conference of the Parties an analysis of the impact of the negotiations on the overall functioning of the Secretariat, together with proposals for a more supportive budget structure. In conclusion, he stressed the importance of completing the work on time and the need to provide resources for the effective management of the negotiating process.

B. Attendance

6. The meeting was attended by representatives of the following States and regional economic integration organizations: Antigua and Barbuda, Argentina, Australia, Austria, Bahamas, Belarus, Belgium, Belize, Benin, Bhutan, Bolivia, Botswana, Brazil, Burkina Faso, Burundi, Cameroon, Canada, Chad, Chile, China, Colombia, Comoros, Cuba, Czech Republic, Democratic Republic of Congo, Denmark, Djibouti, Dominican Republic, Egypt, Ethiopia, European Community, Finland, France, Gambia, Georgia, Germany, Ghana, Greece, Guinea, Haiti, Hungary, India, Indonesia, Iran (Islamic Republic of), Italy, Jamaica, Japan, Jordan, Kazakstan, Kenya, Kiribati, Lao People's Democratic Republic, Lithuania, Madagascar, Malawi, Mali, Marshall Islands, Mauritania, Mauritius, Mexico, Mozambique, Myanmar, Namibia, Nepal, Netherlands, New Zealand, Niger, Norway, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Rwanda, Saint Lucia, Samoa, Saudi Arabia, Seychelles, South Africa, Spain, Sri Lanka, Sudan, Swaziland, Sweden, Switzerland, Thailand, Togo, Tunisia, Turkey, Uganda, Ukraine, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, United States of America, Venezuela, and Zambia.

7. The following United Nations bodies and specialized agencies were represented: Food and Agriculture Organization of the United Nations (FAO), Global Environment Facility (GEF), and World Intellectual Property Organization (WIPO).

8. Representatives of the following intergovernmental organizations attended the meeting: Organisation for Economic Cooperation and Development (OECD) and South Pacific Regional Environment Programme (SPREP).

9. The following non-governmental organizations were also represented: Afri Net, AgrEvo Canada Inc., Akin, Gump, Strauss, Hauer & Feld, American Soybean Association, Applied Life Science Strategies, ASSINSEL, Biotech Industry Organization (BIO), Biotechnology Working Group/Washington Biotechnology Action Council, Canadian Broadcasting Corporation (CBC), Canadian Federation of Agriculture, Charles University, Colorema, Concordia University, Council for Responsible Genetics, Dupont Company, ECOROPA, Environment Business and Development Group/representing WWF International, Europabio, International Seed Trade Federation (FIS), Forum Environment and Development Working Group on Biodiversity, Foundation for International Environmental Law and Development, Friends of the Earth International, Fundacion Ambiente y Recursos Naturales, German Working Group on Biodiversity, Green Industry Biotechnology Platform (GIBiP), Hogan and Hartson, INBio, Kinki University, Legowork Environmental Inc., McGill University, Monsanto, Montreal International, Musée Canadien de la Nature, OECO Capital Life Insurance, O'Mara & Associates, Palm Oil Research Institute

of Malaysia, Pioneer Hi-Bred Intl., Pro Natura/Swiss Working Group on Genetic Engineering, Skadden, Arps, Slate, Meagher & Flom LLP, The Edmonds Institute, The Institute for Agriculture and Trade Policy, Third World Network/Research Foundation for Science, Technology and Ecology, Université du Quebec à Montréal, Université de Sherbrooke, Women's Environmental Network, Working Group on Biodiversity and Forum Environment and Development.

C. Bureau

10. Pursuant to paragraph 1 (b) of decision III/20 of the Conference of the Parties to the Convention on Biological Diversity and rule 24 of the rules of procedure, the following representatives served as the Bureau of the Working Group at its fourth meeting:

Mr. Veit Koester (Denmark) (Chairman)
Mr. Behren Gebre Egziabher Tewolde (Ethiopia)
Mr. Sateeaved Seebaluck (Mauritius)
Mr. Diego Malpede (Argentina)
Mrs. Sandra Wint (Jamaica)
Dr. Ervin Balazs (Hungary)
Dr. Alexander Golikov (Russian Federation)
Dr. Antonio G. M. La Viña (Philippines)
Mr. Jong Ho Choi (Republic of Korea)
Mr. Darryl Dunn (New Zealand)

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

D. Adoption of the agenda

12. The Working Group adopted the following agenda on the basis of the provisional agenda that had been circulated under the symbol UNEP/CBD/BSWG/4/1:

1. Opening of the meeting.

2. Adoption of the agenda.

3. Organization of work.

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

5. Dates and venues of meetings of the Open-ended Ad Hoc Working Group on Biosafety for 1998.

6. Adoption of the report.

7. Closure of the meeting.

E. Documentation

13. The following documents were before the Working Group at the meeting: provisional agenda (UNEP/CBD/BSWG/4/1); annotated provisional agenda (UNEP/CBD/BSWG/4/1/Add.1); compilation of government submissions of draft text on selected items: articles 1, 1 bis and 23-27 (UNEP/CBD/BSWG/4/2); compilation of government submissions of draft text on items other than articles 1, 1 bis, and 23-27 (UNEP/CBD/BSWG/4/3); Chairman's note on articles 3-10, 11 and 12-14 (UNEP/CBD/BSWG/4/Inf.1 and Add.1); Chairman's note on articles 1, 1 bis, and 15-27 (UNEP/CBD/BSWG/4/Inf.2); preamble (UNEP/CBD/BSWG/4/Inf.3); biosafety protocol implementation mechanisms for information-sharing under a protocol on biosafety under the Convention on Biological Diversity (UNEP/CBD/BSWG/4/Inf.4); and the consolidated text from the third meeting of the Open-ended Ad Hoc Working Group on Biosafety (UNEP/CBD/BSWG/4/Inf.5).

F. Organization of work

14. The Working Group decided that the two open-ended sessional Sub-Working Groups established at its third meeting would continue their work on those articles under the mandates set out for them at that meeting (see UNEP/CBD/BSWG/4/1/Add.1, paras. 8 and 9), with a broader scope to enter into negotiations on the content of the consolidated draft text of the protocol and, where possible, reduce the number of options contained under each draft article. In addition, it was agreed that article 14 (Minimum national standards) was to be included in the mandate of Sub-Working Group I. It would be up to the Co-Chairs of the two Sub-Working Groups and Contact Group 2, in consultation with the members of their groups, to decide to what extent the notes prepared by the Chairman on articles 3-10, 11 and 12-14 (UNEP/CBD/BSWG/4/Inf.1 and Add.1),articles 1, 1 bis and 15-27 (UNEP/CBD/BSWG/4/Inf.2) and the preamble (UNEP/CBD/BSWG/4/Inf.3) could provide a basis for the deliberations of the Sub-Working Groups and Contact Group 2, respectively.

15. The Working Group further decided that Sub-Working Group I would continue to be co-chaired by Dr. Erich Schoonejans (France) and Mrs. Sandra Wint (Jamaica), while Sub-Working Group II would be co-chaired by Ms. Amarjeet K. Ahuja (India), nominated by the Group of 77 and China to replace Ms. Hira Jhamtani (Indonesia), who was unable to attend the meeting, and Mr. John Herity (Canada), replacing Mr. David Gamble (New Zealand) on the nomination of the Bureau.

16. It was decided that the Sub-Working Groups would meet concurrently, but not at the same time as the plenary sessions. In addition, it was decided to continue the practice adopted at the third meeting of the Open-ended Ad Hoc Working Group, whereby each regional group would designate four representatives to attend each Sub-Working Group on the understanding that such designation did not confer any special rights on the member concerned, but was merely intended to ensure adequate regional representation. It was also decided that, unless otherwise indicated by the regional group concerned, the core representatives designated at the third meeting would be retained (see UNEP/CBD/BSWG/4/1/Add.1, para. 7). In that connection, at the 2nd session of the meeting, on 7 February, the representative of Hungary, speaking on behalf of the East and Central European Group, announced that

Georgia would temporarily replace Bulgaria as a core member of Sub-Working Group II for the remainder of the meeting and that Kazakstan had been designated as the fourth core member of the Sub-Working Group from the region.

17. It was agreed that the two open-ended Contact Groups established at the third meeting of the Open-ended Ad Hoc Working Group would be retained with the mandates given to them at that meeting (see UNEP/CBD/BSWG/4/1/Add.1, paras. 11 and 12). In addition, Contact Group 2 would consider the issue of the title and preamble of the protocol, as well as the recommendations of the Ad Hoc Working Group to the fourth meeting of the Conference of the Parties. In addition, since its work was closely linked to the tasks of Sub-Working Group I, it was decided to make Contact Group 1 a sub-group of Sub-Working Group I, reporting to it, in order to ensure coordination of the work and avoid duplication in the discussions.

18. Contact Group 1 would continue to be co-chaired by Dr. Gert Willemse (South Africa) and Mr. Piet van der Meer (Netherlands), while Contact Group 2 would be co-chaired by Mr. John Ashe (Antigua and Barbuda), a Co-Chair at the third meeting, and Ms. Katharina Kummer (Switzerland), who had been nominated for the post by the Group of Western European and Other States in accordance with the decision taken by the Working Group at its third meeting.

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

19. At the 2nd plenary session, on 7 February 1998, the Working Group heard the interim reports of the Co-Chairs of Sub-Working Groups I and II and of Contact Groups 1 and 2.

20. Mrs. Wint (Jamaica), Co-Chair of Sub-Working Group I, said that the Group's discussions had been based on the Chairman's notes on articles 3-10 and 12-14, and article 11 (UNEP/CBD/BSWG/4/Inf.1 and Add.1), with other documents being used as resource material. She said that the Co-Chairs had proposed a flow-chart for a plan of action that would result in a consolidated text for articles 3-14 and for the definitions and the annexes, to be presented to the fifth meeting of the Open-ended Ad Hoc Working Group on Biosafety. A first draft of reduced options for articles 4 and 5 was ready for discussion and work had started on article 6.

21. Mr. Herity (Canada), Co-Chair of Sub-Working Group II, said that since the Chairman's note on articles 1, 1 bis and 15-27 (UNEP/CBD/BSWG/4/Inf.2) had initially not been available in all languages, work had started using the compilation of government submissions of draft text on selected items (UNEP/CBD/BSWG/4/2) and the consolidated text from the third meeting of the Open-ended Ad Hoc Working Group on Biosafety (UNEP/CBD/BSWG/4/Inf.5). Now that the Chairman's note was available in all languages, it would be used to assist the work of the Sub-Working Group. The Sub-Working Group had already completed a discussion of draft articles 23-27, which had not previously been taken up. The Group had also produced revised text for draft articles 15-17.

Discussion of draft articles 1 and 1 bis had been postponed, as it was felt that it would be easier to undertake such a discussion after the other articles had been considered. He concluded by expressing satisfaction at the strong participation from all regions in the work of the Sub-Working Group.

22. Mr. Willemse (South Africa), Co-Chair of Contact Group 1, said that it had been agreed that the work of the Contact Group would be based on the requirements of Sub-Working Group I. Its deliberations were being approached from a purely scientific and technical point of view to provide Sub-Working Group I with a text with the least possible number of options for negotiations. Discussions had been initiated on Annex I, which the Contact Group had reviewed and simplified and referred back to the Sub-Working Group. Definitions had been developed for a number of terms, such as transboundary movements, exporter, importer, Party of export, Party of import, notification, competent authority and focal point and the results would be presented to the Sub-Working Group. The Contact Group would then move on to Annex II.

23. Ms. Kummer (Switzerland), Co-Chair of Contact Group 2, said work had begun on legal, institutional and procedural issues. Procedural provisions, such as those relating to signature, ratification, accession and entry into force, had been reviewed to see if they were already covered by the Convention on Biological Diversity. On that basis, the Contact Group had agreed that draft articles 32, 38 and 39, on jurisdictional scope, ratification, acceptance and approval, and accession; were redundant and could be deleted. The content of some of the provisions relating to institutional issues would, however, be dependent on the content of the protocol, and it was therefore difficult to reach a conclusion. Nevertheless, a preliminary discussion had been held on articles 28, 34, 35, 36 and 41. In its discussions on articles 29, 30 and 31 on Conference of the Parties, subsidiary bodies and mechanisms, and secretariat, the Contact Group was drawing on precedents in international environmental agreements, notably the recently concluded Kyoto Protocol to the United Nations Framework Convention on Climate Change.

24. At the 4th plenary session, on 13 February 1998, the Working Group heard the final reports of the Co-Chairs of Sub-Working Groups I and II and of Contact Groups 1 and 2.

25. The Co-Chair of Sub-Working Group 1, Dr. Erich Schoonejans (France), speaking also on behalf of Co-Chair Mrs. Sandra Wint (Jamaica), orally presented the report of the work of the Sub-Working Group in its consideration of those articles entrusted to it. He introduced and made oral corrections to the Sub-Working Group’s document containing revised draft articles 3-14 that it had agreed to submit to the plenary for endorsement (UNEP/CBD/BSWG.4/L.5), noting that the drafts represented good progress and a sound basis for further negotiations.

26. The Co-Chair of Sub-Working Group II, Mr. John Herity (Canada), speaking also on behalf of Ms. Amarjeet K. Ahuja (India), orally presented the report on the work of the Sub-Working Group in its review of draft articles 15 -27. Noting that draft articles 15-22 had already been the subject of discussion at the previous meeting of the Working Group, that draft articles 23-27 had been taken up for the first time at the present

meeting and that a detailed examination of draft articles 1 and 1bis was still to be made, he pointed to the good progress in the work of the Sub-Working Group. He introduced and made oral corrections to the texts of the draft articles that it had agreed to forward to the plenary for endorsement (UNEP/CBD/BSWG.4/L.4 and Adds. 1-5).

27. The Co-Chairs of Contact Group 1, Mr. Piet van der Meer (Netherlands) and Mr. Gert Willemse (South Africa) reported on the deliberations in Contact Group 1. In explaining the modus operandi of the Group with regard to definitions, Mr. van der Meer said that the results of initial deliberations were given to Sub-Working Group I. Comments made in Sub-Working Group I were further discussed in Contact Group 1 and the results were again presented to Sub-Working Group I. Where necessary, Contact Group 1 requested Contact Group 2 to consider the legal questions in the definitions. Contact Group 1 felt that this reiterative process and the close collaboration between the Co-Chairs of all sub-groups clearly benefited the process and optimized transparency and coordination. The definitions submitted for the consideration of the Working Group were contained in document UNEP/CBD/BSWG/4.L.6. After considerable debate on terms related to transboundary movement and export and import, both Contact Group 1 and Contact Group 2 felt that further progress could only be made after the following, more fundamental questions had been addressed by the Sub-Working Groups:

(a) Would the Protocol apply to transboundary movement of LMOs between Parties only, or also between Parties and non-Parties?

(b) Would the Protocol apply to transboundary movement outside the area of jurisdiction of any country (e.g. international waters, Antarctica)?

(c) Would the Protocol apply to transit?

(d) To which entities (i.e. natural or legal persons, States/Parties) were the obligations regarding transboundary movements addressed?

28. Mr Willemse noted that the uncertainty at the current stage with regard to, inter alia, the exact nature and status of an Annex on risk assessment was recognized by the Contact Group to have direct bearing on the information needs as set out in the annex I prepared by the Group. The Group had also prepared a draft for Annex II on risk assessment, containing two illustrative options: a "short" version showing a general approach and a longer version illustrating a more detailed approach. It was recognized that, whichever approach was taken, no list of risk assessment parameters could fully provide for all factors in all instances of risk assessment. Finally, in order to facilitate the work on annexes at the fifth meeting of the Open-ended Ad Hoc Working Group, without prejudging the need for these annexes in the Protocol, Contact Group 1 had prepared a list of annexes to reflect those discussed at the current meeting, annexes identified in government submissions, and annexes referred to in the text of articles discussed by the sub-working groups at this meeting. Contact Group 1 recommended that the list should remain open and be included in the report of the meeting (see annex V below).

29. The Co-Chairs of Contact Group 2, Mr. John Ashe (Antigua and Barbuda) and Ms. Katharina Kummer (Switzerland), reported on the results of its deliberations on draft articles 28-43 and the preamble to the protocol, and presented and orally amended the draft texts resulting from those deliberations, contained in documents UNEP/CBD/BSWG.4/L.2 and Adds. 1-5, for endorsement by the Working Group. In their reports, it was pointed out that agreement had been attained with regard to the drafts of articles 29, 30, 31, paragraphs 1 and 2, 33, 37, 40. 42 and 43, and concerning the deletion of articles 32, 38 and 39. The remaining draft articles within the remit of the Contact Group still contained options and bracketed language that would be the subject of further review. Moreover, as the Contact Group had considered that the preamble could be discussed only after the entire text of the protocol had been put in place, it was stressed that the language of the entire draft preamble remained open and subject to further amendment.

30. The Open-ended Working Group approved, as orally amended, the draft articles resulting from the work of the Sub-Working Groups and Contact Groups as a basis for its future work (see annexes I-IV below), on the understanding that the Secretariat would incorporate them into the new consolidated draft text of the protocol, to be submitted to the Working Group for its consideration at its fifth meeting.

Procedural elements for future work

31. At the 4th plenary session of the meeting, the Working Group agreed that the revised consolidated text which would reflect the outcome of the deliberations would be compiled by the Secretariat and sent to Governments. The annexes that had not been dealt with at the current meeting would be taken up in the consolidated draft. New proposals would be prepared in a separate document. The Secretariat would also prepare a note on Government submissions and background information on the term "products thereof", the deadline for submissions being 1 May. The aim of the document would be to provide for informed discussion at the next meeting of the Open-ended Working Group.

32. The Working Group also agreed that the organizational arrangements established for the fourth meeting would be maintained at its fifth meeting. There would hence be a Sub-Working Group I, Sub-Working Group II, Contact Group 1, Contact Group 2, with the same core representatives as at the current meeting. The same Co-Chairs for the four groups would also remain in office. The representatives in the groups would have the same mandate to fully negotiate and provide text to the plenary. Contact-group 1 would be working mainly with Sub-working Group I but also with Sub-Working Group II.

33. The representative of the Secretariat said that, in preparing the draft text, the Secretariat would request Parties to proceed according to the following principles with regard to the use of square brackets:

(a) Variations identified as separate options would not be bracketed;

(b) Alternative paragraphs within options would not be bracketed but would be identified by the use of a single paragraph number followed by a discrete letter (for example, "3A, 3B, etc.) and separated by the word "or";

(c) Alternative wording within paragraphs would be bracketed;

(d) If there was no agreement on whether a paragraph should be retained, the paragraph in question would be placed in brackets.

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

34. The Working Group took up agenda item 5 at its 2nd plenary session, on 7 February 1998.

35. With regard to the length of the meetings that it still needed to convene, the Working Group confirmed the agreement reached at its third meeting that its fifth meeting would need to be of two weeks' duration and a final meeting would also be required, of one week's duration, immediately preceding the meeting of the Conference of the Parties that would adopt the protocol.

36. With regard to the dates of those future meetings of the Working Group, it was noted that, while the decision on the date of the fifth meeting lay within the purview of the Working Group, any decision on the last meeting of the Group was contingent on what date was decided by the Conference of the Parties for the convening of the meeting of the Conference of the Parties to adopt the protocol. It was recalled that at its third meeting the Working Group had indicated that its fifth meeting should be held in the second half of July 1998. However, noting that the fourth meeting of the Conference of the Parties would be held in Bratislava from 4 to 15 May 1998, and taking into account the general schedule of environmental meetings and the information provided by the Secretariat on the availability of conference facilities, the Working Group decided provisionally that the dates of its fifth meeting should be moved forward to 29 June to 10 July.

37. At its 4th plenary session, on 13 February, the Working Group, taking into account information received regarding the potentially heavy demands on hotel accommodation in Montreal in the first two weeks of July 1998, decided that its fifth meeting should be held in Montreal from 17 to 28 August 1998. It further noted that since the meeting would comprise 11 working days, there would be no need to hold night meetings.

Elements for inclusion in a recommendation to the fourth meeting of the Conference of the Parties

38. On the basis of an informal aide-mémoire prepared by the Chairman, the Working Group at its 2nd plenary session, on 7 February 1998, identified and discussed issues arising in connection with the protocol on which the views of the Working Group could be set down in a recommendation to the fourth meeting of the Conference of the Parties.

39. Concerning the status of the meeting of the Conference of the Parties that would adopt the final protocol, the Working Group expressed a certain preference for an extraordinary meeting of the Conference of the Parties, since it would demand a dedicated agenda, focused on the protocol itself.

There was general support for holding the meeting in December 1998, so that the protocol might be concluded within the timeframe set by the Conference of the Parties at its second and third meetings.

40. It was agreed that issues pertaining to the funding of meetings of the Working Group lay within the purview of the Conference of the Parties and should not be dealt with by the Working Group itself.

41. In connection with the date for the deadline for government submissions of new text for the protocol, it was recalled that, under Article 28, paragraph 3, of the Convention, the text of any proposed protocol shall be communicated to the Parties no later than 6 months before the meeting at which it is to be adopted. Moreover, the deadline date to be identified in a decision of the fourth meeting of the Conference of the Parties would, preferably, need to be early enough to allow the Open-ended Ad Hoc Working Group to consider all the submissions at its fifth meeting. The Working Group thus decided to recommend to the Conference of the Parties that 1 June 1998 be designated as the date for deadline of submissions.

42. Support was also expressed for including a recommendation to the Conference of the Parties to consider including in the agenda of the meeting of the Conference of the Parties for the adoption of the Protocol, interim arrangements and budgetary considerations in preparation for the first meeting of the Parties to the Protocol, as well as a catalogue of matters to be addressed prior to that meeting.

43. The Working Group endorsed the decision of the Bureau to designate Bureau member Dr. Antonio G. M. La Viña (Philippines) as the coordinator to compile and circulate the draft text of a recommendation of the Working Group, for submission, through Contact Group 2, to plenary, for eventual transmission to the Conference of the Parties.

44. At the 3rd session of the meeting, on 11 February, the Working Group adopted a recommendation for submission to the fourth meeting of the Conference of the Parties on the basis of a draft text (UNEP/CBD/BSWG/4/L.3) prepared in accordance with the procedure outlined in paragraph 43 above. The recommendation was amended by the Working Group at its 4th session to reflect its decision on the dates of its fifth meeting (see paragraph 37 above) and reads as follows:

> "The Open-ended Ad Hoc Working Group on Biosafety,
>
> "Recalling decisions II/5 and III/20 concerning issues related to biosafety, in particular that it should endeavour to complete its work in 1998,
>
> "Recalling also part A of the annex to decision III/24, containing the budget of the trust fund for the Convention on Biological Diversity for the biennium 1997 and 1998, and, in particular, its item 3, "Servicing meetings of the Open-ended Ad Hoc Working group on Biosafety", which provided funds for two one-week meetings to be held in 1997 and 1998,

"Noting that the Open-ended Ad Hoc Working Group held a ten-day meeting in Montreal from 5 to 13 February 1998,

"Recognizing the difficulties imposed by the pressures on Governments with respect to administrative and travel requirements and the multiple calls on their time by other international commitments,

"1. Recommends to the Conference of the Parties that two further meetings of the Open-ended Ad Hoc Working Group should be convened in 1998 in order to complete its work and, to this end, proposes to hold a two-week meeting from 17 to 28 August 1998 in Montreal, Canada, and a final meeting in December 1998, followed immediately by a meeting of the Conference of the Parties to adopt the Protocol;

"2. Proposes that, in the event that the Conference of the Parties decides not to hold the final meeting of the Open-ended Ad Hoc Working Group in December 1998, it should convene that meeting, followed by a meeting of the Conference of the Parties for adoption of the Protocol, early in 1999 but, in any event, no later than February 1999;

"3. Recommends to the Conference of the Parties that the agenda for its meeting adopting the Protocol should include all practical matters relating to:

"(a) The adoption of the Protocol; and

"(b) The preparations for the first Meeting of the Parties, with regard to, inter alia, interim arrangements and budgetary considerations;

"4. Calls on the Conference of the Parties to establish a deadline of 1 June 1998 for the receipt of government proposals for provisions to be included in the Protocol, in accordance with the six-month rule for consideration of the draft protocol under Article 28, paragraph 3, of the Convention, and thereby enable the Open-ended Ad Hoc Working Group to consider those proposals during its meeting in August 1998;

"5. Requests the Conference of the Parties to consider ways and means to ensure that sufficient funds will be available to service the additional meetings proposed for 1998;

"6. Urges the Conference of the Parties, in the event that it decides to convene the final meeting of the Open-ended Ad Hoc Working Group and a meeting of the Conference of the Parties early in 1999, to ensure in its budgetary provisions that sufficient funds are available for the holding of those meetings."

45. At the same session, the Working Group also noted that the draft decision requested of the Secretariat by the Bureau of the third meeting of the Conference of the Parties would be prepared on the basis of the recommendation adopted by the Working Group.

IV. OTHER MATTERS

Statements by representatives of non-governmental organizations

46. At the 3rd session of the meeting, on 11 February 1998, the Working Group heard two statements from representatives of non-governmental organizations.

47. The representative of the Third World Network, speaking on behalf of 18 public interest groups and citizens' organizations, took issue with the argument that, because national laws existed for specific issues related to biosafety, or because the Convention itself contained general provisions, there was no need for the protocol to contain provisions on those issues. Discussions had identified gaps in international law on biosafety, and she considered that the Working Group should pursue the mandate set by the Conference of the Parties at Jakarta. She countered assertions about the complexity of biosafety issues, saying that the problem lay not in the lack of legal and technical expertise available but, rather, in the struggle between safety, health and conservation of biological diversity, on the one hand and, on the other, commercial and trade interests, which were best dealt with by other forums. Concerning non-Parties, the Working Group should not set a precedent by granting rights, benefits and privileges to non-Parties, without their corresponding assumption of any obligations or responsibilities. Regarding a liability regime in the protocol, she pointed to the urgent need to address the question of potential harm to health, to the environment and to biological diversity caused by LMOs and their products, and considered that delaying negotiations on that issue would leave a serious vacuum. Regardless of the outcome of those negotiations, she believed that a multilateral fund for compensation should be set up under the protocol, as an interim measure. Noting that many countries had banned or delayed the licensing of a number of LMOs and their products, based on new scientific evidence, she urged that the precautionary principle be applied, and reiterated the call for a global moratorium on commercial releases of LMOs and the products thereof.

48. The representative of Europabio, speaking on behalf of industry, trade associations, commodity groups and allied fields involved with living modified organisms, stated that they were committed to making a positive contribution to the development of a protocol. She noted that biotechnology improved agricultural productivity not only in industrialized countries but also in subsistence and export agriculture in developing countries as well. Biotechnology also benefitted biodiversity conservation and sustainable use of resources. The representatives on whose behalf she was speaking were committed to the principles of information-sharing, capacity-building and cooperative engagement. They believed that national biosafety regulations and regional biosafety guidelines should be the foundation for the protocol and its mechanism of Advanced Informed Agreement and that that foundation should be based on a rigorous and accepted scientific approach to risk assessment and risk management. It was not appropriate for the protocol to address socio-economic impacts and questions of liability, which should be covered by other mechanisms. The protocol should be practical and capable of being implemented by all involved in its execution. To remain effective, it

should be adaptable and able to evolve with new technical developments. International industry supported a protocol that would not place unnecessary restrictions on international trade, the development of new products, or the ability of States to attract investment in research and development.

V. ADOPTION OF THE REPORT

49. The present report was adopted at the 3rd and 4th sessions of the meeting, on 11 and 13 February 1998, on the basis of the draft report contained in document UNEP/CBD/BSWG/4/L.1 and Add. 1 and 2.

VI. CLOSURE OF THE MEETING

50. After the customary exchange of courtesies, the Chairman declared the fourth meeting of the Open-ended Ad Hoc Working Group closed at 1.30 p.m. on Friday, 13 February 1998.

Annex I

ARTICLES REVIEWED BY SUB-WORKING GROUP I

Articles 3-14

ARTICLE 3A - THE SCOPE OF THE PROTOCOL

Option 1

No provision for the scope of the Protocol.

Option 2

1. The scope of the AIA is the same as the scope of the Protocol.

OR

1. This Protocol [shall, without prejudice to paragraph 2 below, apply] [applies] to the transboundary movement [, handling and use] of living modified organisms resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

[2. This Protocol shall not apply to:

(a) Transboundary movements of LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as specified in Annex X;

(b) Requirements for transport operations;

(c) Transit of LMOs and transboundary movements destined for subsequent contained use, except as regards Articles 1 bis (General obligations) and 15 (Unintentional transboundary movements).]

ARTICLE 3B - THE APPLICATION OF THE AIA PROCEDURE

1. Each Party shall apply the Advance Informed Agreement procedure with respect to [the transboundary movements of] all living modified organisms defined in this Protocol.

OR

1. [All initial] The [first] transboundary movements of [[a specific] LMO] [resulting from modern biotechnology] [or products thereof] [covered by the Protocol] [intended for deliberate release in the environment] [that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health] [except those mentioned in paragraph 1 bis below] shall be subject to [an] AIA.

[1 bis. The scope of application of the AIA procedure shall not apply to:

(a) LMOs subject to [unilateral declaration as well as] bilateral, multilateral or regional agreements or arrangements exempting LMO from AIA as provided in Article X;

(b) [Organic materials which are components of LMOs but are not self-reproducible in the environment, such as DNA or RNA segments, plastids and peptides; or LMO products which do not contain live cells;]

(c) [The transit of LMOs] [LMOs which are subject to any other international agreement related to transboundary transfer of LMOs];

(d) LMOs requested to be imported by the competent authority of the Party of import for the purpose of carrying out risk assessment as a process of the AIA procedures stipulated in this Protocol;

(e) [The transboundary movements of] LMOs [destined for subsequent contained use] [imported into contained facilities] [to be used [exclusively] under contained conditions] [defined in this Protocol and if it is established by the Conference of the Parties to the Protocol that there does not exist any risk to the environment and human health by the use of those LMOs under the conditions so defined];

(f) The transboundary movement of LMOs not likely to have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as specified in Annex X. 1/

OR

1. The LMOs to be included in the AIA procedure will be based on criteria listed in an annex.

OR

1. The scope of application of the AIA procedure shall apply to:

(a) [All LMOs] [LMOs intended for deliberate release into the environment];

(b) An LMO intended for field testing in the Party of import; or

(c) An LMO that has not been imported into the Party of import and is not being produced in the Party of import, and is one:

(i) That is intended for first field growth in the Party of import, including in particular first field growth in a centre of origin or genetic diversity for that product;

1/ Annex X, Group I: the LMOs which every Party to this Protocol agrees do not have any risks to biological diversity and human health; Group II: the LMOs which a Party to this Protocol has unilaterally declared do not fall in the category of AIA procedure to that Party.

(ii) That has been banned or refused approval in the Party of export because of potential adverse effect on the conservation and sustainable use of biodiversity that were identified during the review process;

(iii) For which approval is in the process of being sought in the Party of export;

(iv) For which approval in the Party of export would have been required had the LMO been intended for domestic commercialization, field testing, or field growth in the Party of export;

(v) For which approval in the Party of export would have been required had the LMO been intended for domestic commercialization or growth in the Party of export but for which an application or request for approval was withdrawn; or

(d) An LMO that has been imported into the Party of import, but subsequent to such import, the exporting Party has banned or refused approval of the LMO because of potential adverse effects on the conservation and sustainable use of biological diversity, and the Party of import has not approved the LMO for import or growth since such exporting Party ban of refusal of approval. 2/

2. The [Party of import] may, however, declare that low-risk micro-organisms and other low-risk research organisms intended for contained use shall not be covered by the AIA procedure.

ARTICLE 4 - NOTIFICATION [PROCEDURE] [FOR AIA]

1. [The] [Each] [applicant] [Party of [export] [import]] [The importer] [The exporter] [The designated national [competent] authority of the Party of origin] [who] shall notify [or require] [ensure][that] [the] [exporter] [importer] [the Party of export] [to notify], in writing [in a language that is acceptable to the importer], [the designated national competent authority] [the national authority of the receiving Party and, where applicable, the designated [competent] national authority of the Party of transit] of the Party of import prior to [the first] [any] [intentional] transboundary movement to the Party of import of [any] [an] LMO [or products thereof] [that fall[s] under the scope of Article 3].

2. The notification to the [Party of import] [national [competent] authority [national focal point] of the receiving Party] shall contain the information specified in [Annex I] [a list to be established by the Meeting of the Parties].

3. No provision on the responsibility for the accuracy of information is necessary.

2/ This provision could be addressed by Article 6.

OR

3. [The Party of [origin] [export]] [The exporter] [Each Party shall make [its importer] [its exporter]] [shall be] responsible for the accuracy of the information provided [by the importer] in the notification and for any new information provided.

ARTICLE 5 - RESPONSE TO [AIA] NOTIFICATION

Option 1

No acknowledgment of receipt is required.

Option 2

1. The Party of import shall acknowledge receipt of the notification, in writing, to the [exporter/importer/competent authority of the Party of export/applicant/the designated national authority of the Party of export/notifier] [within [x] [30] days] [within a reasonable period of time].

2. The acknowledgment shall state the date of receipt of the notification [and inform the notifier whether the notification is in the correct form and it is accepted for consideration].

3. Failure to acknowledge will not imply consent for transboundary movement.

4. The Party of import [shall] [may], within the period of time referred to in paragraph 1, inform the notifier whether to proceed according to the Party of import's domestic regulatory framework, provided that the [notification concerns subsequent imports] [and that] [framework is consistent with this Protocol, or according to the procedures provided for in Article 6 of this Protocol].

5. 3/ The Party of import shall [within X days] [within a reasonable period of time] inform the notifier whether the notification [contains *prima facie* the [requested] [required] information] is complete or whether further information [in accordance with Annex II] is needed [and whether [additional] [risk assessment] [field trial] is to be carried out] [or whether an extended period of time to respond is needed].

6. 3/ The Party of import shall, within the period of time referred to in paragraph 1, inform the notifier whether, at the end of the period specified in Article 6:

(a) The intentional transboundary movement may proceed without written consent, provided that the Party of import has not, with justification, requested additional information, imposed conditions, or prohibited the transboundary movement; or

(b) The intentional transboundary movement may proceed only after the Party of import has given its written consent.

3/ Paragraphs 5 and 6 may be included in Article 6.

ARTICLE 6 - DECISION PROCEDURE FOR AIA

1. Decisions shall be based on [scientific information provided by the exporter] [scientific principles and supported by the best available scientific evidence[, including technical experience]] [scientific risk assessment of the adverse effect on the conservation and sustainable use of biological diversity], [taking also into account risks to human health] [in accordance with Annex II] [and social, economic and cultural criteria].

2. 4/ The Party of import shall within the period of time referred to in [Article 5] inform the notifier that:

[(a)] The intentional transboundary movement may proceed [after x days] without a written consent, provided that the Party of import has not, [with justification] [giving reasons], requested additional information, imposed conditions, or prohibited the transboundary movement or;

[(b)] The intentional transboundary movement may proceed only after the Party of import has given its written consent.

3. 4/ The Parties shall cooperate with a view to deciding, as soon as possible, to what extent in relation to the procedures, and in which cases, to be specified in an annex, a transboundary movement cannot proceed without an explicit consent.

4. 4/ The Party of import shall [within [x days] a reasonable period of time] inform the notifier whether the notification [contains prima facie the [requested] [required] information] is complete or whether further information [in accordance to Annex II] is needed [and whether [additional] [risk assessment] [field trial] is to be carried out] [or whether an extended period of time to respond is needed].

5. [Within [xxx] days of [acknowledgment of] [receipt] [transmission] of notification] [In accordance with a time-frame determined by the Party of import] [and the Party of export] [the decision of], the Party of import [may] [shall] respond, [in writing], to the notifier [and the Clearing-house] [shall consist of] with:

(a) [Allowing] [A decision to approve] imports, with or without [specified] conditions;

(b) [Prohibiting] [A[n absolute or provisional]] [decision to prohibit] import, [based on the best available scientific evidence, including technical experience, scientific risk assessment of adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;]

(c) [Requesting] [A request for] additional relevant [scientific] [technical] information [additional field trials] [before allowing or prohibiting the import]. When calculating the time for the Party of import to communicate its decision to the notifier under paragraph 2, the number of

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4/ Paragraphs 2, 3 and 4 may be included in Article 5.

days for which the Party of import is waiting for additional relevant [scientific] [and technical] information [additional field trials] which it has requested from the notifier shall not be taken into account;

(d) [Determining] Whether and how the decision applies to subsequent imports of the same LMO;

(e) [Determining] Whether notification is required for subsequent imports of the same LMO, in accordance with Article 10;

(f) [Informing] [The Party of import may inform] the notifier [with justification] that the period specified in this paragraph is extended by [a defined period no longer than xxx days] [as much time as is necessary to assess the information it has received from the [notifier] so as to enable it to reach an informed decision on the application and make its own risk assessment decisions on the transfer, handling or use of the LMO.]

6. In cases where the [State of import] [Party of import] in applying the precautionary principle considers that the information provided by the [notifier] is not sufficient in order to determine the potential adverse effects of an LMO, or determines that there are potential adverse effects of an LMO, the State of import has the right to prohibit import of the LMO in question. Lack of full scientific certainty or of scientific consensus shall not prevent the [State of import] [Party of import] from prohibiting the import of the LMO in question.

7. The transboundary movement of any living modified organisms should not take place without the authorization, or contrary to the decision, of the receiving Party.

8. Should the importing Party [of export] impose conditions on the import, deny permission for the import, [or request additional information] it shall state its reasons [in writing] to the [notifier] [importer] [Party of export] [Clearing-house], [for its decision] including information describing the legislative and/or administrative measures on which its decision is based.

9. If, [after acknowledgement of receipt [and after repeat notification to the Party of import] [as well as to the Clearing-house Mechanism] [and it is not the case in which a movement may not proceed without an explicit consent] the Party of import does not respond within the period specified under paragraph[s] X [and Y], [the exporter [may] [may not] [should not] proceed with the transboundary movement] [the Party of export shall not allow the exporter to commence with the proposed transfer until the AIA of the Party of import has been received.] [The competent authority of the Party of import shall be deemed to have [approved] [prohibited] import of the LMO[s] concerned.]

OR

9. If the Party of import fails to communicate its final decision within [X] days of the transmission of the notification, the transboundary movement is no longer governed by the terms of this Protocol and the Party of export shall have no further obligations under this Protocol with respect to such transboundary movement.

OR

9. [A] [The] Party of import has the right to address the consequences of its failure to respond following [a notification] [acknowledgement as in Article 5], according to its domestic legislation as it sees appropriate, in accordance with principles set out in this Protocol.

ARTICLE 7 - REVIEW OF DECISIONS [UNDER AIA]

1. [The Party of import shall require that] If at any time a Party of [import] [export] [transit] [or any other person] [has reason to believe, taking into account available scientific information,] [becomes aware of relevant new information] that an LMO [and/or products thereof] [is likely to] [may] cause [significant] adverse effects on [conservation and sustainable use of biological diversity, [including within the Party of import][taking also into account risks to human health]] [the environment, biological diversity, human and animal health and agriculture], that Party may prohibit such movements or specify the conditions under which all such movements may take place. In such a case, the Party must [promptly] [within [15] [30] days] inform [any notifiers who have previously notified movements, to [or from] the Party of the LMO [and/or products thereof], [Parties concerned,][the Party of import] [the Secretariat] [and the Clearing-house] and giving the reasons for its decision.

2. A Party of export [exporter] may request a Party of import [through its designated [national] competent authority] to [conduct risk assessment in order to] review a decision it has made in respect of it under Article 6 where the Party of export considers that:

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

(b) Additional relevant scientific or technical information has become available; [or]

(c) There is reasonable evidence that the decision has not been based on scientific [socio-economic, cultural or the precautionary] principle[s] and supported by the best available scientific evidence.

In such a case, the receiving Party shall be able to require the Party of origin to cover some or all the costs of the assessment.

3. Exporting Parties [may] [shall] provide any additional information which [they consider][is] relevant to a review of the import decision. Importing Parties shall respond to such requests, in writing, within a reasonable period of time, and provide full details on the basis for their decision. In light of new scientific evidence and information made available to the receiving country Party, a new application may be submitted in respect of a previously rejected application.

4. A [receiving Party] [Party of import] may at any time in light of information or evidence, unilaterally review its decisions on any transfer, handling or use of LMOs into its country and employ any review mechanism

established through its national legislation or any other national procedures. [In a case of dispute the costs of risk assessment will be borne by the exporter.]

ARTICLE 8 - NOTIFICATION OF TRANSIT

Option 1

No provision on notification of transit is necessary.

Option 2

1. [Parties] [The State [Party] of export] [may] [must] require notification [by the exporter], in writing, [through their focal point] [through the channel of the competent authority of the State of export or by providing a copy to this authority] of other Parties intent to transit [for the first time] a living modified organism [or products thereof] through their territory [for a specified use or purpose] [as well as assuming responsibility for any cases of accidental release in those States]. [All the requirements for labelling, packaging and transportation shall be met]. Where such notification is required, [Parties that require notification of intent to transit living modified organisms [or products thereof], through their territory][the State of export] [shall/should] [provide information /stipulate] [included in Annex X] [to the Clearing-house] on:

(a) Details of the categories of living modified organisms [and products thereof] for which notification is required; and

(b) Information to be provided with the notification, [based on that set out in Annex Y].

2. The State of transit shall [promptly] acknowledge the receipt of the notification to the notifier. It may subsequently respond to the notifier, in writing, within 30 days:

(a) Consenting to the transit movement with [or without] conditions;

(b) Denying permission for the movement; or

(c) Provide an interim response, that may contain a statement to import with [or without] specified conditions or prohibiting import during the interim period. This may include a statement that a final decision is under consideration and/or a request for further information and/or extended period of time to respond.

3. The State of transit may declare in writing whether or not a notification is required for subsequent transit movements of the same living modified organism [or products of an LMO] and it shall inform the Secretariat and previous notifiers of such decisions. The handling and transport requirements for living modified organisms referred to in Article 4 shall be followed in all transit movements.

4. The documentation provided for the transport of living modified organisms [or products of an LMO] [shall as appropriate][must] specify the care needed during their transit.

ARTICLE 9 - SIMPLIFIED PROCEDURE

Option 1

No provision for a simplified procedure in the Protocol. 5/

Option 2

1. [Without prejudice to paragraph X of Article 6,] a Party of import [shall] [should] [may] [by means of a unilateral declaration or a bilateral, regional or multilateral agreement [or arrangement]], [giving reasons,] [on the basis of the best available scientific knowledge and experience and any other relevant information] [provided that any relevant international standards are applied and that adequate measures are observed to ensure the safe transboundary movement of living modified organisms resulting from modern biotechnology, in accordance with the objectives of this Protocol], specify in advance [communicate in its response [under the AIA Procedure] to the State [Party] of export] [to other Parties]:

(a) Cases for which [repeated] transboundary movement to that Party may proceed according to its regulatory framework implementing Article 8(g) of the Convention on Biological Diversity, provided that the framework includes a control mechanism for transboundary movement consistent with this Protocol; and

(b) Cases for which [repeated] [subsequent imports of the same LMO] transboundary movement can take place at the same time as the movement is notified to the Party of import [or the importer] [Cases for which the AIA [for subsequent imports of the same LMO] can be substituted by notification] [simplified procedures]. Such notifications may apply to subsequent similar movements to the same Party;

(c) LMOs to be exempted from the AIA procedure.

The information relating to a transboundary movement that is to be provided in the notification referred to above is the information specified in Annex X.

OR

1. Parties of import may introduce simplified procedures for Advance Informed Agreement for [subsequent] imports of living modified organisms [or products of an LMO], provided that any relevant international standards are

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5/ This provision can be reflected in Articles 6 (Response to AIA notification), 10 (Subsequent imports) or 11 (Bilateral and Regional Agreements).

applied and that adequate measures are observed to ensure the safe transboundary movement of living modified organisms resulting from modern biotechnology, in accordance with the objectives of this Protocol.

2. If a State of import decides, pursuant to this Article, to exempt certain living modified organisms [or products of an LMO] from the application of the AIA procedures or to apply simple notification procedures to certain living modified organisms [or products of an LMO], it shall inform the [Biosafety Database] [Secretariat of the Protocol] in writing accordingly. [The Secretariat shall forthwith inform all [Contracting Parties] of such decisions.]

ARTICLE 10 - SUBSEQUENT IMPORTS

Option zero

No provision for subsequent imports is necessary. 6/

Option 1

[Provided the first transboundary movement has received AIA without conditions, then] [No provision on subsequent imports is necessary] [subsequent transboundary movements to the same Party of import may be covered by a single notification].

Option 2

1. Notification of subsequent imports of the same living modified organism into the same [State] [Party] of import [shall] [may] not be required unless specifically requested in writing by the [State] [Party] of import in cases where there may be:

(a) A change in the intended use of the living modified organism; or

(b) Variation in the receiving environment; or

(c) Other factors likely to affect the risk assessment or risk management.

2. Where notification for subsequent imports is specifically requested by the importing Party, full details regarding the information required [shall] [should] be provided, in writing, to exporting Parties or exporters and to the Clearing-house. The information required [shall] [should] be based on that identified in [Annex I] [information required for notification of import of a living modified organism].

Option 3

1. Notification in writing is required for all subsequent imports of the same living modified organism [and products thereof] into the same Party of import.

6/ The provisions of this article could be reflected in Articles 6 or 9.

2. The State of import will acknowledge receipt of notification as quickly as possible and will inform the State of export that:

(a) Importation can proceed; or

(b) A new risk assessment procedure will be undertaken.

Option 4

1. A [State] [Party] of import may at any time declare that subsequent imports of a specific LMO [or products of an LMO] into its territory for specified uses or purposes, are exempted from the requirement of AIA in Article X. Such an exemption [may] [shall] specify a procedure for a [simple] [prior] notification [indicating that the intentional transboundary movement can take place at the same time, that a specific movement is notified to the State of import specifying the information to be contained in the notification and procedures for risk assessment and decision-making alternatives to those established for the first import].

2. The [State] [Party] of [export][import] shall inform the Secretariat [clearing-house mechanism] [of such declaration] [and previous notifiers of any declaration that it has made pursuant to paragraph [x] of the Article.

3. When AIA for the first transboundary movement has been given but with conditions, then the importing Party will specify that subsequent imports be notified, and [shall] [may] establish for this purpose:

(a) Notification procedures;

(b) Information requirements to be contained in the notification; and

(c) Procedures for risk assessment and decision making alternatives to those established for first import.

ARTICLE 11 - [INTERNATIONAL COOPERATION] MULTILATERAL, BILATERAL AND REGIONAL AGREEMENTS [OTHER THAN THE PROTOCOL]

Option zero

No provision for [international cooperation], multilateral, bilateral and regional agreements is necessary.

OR

Option 1

1. [Recipient] [Contracting] Parties may enter into bilateral, multilateral, or regional agreements or arrangements [with Parties] [or non-Parties] regarding [procedures and information exchange relating to] transboundary movement of LMOs [or products of an LMO] [falling within the scope of this Protocol] [in lieu of the AIA requirements] [provided] [that] such agreements or arrangements] [will not derogate from the provisions of this Protocol] [do not derogate from the environmentally sound management of living modified organisms as required by this Protocol] [do not result in a

lower level of protection than the one provided for by the Protocol] [stipulate provisions which are not less environmentally sound than those provided for by this Protocol in particular taking into account the interests of developing countries].

2. [The provisions of this Protocol shall not affect transboundary movements that take place pursuant to such agreements and arrangements as between the Parties to that agreement or arrangement.]

[3. Bilateral, multilateral or regional agreements or arrangements give further basis for:

(a) The identification of categories of LMOs [or products of an LMO] to which the simplified procedures provided for in Article 9 apply;

(b) A guidance to transboundary movement of LMOs [or products of an LMO] involving non-Parties.]

4. Parties shall notify the Secretariat of [any] such [bilateral, regional and multilateral] agreements or arrangements entered into [either before or after entry into force of this Protocol]. [Any Party may notify the Secretariat at any time that AIA provisions shall not apply with respect to imports to such Party.]

5. 7/ The Parties [shall][should] cooperate among themselves in exchanging information [and when appropriate], developing appropriate technical guidelines and/or codes of practice, and monitoring the [benefits of modern biotechnology] the effects of [risks posed by] living modified organisms [and products thereof] on [human and animal health,] biological diversity, the environment and [socio-economic welfare of societies] with a view to promoting the safe management of these organisms [and products]. The Parties [shall] [should] assist developing countries in the implementation of this Protocol, taking due account of their needs with respect to capacity-building in order to promote the development and transfer of safe biotechnology and knowledge.

6. 8/ A regional economic integration organization, which itself is a Contracting Party to the Protocol and has a specific legal framework for biosafety, may declare that the Protocol shall not apply to movements within its territory.

ARTICLE 12 - RISK ASSESSMENT

Option zero

No provision on risk assessment is necessary in the Protocol.

7/ Some delegations indicate that this paragraph could be moved either to the article on general obligations or to the article on information exchange and/or capacity-building.

8/ This will be referred to Contact Group 2 so as to seek advice on the most appropriate place for this provision.

Option 1

1. [Risk assessment] [Each decision [under Articles X...[based on risk assessment]]] [shall] [should] be undertaken [on a case-by-case basis] [in a scientifically sound [and transparent] manner] [be based [exclusively] on [the information provided by the Party of export in accordance with Annex I] [scientific grounds, the precautionary principle, socio-economic and cultural concerns and experience] [on scientific information provided by the [exporter] [importer] and other available scientific evidence] to identify and evaluate the possible adverse effects [due to the genetic modification] of [that] LMO[s] [or products [of an LMO]] [thereof] on [the environment of the State of import as regards in particular] conservation and sustainable use of biological diversity, [taking into account the risks to human health], [agriculture, human and animal health], [ecological stability concerns] [and social and ethical considerations][as the basis for decisions under the AIA procedure[s]].

2. Risk assessment [as described in Annex X and] as referred to in paragraph 1 above [shall] [should] be undertaken, [or be required to be undertaken] by [the] [competent authority of] [[Party of import] [each Party] [any natural and legal person [under its jurisdiction] who intends to [undertake a] transfer [handle or use] [of] an LMO] [the Party of export] [and] [a regional group of Parties as agreed to by such Parties].

OR

2. The importing Party may ask the exporter [notifier] to carry out the risk assessment. The importing Party may then ask for the results of the risk assessments carried out by the exporter [notifier] or verify that the assessment was carried out according to international standards. The importing Party shall then be responsible for the risk assessment.

3. Each Party shall determine for itself, in accordance with its own legislation, the institutional arrangements for the conduct of risk assessments under this Protocol and for the preparation of technical findings in relation to requests for transboundary movement.

4. Risk assessment [shall] [should] be [required to be] undertaken [prior to the [first] [import] [release] of an LMO [a specific LMO for specific uses or purposes] [into the environment]] [prior to the use, transboundary [movement] [transfer] or handling of LMOs to or within the [State] [Party of import] [any Party]] [and for subsequent imports of the same LMO into the same State of import at the discretion of the State of import, except for the following cases where [alternative procedures for] risk assessment shall be required:

(a) Where there is a change in the intended use of the LMO;

(b) Where there is a variation in the receiving environment; or

(c) Where there are other factors likely to affect the risk assessment or risk management of the LMO].

5. Risk assessments as described in paragraph X of this article [shall] [should] [be carried out in accordance with Annex X] [and take into account existing guidelines relevant to biosafety]. A Party of import may, however, apply parameters additional to those specified in that Annex.

OR

5. [The Conference of the Parties shall establish [will consider the establishment of] a minimum standard of risk assessment of LMOs. The minimum standard shall be reviewed periodically by the Conference of the Parties in light of the most recent and best available scientific [, socio-economic and cultural] knowledge and experience, as well as other relevant information. The Conference of the Parties may establish a technical advisory body for providing them with scientific backgrounds for reviewing the standard.

6. No provision on responsibility is necessary.

OR

6. The [exporter] [importer] [notifier] is responsible for the reliability of the information provided.

7. No provision on financial responsibility for risk assessment is necessary.

OR

7. The financial responsibility for risk assessment shall rest with the [Party of export] [notifier].

8. The Parties shall, taking into account in particular the needs of developing countries and countries with economies in transition, cooperate in order to promote international harmonization in risk-assessment [and risk-management] procedures. 9/

9. No provision on microorganisms is necessary.

OR

9. Parties shall ensure that risk-assessment and management processes of microorganisms are conducted in contained conditions.

Elements for consideration for inclusion in Article 21

[The Party of import may request technical or financial assistance from the Party of export or the exporter with the carrying out of the risk assessment. Such requests [should] [shall] be met to the extent possible, especially in cases where the Party of import does not have sufficient experience of the LMO in question or lacks the financial and technical capacity to carry out the risk assessment. Parties should [,where appropriate,] collaborate with the State of import in carrying out risk assessment [through the sharing of information and expertise].]

9/ Could be dealt with under Article 21 (Capacity-building).

ARTICLE 13 - RISK MANAGEMENT

Option 1

No article containing provisions concerning risk management is required.

Option 2

1. In accordance with Article 8(g) of the Convention, [each Party] Parties [intending to undertake any transfer, [handling or use] of living modified organisms to or within the Party of import] shall establish and maintain [appropriate] national [mechanisms] [measures and strategies] to regulate, manage or control risks [identified under the risk assessment provision of the Protocol] [associated with the [safe use, handling and] transboundary movement of LMOs [or products of an LMO]].

OR

1. The Party of export shall ensure that the risk-management strategies and measures proposed for implementation by the Party of import shall [correspond to the results of the assessment referred to in Article X] [be established for both confined and contained uses and semi- and commercial releases] [incorporate strategies and measures that will minimize, [prevent or mitigate] the potential [negative] socio-economic effects and impacts within the Party of import], [particularly where the introduction of living modified organisms into the environment of the Party of import may entail a displacement of a particular agricultural or resource use system or the culture and livelihood of the local people.]

2. The type of risk management to be employed shall be appropriate to the living modified organisms and activity in question and such risk-management strategies and measures shall [be commensurate with] [correspond to the results of] the assessment of risk. The type of risk management and the [practices] [measures] set out in Annex X shall be employed as a minimum.

3. [If the Party of import lacks the financial and technical capacity to do so,] [it may request] the Party of export [shall offer technical and financial assistance and] shall collaborate with the Party of import [for risk management].

4. Without prejudice to paragraph x above, each Contracting Party in order to ensure genomic and trait stability in the environment, any LMO [or products of an LMO], whether imported or locally developed, shall undergo a period of observation commensurate with its life-cycle or generation time as the case may be before it is put to its intended use. Risk-management schemes shall take due account of the different purposes or uses for which the living modified organisms or the products thereof are being developed or produced.

5. Parties shall cooperate with the view to ban or phase out, LMOs[or products of an LMO] or specific traits of LMOs[or products of an LMO], that may have global adverse effects on the conservation and sustainable use of biological diversity or human health.

6. Parties shall require producers of living modified organisms to phase out all antibiotic resistance marker genes in living modified organisms by the year 2002.

7. Import restrictive measures based on risk assessment [and in particular on sound and scientific information] [shall] [may] be imposed [to the extent necessary] to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, [human health and socio-economic considerations] within the territory of the State of import. [Lack of full scientific certainty or of scientific concern regarding the level of risk shall not be used as a reason for postponing measures to prevent harm.]

ARTICLE 14 - MINIMUM NATIONAL STANDARDS 10/

Option 1

No provisions are necessary.

Option 2

1. 11/ Each Party shall ensure that appropriate legal, institutional and administrative measures concerning the safe research and development, manufacture, transfer, handling and use of living modified organisms are in place [upon the date of entry into force of this Protocol for that Party] [two years after the date of ratification of accession of this Protocol]. [In addition to establishing such measures at the national level, Parties shall also cooperate in establishing at the international or regional level, procedures to carry out risk assessment under Article X.

2. Such measures shall adequately regulate both contained use and deliberate release. With regard to contained use of living modified organisms [or products thereof], each Party shall apply the measures set out in Annex X.

3. 11/National measures shall, as a minimum, fulfil the requirements set out in this Protocol with regard to the safe transfer, handling and use of living modified organisms, including those relating to risk assessment under Article 12 and enforcement conditions or prohibitions under Article 13.

4. 11/ Parties may impose more stringent or comprehensive requirements, based on [the precautionary principle] [scientific considerations].

10/ It was noted that Minimum National Standards should be linked to capacity-building.

11/ The paragraphs 1, 3 and 4 of option 2 can be addressed in Article 1 bis (General obligations).

Annex II

ARTICLES REVIEWED BY SUB-WORKING GROUP II

Articles 1, 1 bis and 15-27

ARTICLE 1 - OBJECTIVES

[Option 1

The objectives of this protocol, to be pursued together with the relevant objectives and provisions of the Convention, is to safeguard human and animal health, the environment, biological diversity and the socio-economic welfare of societies from the potential risks of biotechnology, particularly modern biotechnology involving the development, handling, transfer, use and release of living modified organisms and products thereof.

Option 2

1. The objective of this Protocol is to [contribute to ensuring an adequate level of protection in the field of biosafety specifically focusing on] [promote [shared responsibility and co-operative efforts among Parties to achieve] the safe] transboundary movement of [all] LMOs [and products thereof] resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity [, taking also into account the risks to human health] [by promoting and facilitating information exchange and providing for appropriate procedures] [including through exchange of information and a scientifically-based and transparent system of advance informed agreement].

2. [The objective of this Protocol is to ensure that transboundary movements of LMOs take place in conditions that are safe for the conservation and sustainable use of biological diversity and human health; to mitigate the harmful effects of unintentional transboundary movement; as well as to strengthen the capacities of developing countries and countries with economies in transition, inter alia, through adequate financing; to control transboundary movement; and for the environmentally sound management of the organisms subject to this Protocol.]

Option 3

The objective of the Protocol is to ensure safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity taking into account the risks to human health. [The objective is also to ensure that these activities take into account human and animal health, and take place in accordance with the principle of sustainable development and in a socially and [ethically] [economically] justifiable way.]

Option 4

The [objective of this] Protocol [shall apply] [is] to [ensure] the safe transfer, handling and use [, in a transboundary context,] of LMOs resulting from [modern] biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.

Option 5

The objective of this Protocol, to be pursued in accordance with its provisions and those of the Convention on Biological Diversity, is, with a view to attaining the objectives of the Convention, to set out appropriate procedures, including, in particular, advance informed agreement (hereinafter referred to as "AIA"), in the field of the safe transfer, handling and use of any living modified organisms (hereinafter referred to as "LMOs") resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, [on human health and on socio-economic well-being].

Option 6

The objective of this Protocol is to promote the establishment and maintenance of a system of Biosafety with special consideration to transboundary movement of LMOs resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account the risks to human health.]

ARTICLE 1 BIS - GENERAL OBLIGATIONS

Option zero

No provision necessary.

Option 1

1. The Parties to the present Protocol undertake to implement the provisions of the Protocol and the Annexes hereto which shall constitute an integral part of the present Protocol.

2. Parties shall ensure that the development, handling, transport, use, transfer and release of any LMOs [or products thereof] are undertaken in a manner that prevents or reduces to [acceptable levels, risks] [the minimum possible risks, within an acceptable range] to human and animal health, biological diversity[,] [and] the environment [and socio-economic welfare of societies].

3. [Parties shall prohibit the export of LMOs or products thereof unless they obtain] [Subject to the provisions of Article [ ], Parties shall not approve or allow the export of LMOs until such time as they have obtained] an advance informed agreement in writing from the State of import for the specific import.

4. Parties shall prohibit the export of any LMOs or products thereof to the Parties which have prohibited the import of such organisms [or products]. Parties exercising their right to prohibit the import of LMOs [or products thereof] shall inform the Secretariat and the Biosafety Clearing-house of their decision.

[5. No Party shall export or import LMOs [or products thereof] to or from non-Parties.]

6. Parties shall cooperate among themselves in order to achieve an environmentally sound system of management of the potential risks of LMOs [and products thereof].

7. Each Party shall take the appropriate [legal, administrative and other] measures to:

(a) Ensure safety in biotechnology, especially in the transboundary transfer and [handling, use and] release of LMOs resulting from modern biotechnology;

(b) Ensure that persons involved in the development, handling, transfer, use or release of LMOs [and products thereof] take such steps as are necessary to avoid unacceptable risks to human and animal health, biological diversity [,] [and] the environment [and the socio-economic welfare of societies];

(c) Require that information about a proposed transboundary transfer of any LMOs [or products thereof] be provided to the States concerned according to the appropriate procedures of notification set out in Article [ ] of this Protocol;

(d) Prohibit the export of any LMOs [or products thereof] to a State, or group of States belonging to a regional economic integration organization that includes Parties, which has prohibited imports of such LMOs by its legislation [, or if it has reason to believe that the organisms or products in question will not be managed in an environmentally sound manner, according to criteria to be decided on by the Parties at their first meeting];

(e) Cooperate with other Parties and may involve interested organizations as appropriate, directly and through the Secretariat and the Biosafety Clearing-house, with respect to the necessary measures for safety in biotechnology, including the dissemination of information on LMOs [or products thereof, in order to ensure the environmentally sound management of such organisms and products and to achieve the prevention of illegal traffic and unintended releases];

(f) Ensure that appropriate national authorization is required for all activities, including experimental, involving development, handling, use, transfer and release of LMOs [or products thereof];

(g) Require that LMOs [or products thereof] that are to be the subject of transfer or a transboundary transfer be packaged, labelled, and transported in conformity with the rules and requirements to be set out by the Secretariat and the competent authorities of the States concerned;

(h) Require that LMOs [and products thereof] be accompanied by a transfer document from the point at which a transfer and transboundary transfer commences to the point of use or release.

[8. The Parties agree that failure to provide all the necessary information available about the LMOs or products thereof and any illegal traffic are criminal.]

[9. Each Party shall take appropriate legal, administrative and other measures to implement and enforce the provisions of this Protocol, including measures to prevent and punish conduct in contravention of the Protocol.]

[10. The obligation under this Protocol of States in which the LMOs or products thereof have been developed and in which they have originated is to require that those organisms or products are managed in an environmentally sound manner and may not under any circumstances be transferred to the States of import.]

11. Nothing in this Protocol shall prevent a Party or group of Parties from imposing additional requirements that are consistent with the objective and provisions of this Protocol and are in accordance with the rules of international law [, in order to better protect human and animal health, biological diversity, the environment and the socio-economic welfare of societies].

Option 2

General

1. Parties shall take all [necessary] [appropriate legislative and/or administrative] measures to comply with the provisions set out in this Protocol for the safe transboundary movement of LMOs resulting from modern biotechnology [, and, in particular, measures to prevent transboundary transfer of LMOs not pursuant to the provisions of the Protocol].

AIA

2. Parties shall introduce, as necessary, implement and enforce national provisions in order to ensure compliance with the advance informed agreement procedures set out in Articles 6-11 of this Protocol, and shall ensure that advance informed agreement measures for the import of a LMO are implemented in a transparent manner, based on scientific principles and supported by the best available scientific evidence.

Information exchange

3. The Parties shall, in accordance with this Protocol, exchange information on LMOs in order to contribute to the environmentally sound management of biotechnology.

Cooperation

4. Each Party shall cooperate with other Parties for the internationally harmonized implementation of the provisions of the Protocol.

Disguised restriction on trade

5A. The Parties shall ensure that measures taken for the oversight of transboundary movement of LMOs do not create unnecessary obstacles to, and/or constitute a means of arbitrary or unjustifiable discrimination or disguised restrictions on international trade.

OR

5B. Parties shall ensure that AIA measures for the import of a LMO are not more restrictive than measures applied to the same LMO produced domestically or imported from other Parties and are applied in a manner which does not constitute a disguised restriction on international trade.

Additional requirements

6. Parties may impose additional requirements for the safe transboundary movement of LMOs resulting from modern biotechnology, provided that they are consistent with the provisions of this Protocol and accord with other relevant international agreements.

Transport of LMOs

7. Without prejudice to compliance with relevant international requirements for transport operations, the Parties shall, where appropriate, ensure that LMOs within the scope of this Protocol and subject to intentional transboundary movement are accompanied by relevant information on LMOs, as specified in Annex [ ], and that the exporter shall be able to prove that the movement is in conformity with the requirements of the Protocol. Transport of LMOs shall be carried out under safe conditions in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Territorial sea and exclusive economic zone

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

Option 3

1. Each Party shall, in accordance with its particular conditions and capabilities:

(a) Develop an institutional framework for the execution of the provisions set out in this Protocol;

(b) Develop national strategies, plans or programmes for the provisions set out in this Protocol or adapt, for this purpose, existing strategies, plans or programmes;

(c) Integrate, as far as possible and as appropriate, the provisions set out in this Protocol into relevant national strategies, plans or programmes.

2. Importing Parties may impose additional requirements, for the safe transboundary movement of LMOs, and products thereof, provided that they are:

(a) Based on scientific principles and supported by the best available scientific evidence;

(b) Detailed in national laws and regulations of the importing Party; and

(c) Consistent with the provisions of this Protocol and in accord with other relevant international agreements.

MERGER OF ARTICLE 15 AND ARTICLE 16 - UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

[1. The Parties shall [take the necessary measures] and [ensure that], [as soon as] [whenever] [it comes to their knowledge], [immediately] [notify] affected and potentially affected Parties, [generally through] the competent authorities of the States concerned [and the Clearing-house mechanism] [of the Protocol] [are immediately notified] in the event of:

[(a) An accident, and/or]

[(b) Unintentional transboundary movement of living modified organisms [and known domestic releases of LMOs which may result in unintentional transboundary movements]]

[which occur in the course of a transboundary movement and would otherwise be subject to AIA or to conditions imposed by a previous AIA decision and] which are likely to have significant adverse effects on the conservation and sustainable use of biological diversity, [taking also into account human health, [welfare and the environment]].

[2. Such [Each] notification should include information [considered relevant] regarding inter alia:

(a) Adverse effects on human health, the conservation and sustainable use of biological diversity and/or the environment [and agricultural production] in other States;

(b) The circumstances of the accident and/or unintentional movement;

(c) The identity, relevant characteristics and numbers/volumes/ quantities of the LMOs involved and released;

(d) Any available information necessary to assess the effects of the accident and/or unintentional movement, including their effects on human and animal health, the environment, and biological diversity;

(e) An assessment of the risks to the conservation and sustainable use of biological diversity and/or human health, [as well as] risk-management measures needed, including those regarding the handling of the organisms;

(f) Emergency measures taken or needed to be taken, including measures identified under Article 14 (1) of the Convention.

(g) The information specified in Annex I;

(h) Any other [available] information considered relevant.

[3. The Party which is the origin of an accident and/or unintentional transboundary movement [which is likely to present a threat] shall immediately [notify and] take action, [at its own cost] in consultation with the affected Party, to minimize negative impacts on the environment and to prevent further release or transboundary movement of the LMO.]

[4. If necessary, the affected Party(ies) may request the Party from which the unintentional transboundary movement originates, to assist in emergency measures with the aim of minimizing adverse effects on conservation and sustainable use of biological diversity and human health.]

[5. The States concerned shall, where information is provided, ensure that in any emergency, the medium- and long-term measures necessary are taken, including the immediate alerting of any other State which could be affected by the accident.]

[6. The affected State(s) may ask for consultations among the concerned States.]

[7. Each Party shall avoid any activity that may lead to accidental or unintended releases of aquatic living modified organisms, in particular into freshwater and marine ecosystems.]

ARTICLE 17 - HANDLING, TRANSPORT, PACKAGING AND LABELLING

Option 1

[No provision necessary]

Option 2

[1. In order to maintain adequate safety levels during transport, each exporting Contracting Party shall [establish appropriate] [promote, as appropriate,] measures for handling, transportation [,] [and] packaging [and transit] of LMOs [subject to the article on AIA] for transboundary transfer.]

[2. The [Conference of the] Parties shall aim at developing standards with regard to packaging and transport practices under the Protocol.]

Option 3

[1. Parties shall ensure that LMOs [subject to AIA]/[within the scope of the Protocol] and subject to transboundary movement are:

[(a) Clearly [identified]/[labelled] as LMOs, including information on the type of LMO, names and contact details of the importer, exporter and focal points of the importing and exporting Parties;]

[(b) Subject to no less stringent requirements of classification, packaging and labelling than comparable products destined for use in the State of export;]

[(c) Handled, packaged, [labelled] and transported under safe conditions [in accordance with international rules and standards,] [particularly in accordance with the United Nations Recommendations on the Transport of Dangerous Goods] in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;]

[(d) Accompanied by [relevant][information on the LMOs [and the products thereof]], [movement document/documentation from the point at which the transfer commences to the point of use] [and] [appropriate labelling] [as specified in Annex [xx].]]

[2. The Parties shall aim at developing standards with regard to packaging and transport practices under the Protocol.]

ARTICLE 18 - COMPETENT AUTHORITY/FOCAL POINT

[1. To facilitate the implementation of this Protocol, each Party shall designate [and, if it does not have one, establish] one [or more] national focal point(s) which shall be responsible for liaison with the Secretariat on behalf of that Party. Each Party shall also designate one or more competent [government] authority(ies), [who is authorized to deal with all aspects relating to the stipulations of the Protocol] whose responsibilities shall include, [inter alia, establishing national guidelines and/or regulations] receiving applications and notifications and communicating decisions on living modified organisms in accordance with the Advance Informed Agreement procedure set out in articles 3, 4 and 5 and ensuring that risk assessments are undertaken, as necessary, in accordance with article 12.

2. Where a Party designates more than one competent authority, and/or more than one focal point, it shall specify the areas of responsibility for each [with sufficient precision for a notifier to know which competent authority deals with which type of living modified organisms/area of responsibility]. The competent authorities shall be authorized to act on behalf of the Party with respect to these responsibilities. A Party may designate a single agency to fulfil both functions of focal point and competent authority.

3. Each Party shall inform the Secretariat [no later than the date of entry into force of the Protocol] [within three months of the date of entry into force of the Protocol] for that Party in question, which agencies have been designated as its focal point(s) and its competent authority(ies).

4. Parties shall inform the Secretariat [and the Biosafety Clearing-house] [immediately] [within [ ] days of the date of decision] of any changes regarding the designation made by it under paragraphs 1 and 2 above.

5. The Secretariat shall forthwith inform the Parties of notifications received under paragraphs 2 and 3 above.

6. The Secretariat shall also transmit the information from Parties in accordance with paragraphs 1, 2, 3 and 4 above for inclusion in the [database] [Clearing-house mechanism] provided for in article 19, on information-sharing.]

ARTICLE 19 - INFORMATION SHARING/BIOSAFETY CLEARING-HOUSE/ [BIOSAFETY DATABASE]

[Option 1

1. The Parties shall facilitate the collection and exchange of [publicly available] [scientific, technical, environmental and legal] information on, and experience with, LMOs to enable Parties to make informed decisions related to biosafety, taking into account the special needs of developing countries and the countries with economies in transition, through a [Biosafety Clearing-house] [Biosafety Database].

2. Each Party shall make available to the [Biosafety Clearing-house] [Biosafety Database] whenever it comes to its knowledge, relevant [publicly available] information when an unintentional release of a LMO is likely to present risks to the conservation and sustainable use of biological diversity.

[3. The terms of reference and functioning of the Clearing-house, including elements of information, and the conditions under which that information is submitted by the Parties, should be determined by the first meeting of the Parties to the Protocol.]

Option 2

1. The Parties shall provide the Secretariat of the Protocol with the following information:

(a) National regulatory framework for the implementation of the Protocol, including:

(i) Names, addresses and telecommunication numbers of the national focal point and the competent authorities;

(ii) National guidelines and/or regulations for the implementation of the Protocol, including information required for the AIA procedures and for risk assessment;

(iii) Any bilateral, regional and multilateral agreements or arrangements as well as unilateral declarations on the exemption and/or the simplification of the AIA procedures.

(b) Periodic reports on the implementation of the AIA procedures, including statistics.

2. The Secretariat of the Protocol shall circulate the information received pursuant to paragraph 1 above to all Parties.

3. The Parties are encouraged to make available to all interested parties, including other Parties, regional and international institutions as well as individuals, information on the implementation of the Protocol, not included in paragraph 1 above.

Option 3

1. The Parties shall facilitate the collection and exchange of [publicly available] [scientific, technical, environmental and legal] information on, and experience with, LMOs to enable Parties to make informed decisions related to biosafety, taking into account the special needs of developing countries and the countries with economies in transition, through a [Biosafety Clearing-house]/[Biosafety Database].

2A. The mechanism for the exchange of information and cooperation under the Protocol shall be the clearing-house mechanism established by the Convention in its Article 18, paragraph 3.

OR

2B. A [Biosafety Clearing-house]/[Biosafety Database] should be established no later than the date of entry into force of this Protocol [on the basis of existing international biosafety exchange mechanisms].

3. The [Biosafety Clearing-house]/[Biosafety Database] shall serve as a body for information exchange, [monitoring of implementation,] and scientific and technical cooperation among Parties. [It shall report regularly to the [Meeting of the Parties] [Conference of the Parties serving as the Meeting of the Parties to this Protocol] on all aspects of its work and to the Secretariat [regarding the implementation of procedures on notification and Advance Informed Agreement.]] [The modalities of establishment of the [Biosafety Clearing-house]/[Biosafety Database] shall [should] be considered and decided upon by the Parties at their first meeting.]

4A. Each Party of import shall make available to the [Clearing-house mechanism]/[Biosafety Database], subject to appropriate protection of confidential, business information identified in 5(b), 5(h) and 5(j) [below];

OR

4B. Each Party shall make available to the [Biosafety Clearing House]/[Biosafety Database], information pertaining to that Party with respect to paragraph 5(b) and [publicly available] information pertaining to that Party with respect to 5(c) and 5(e)[below].

5. Without prejudice to the protection of confidential information [Article 20 (Confidential Information)], the [Clearing house mechanism]/[Biosafety Database] shall [include] [contain and provide public access to] information [relevant to the implementation of the Protocol] as follows:

(a) Information on measures adopted under national legislation;

(b) Information to assist other Parties in decision-making under the Protocol with respect to national laws, regulations, guidelines, codes of practice and administrative procedures for the safe transfer, handling and use of LMOs;

(c) Information on risk assessments or environmental reviews generated by the regulatory process [,including the time taken for import decisions to be made];

(d) Information relating to the appropriate assessment and management of risks;

(e) Information on decisions regarding the importation, field testing, or commercial use of any LMO [,including the time taken for import decisions to be made];

(f) Information on decisions adopted by countries with regard to the transboundary movement of LMOs;

(g) All living modified organisms which have been subject to bans or restrictions in that Party;

(h) Information on accidental or unintended movements of LMOs, including contingency or mitigation plans to be used in such event;

(i) A list of LMOs subject to advance informed agreement which have been assessed or imported into or used in its territory at the time of coming into force of this Protocol for that Party, including a description of any conditions attached to imports of such LMOs;

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

(k) Any other information regarding LMOs that the Party considers would be of benefit to other Parties and to the public, including information with respect to risk assessment and management, and other scientific information;

(l) General description of products consisting of or containing LMOs having received consent by a Party or Parties for placing on the market;

(m) A summary of any methods and plans for monitoring LMOs;

(n) [Information on] any decision on a notification of an intentional transboundary movement [and the summary of the risk assessment] [decisions adopted by countries regarding the transboundary movement of LMOs];

(o) Information concerning [the] biosafety regulatory framework on LMOs [of each Party];

(p) [Information on]/[A summary of] any [notified] unintentional [accidental] transboundary movements [including contingency or mitigation plans to be used in such event] [which are likely to have significant adverse effects in another Party or non-Party on the conservation and sustainable use of biological diversity, taking also into account risks to human health];

(q) The text of decisions taken pursuant to Article [safeguard clause as referred to in UNEP/CBD/BSWG/3/3/Add 1.];

(r) Relevant data on designated competent authority or focal point(s) provided under Article 18.

[6. The Secretariat shall keep this database up-to-date and accurate; submit as soon as possible to the Conference of the Parties a proposal for the format to be used for the inclusion of information in the Database.]

7. Each Party shall inform its public about the contents of, and mode of public accessibility to, the Biosafety Clearing-house.]

ARTICLE 20 - CONFIDENTIAL INFORMATION

[Option 1

No provision necessary

Option 2

1. The importing Party shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the importing Party as part of the Protocol's Advanced Informed Agreement process that should be treated as confidential. Justification must be given in such cases upon request.

2. The importing Party shall consult with the notifier if it believes that information identified by the notifier as confidential does not qualify for such treatment and shall inform the notifier of its decision prior to disclosing the information.

3. A Party shall [protect] [protect and not disclose] confidential information, [including commercial in confidence information] received under the Protocol, including any confidential information received in the context of the Protocol's Advanced Informed Agreement process. [Each Party shall ensure that it has procedures to protect such information [and shall protect the confidentiality of such information in a way no less favourable than its treatment of confidential information in connection with domestic LMOs]].

4. A receiving Party may not use such information for a commercial purpose, except with the agreement of the notifier.

[5. If, for whatever reason, including in cases where the competent authority and notifier disagree, a notifier withdraws a notification, the confidentiality of all the information supplied [and indicated as confidential] must be respected by the competent authorities and focal points, [subject to national legislation].]

[6. Without prejudice to paragraph 5 of this Article, [in no case may the following information be kept confidential] [the following information should not generally be considered confidential]:

(a) The general description of the LMO or LMOs, the name and address of the notifier [, and the purpose of the transboundary movement];

(b) A summary of the risk assessment of effects on the conservation and sustainable use of biological diversity, taking also into account human health; and

(c) Any methods and plans for emergency response.]]

ARTICLE 21 - CAPACITY-BUILDING

Option 1

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, through the appropriate international, regional and national institutions. They shall take due account of the needs of developing countries with respect to capacity-building in order to promote the development and transfer of safe biotechnology and knowledge.

Option 2

1. The Parties [will be encouraged to] [shall] design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and biosafety, through the appropriate international, regional and national institutions. Capacity-building programmes should maximize the use of existing multilateral, regional and bilateral mechanisms [,including those addressed under the Convention] and should be particularly aimed at developing countries.

2. Capacity-building shall aim to ensure that Parties develop and strengthen their capacities to implement the Protocol, including the development of national legislation, frameworks and guidelines related to biosafety. Capacity-building shall also aim to ensure that States involved in the transfer, handling and/or use of living modified organisms [and/or products thereof] are aware of any associated risks and are able to achieve safety through the development of procedures for risk-assessment and risk-management of living modified organisms prior to their introduction. Capacity-building shall also ensure that regional or subregional

activities/centres for training and capacity-building regarding the safe management of living modified organisms shall be established according to the specific needs of different regions and subregions with financial assistance provided through the financial mechanism under the Convention on Biological Diversity.

3. The Parties shall [promote][cooperate towards] capacity-building, in particular, scientific and technical cooperation [assistance], which may include training of personnel, exchange of experts, exchange of information, and educational and institutional strengthening, [in order to strengthen the ability of Importing States] [to build capacity] to perform risk-assessments and to develop and implement [decision-making and] risk-management procedures.

4. The building of national capacity shall be achieved, inter alia, through:

(a) New and additional financial resources;

(b) Training and technical assistance and cooperation;

(c) Technology transfer relevant to the scope of this Protocol;

(d) Technical and financial assistance from the private sector, which should be facilitated and encouraged.

(e) Educational and institutional strengthening.

5. The developed country Parties, recognizing the need for the distribution of benefits from the potentials of biotechnology through training in science related to safety in biotechnology and in the use of risk-assessment and risk-management techniques, and [through] the transfer of relevant knowledge [in biotechnology and biosafety] on fair and most favourable terms, including on concessional and preferential terms, shall establish effective measures to:

(a) Enhance the capacity of developing country Parties [for [strengthening] [developing] human resources and institutional capacities in biotechnology and biosafety];

(b) [Acquire] [develop] relevant biotechnology, and its proper and safe management;

(c) Build up their local, technological and institutional competence [encompassing technical, financial and institutional provisions].

6. The Secretariat shall for the purpose of this article:

(a) Develop and implement programmes based on the identified needs of the concerned parties;

(b) Assist, in particular, developing countries in their efforts to identify, plan and implement their capacity-building requirements, and secure funds including new and additional resources;

(c) Provide, upon request by the Parties to this Protocol or any of its Signatories, any relevant information, scientific, technical or other assistance in particular in the context of risk-assessment and risk-management, in the event of accidents, application of emergency measures and dispute settlement.

ARTICLE 22 - PUBLIC AWARENESS/PUBLIC PARTICIPATION

1. Parties shall [ensure, in accordance with national laws and regulations, that adequate information on the safe transfer, handling and use of LMOs is provided to the public and shall] [take appropriate measures] [to encourage understanding of the safe use, handling and management of LMO's in relation to the transboundary movement and the conservation and sustainable use of biological diversity, including human health,] [and] to enhance [public awareness][adequate public information on][and/or public participation in] the implementation of the protocol, whilst respecting [confidential] [commercial][commercial-in-confidence] information.

[2. The Parties shall cooperate, as appropriate, with other States and international organizations in developing educational and public awareness programmes [with respect to any risks and benefits associated with][on safety in] modern biotechnology.]

[3. Each Party shall promote and facilitate, [at the national, subregional and regional levels], as appropriate, and in accordance with national laws and regulations, [and within their respective capacities,] the development [and implementation] of educational public awareness programmes on safety in biotechnology.]

[4. Parties are encouraged to facilitate public participation in [and access to information on] risk assessment results and decisions [concerning the transboundary movement of LMOs.]

[5. Each Party shall, in accordance with its national laws and regulations, provide the public with an opportunity for involvement in [the processes for] approving the release of [such] living modified organisms, and information on the results of these processes.]

ARTICLE 23 - NON-PARTIES

Option zero

[No provisions needed]

Option 1

[No Party shall export or import living modified organisms or products thereof to or from non-Parties.]

Option 2

[Non-Parties in compliance with the substantive provisions of this Protocol shall be treated on an equal basis with Contracting Parties.]

Option 3

[Parties and non-Parties may enter into bilateral, regional or multilateral arrangements regarding transboundary movements of living modified organisms provided that such arrangements are [compatible with the Protocol.] [in accordance with the [objectives] [the substantive provisions] of this Protocol.][Parties shall not be restricted from trade in living modified organisms with non-Parties, provided that adequate measures are observed to ensure the safe transboundary movement of living modified organisms resulting from modern biotechnology.] Such agreements should be made available to Parties through the Clearing-house mechanism and through the Secretariat of the Protocol.

Option 4

[[1A. Parties shall not be restricted from trade in living modified organisms with non-Parties], provided that adequate measures are observed to ensure the safe transboundary movement of LMOs resulting from modern biotechnology, in accordance with the [objectives] [the substantive provisions] of this Protocol.

OR

1B. In their relations with non-Parties, Parties shall promote the objectives of the Protocol.

OR

1C. [Notwithstanding the provisions in paragraph 1 above], imports and exports of living modified organisms may be permitted from and to any State not party to this Protocol, if that State has submitted data and is determined on the basis thereof by the Meeting of the Parties to be in full compliance with the provisions of this Protocol.]

[2A. Non-Parties in compliance with the substantive provisions of this Protocol shall be treated on an equal basis with Contracting Parties.]

OR

2B. Parties shall conduct their relations with non-Parties in such a way that non-Parties shall not be allowed a more favourable treatment than Parties.

3. A Party shall require that transboundary movement from a non-Party to it takes place in conformity with the notification and/or AIA requirements of the Protocol.

4. Transboundary movements from a Party to a non-Party shall take place in accordance with the regulatory framework of the non-Party provided that the framework does not result in a lower level of protection of biological diversity than the one provided for by the Protocol. In the absence of such a framework, the Parties shall endeavour to ensure that the transboundary movement takes place in accordance with the notification and/or AIA requirements of the Protocol.]

Option 5

[Within five years of the date of entry into force of this Protocol, the Parties shall determine the feasibility of banning or restricting, from States not Party to the Protocol the import and export of living modified organisms covered by this Protocol. If determined feasible, the Parties shall elaborate in an Annex the measures and conditions that will be applicable in such circumstances.]

ARTICLE 24 - NON-DISCRIMINATION

Option 1

[No provision necessary.]

Option 2

1. [During the course of the AIA procedures, in particular the risk-assessment procedures, the recipient Parties shall not treat LMOs of foreign origin that are imported from other Parties or non-Parties with which an agreement or arrangement mentioned in Article 23 has been concluded more restrictively than those of domestic origin merely on the grounds that the LMOs in question are of foreign origin.]

2. [The recipient Contracting Parties may impose specific conditions when living modified organisms of foreign origin are imported from non-Parties with which no agreement or arrangement mentioned in Article 11 has been concluded, as far as such conditions are not more restrictive than the provisions of this Protocol as well as being consistent with the non-discriminatory provisions of the WTO Agreement.]

3. [The importing Party shall ensure that any ban or condition with respect to the import of an LMO does not result in treatment which is less favourable than with regard to such LMOs produced domestically or which are imported from any other country.]

4. [Parties shall not discriminate between imported living modified organisms and those produced locally and/or those that have been previously authorized to be imported from a third party.]

5. [Parties shall ensure that measures taken to [implement] [regulate the safe transfer, handling and use of living modified organisms resulting from biotechnology under] this Protocol do not create unnecessary obstacles to, and/ or constitute means of arbitrary or unjustified discrimination or disguised restrictions on international trade.]

Option 3

[Parties shall ensure that measures taken to [implement this Protocol] shall not discriminate between imported living modified organisms and those produced locally and/or those that have been previously authorized to be imported from a third party, nor create unnecessary obstacles to, and or constitute means of arbitrary or unjustified discrimination or disguised restrictions on international trade.]

ARTICLE 25 - ILLEGAL TRAFFIC 1/

Option 1

[No provisions necessary.]

Option 2

Each Party shall adopt appropriate domestic legislation that prevents and penalizes illegal traffic. Parties shall cooperate in this respect with a view to achieving the objective of this Protocol.

Option 3

1. In the case of illegal traffic of living modified organisms or products thereof, the State of import shall have the right to destroy or dispose of the organisms or products in question or to request the State of origin, if known, to remove at its own expense the organisms or the products from the environment of the State of import.

2. Each Party shall immediately inform the Secretariat [and the Biosafety Clearing-house] of any illegal traffic. [Data concerning known cases of illegal traffic should [shall] be included in the information-exchange mechanism established under article 19.]

3. The Secretariat shall record all known cases of illegal traffic and transmit as quickly and efficiently as possible to all Parties, particularly to Parties that are likely to be affected, all available relevant information concerning the illegal traffic and any associated risks.

4. Each Party shall adopt appropriate domestic legislation that prevents and penalizes illegal traffic. Parties shall cooperate in this respect with a view to achieving the objective of this Protocol.

ARTICLE 26 - SOCIO-ECONOMIC CONSIDERATIONS

Option 1

No reference in the Protocol [refer to COP] [refer to other more relevant forums].

Option 2

1. The Parties shall ensure that the socio-economic impacts specific and unique to the use of LMOs that may manifest adverse consequences are appropriately considered during the assessment and management of risks [taking into account the fact that socio-economic considerations will vary

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1/ Contact Groups 1 and 2 have been requested to review the definition of Illegal Traffic as given in the consolidated text (UNEP/CBD/BSWG/3/6).

considerably from Party to Party]. [In particular, the importing country shall take into account such adverse consequences as genetic erosion and associated loss of income and dislocation of traditional farmers and farm products.]

2. Parties shall encourage research on socio-economic considerations relating to the use, handling and transfer of LMOs and the exchange of the results of such research.

Option 3

1. Parties shall ensure that the socio-economic impacts of the introduction, transfer, handling or use of living modified organisms and products thereof on or within the importing Party and its environment, are considered during the assessment and management of risks, in particular with the aim of ensuring the conservation and sustainable use of biological diversity, and also taking into account impacts on human health, agriculture and welfare. The user shall also take due account of the long observation period that these socio-economic impacts may require to manifest such adverse consequences as genetic erosion and associated loss of income and dislocation of traditional farmers and farm products.

2. Parties shall ensure that the risk-management strategies and measures developed and implemented in accordance with the relevant provisions of this Protocol incorporate strategies and measures that prevent, or mitigate the potential socio-economic adverse impacts of living modified organisms and products thereof.

3. A Party that intends to produce, using a living modified organism, a hitherto imported commodity, shall notify the other Party or Parties whose export is to be affected long enough, and in no case less than seven years in advance so as to enable them to diversify their production and to implement measures concerning the biodiversity that would be reduced following the disruption of production of the commodity in question. The Party substituting its import in such an unnatural way shall, when the affected Party is a developing country, provide financial and technical assistance to the affected Party.

4. Each Party shall develop or maintain appropriate policy and legislation that protect the general public from a monopolistic manipulation of the biotechnological, seed, chemical and related industries by individual private-sector entities.

5. Each Party shall ensure that activities involving LMOs by both public and private entities are adequately regulated in order to ensure a fair and effective implementation of the provisions of this Protocol and to protect the fundamental moral and socio-economic interests of the general public.

ARTICLE 27 - LIABILITY AND COMPENSATION

[Option 1

[No provision]

Option 2

1. The Parties to this Protocol shall, at their first meeting, examine [whether and] how to establish procedures in accordance with article 14, paragraph 2, of the Convention, for developing appropriate rules and procedures in the field of liability and redress, including restoration and compensation for damage resulting from living modified organisms to biological diversity.

Option 3

1. In the event that harm including transboundary harm, that proves detrimental to the environment, biological diversity, human or animal health or socio-economic welfare, arises as a consequence of LMOs or products thereof, the Party of origin shall be strictly liable and shall fully compensate the affected Party.

2. If, as a consequence of the harm referred to in the preceding paragraph, there is also harm to persons or damage to property of the affected Party, compensation by the Party of origin shall also include compensation for such harm.

3. The preceding paragraphs shall not prevent a Party, or any individual or legal entity represented by a Party, that considers that it has been injured as a consequence of an activity or product involving LMOs, from submitting a claim to the courts of the Party of origin or, where access to courts is permitted by domestic law, to the courts of the affected Party. In that case there shall be no more than one claim made for the same harm.

4. Parties shall, at their first meeting, initiate a process to further elaborate and adopt the details of the rules of liability and compensation, in particular procedural rules such as dispute settlement procedures and period of limitation.

Option 4

1. Parties are responsible for the fulfilment of their international obligations concerning the conservation and sustainable use of biological diversity and preservation of the environment. They shall be liable in accordance with international law.

2. With the objective of assuring prompt and adequate compensation in respect of all damage caused by the use, handling and transfer of living modified organisms, Parties shall cooperate in the implementation of existing international law and the further development of international law relating to responsibility and liability for the assessment and compensation of damage and the settlement of related disputes, as well as, where appropriate, development of criteria and procedures for payment of adequate compensation, such as compulsory insurance and compensation funds.

[3. Parties shall ensure that recourse is available in accordance with their legal systems for prompt and adequate compensation or other relief in respect of damage caused by the use, handling and transfer of living modified organisms by natural or juridical persons under their jurisdiction.]

Option 5

1. If harm, including transboundary harm, arises as a consequence of living modified organisms or activities or products involving such organisms, the operator in respect of production, handling, export and supply of those living modified organisms shall be liable for the harm, and the harm must be compensated.

2. When the operators are unable to discharge their liability the State or States of origin shall be liable to the extent of the breach of due diligence obligation of the State of origin.

3. If the harm, including the transboundary harm, proves detrimental to human or animal health, biological diversity and the environment:

(a) The operator responsible for causing such a harm shall restore as far as possible, the conditions that existed prior to the occurrence of the harm. The nature and magnitude of harm is such that it is impossible to restore those conditions full by operator alone the state of origin shall endeavour to restore;

(b) If, as a consequence of the harm referred to in the preceding subparagraph, there is also harm to persons or damage to property in the affected States, payments by the operators/State of origin shall also include compensation for such harm.

4. In the cases referred to in paragraph 3, if there is more than one operator/State of origin, they shall be jointly and severally liable for the resulting harm, without prejudice to any claims which they may bring among themselves for their proportionate share of liability.

5. There shall be no liability on the part of the State of origin if the harm was directly due to a natural catastrophe of an exceptional, inevitable and irresistible character.

Option 6

1. Liability

Signatory Parties to this Protocol, recognizing the risk involved in the transboundary movement of living modified organisms as well as the procedures of Advanced Informed Agreement and risk assessment, adopt within this Protocol liability of States for damage arising from the transboundary movement of living modified organisms, when they occur as:

(a) The consequence of an action or omission attributable to the State under the provisions established by this Protocol;

(b) Conduct that constitutes a breach of an international obligation of the State under the terms of this Protocol.

2. Civil liability

States, through national legislation and procedures are sovereign to determine whether liability is deemed as an act of a public, civil or individual party under national jurisdiction.

3. Compensation

Given a contingency in the transboundary movement of living modified organisms compatible with paragraph (liability), the State of origin shall ensure that compensation is made for harm caused to receiving Parties. The State of origin shall bear the costs of the contingency plan to restore, as far as possible, the conditions that existed prior to the occurrence of the harm. If it is impossible to restore these conditions in full, agreement may be reached on compensation, monetary or otherwise, by the State of origin for the deterioration suffered.

4. Measures of reinstatement

Any reasonable measures aiming to reinstate or restore damage or destroyed components of the environment, or to introduce, where reasonable, the equivalent of this components into the environment. National Competent Authorities are entitled to take such measures.

5. Prescription of liability

Proceedings in respect of liability under this Article shall lapse after a period of NNN years from the date on which the affected Party learned, or could reasonably be expected to have learned, of the harm and of the identity of the State of origin of the transboundary movement of the living modified organism causing damage.

6. Emergency Fund

Signatory Parties decide to establish an Emergency Fund to fulfil requirements arising from contingencies in the transboundary movement of living modified organisms. This Fund will be constituted by contributions from all signatory Parties.

7. Exceptions

There shall be no liability on the part of the State of origin if the harm was directly due to an act of war, hostilities, civil war, insurrection or a natural phenomenon of an exceptional, inevitable and irresistible character.

Option 7

1. While importing Parties remain responsible for the use of LMOs, and products thereof, within their national territories, exporting Parties shall be liable for any negative or harmful effects of LMOs, or products thereof, which could not have reasonably been foreseen on the basis of the information provided at the time of the first import.

2. Exporters shall also be liable for any negative or harmful effects produced as a result of any breach of the obligations under this Protocol.

3. Exporters shall also be liable for all forms of transboundary movement of LMOs and products thereof deemed illegal traffic under Article 25 of this Protocol.

4. All cases of proven liability shall result in the payment of fair and adequate compensation by the exporters to Parties affected.

5. If necessary, the importing Parties may impound, destroy or re-export unauthorized LMOs, or products thereof, at the cost of the exporter.]

Annex III

ARTICLES REVIEWED BY CONTACT GROUP 2

Preamble and Articles 28-43

PREAMBLE

Option 1

The Parties to this Protocol,

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

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

Recalling also decision II/5 of the Conference of the Parties to the Convention to develop a protocol on biosafety, specifically focusing on transboundary movement of any living modified organism (LMO) resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement,

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

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

Have agreed as follows:

Option 2

The Parties to this Protocol,

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

Recalling Article 19, paragraphs 3 and 4, and Articles 8(g) and 17 of the Convention, and recognizing the linkages between them,

Recalling also decision II/5 of the Conference of the Parties to the Convention to develop a protocol on biosafety, specifically focusing on transboundary movement of any living modified organism (LMO) resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement,

Reaffirming decision III/20 of the Conference of the Parties to the Convention and, in particular its support for a two-track approach through which the promotion of the application of the UNEP International Technical Guidelines for Safety in Biotechnology can contribute to and complement the implementation of this Protocol,

Noting the potential contribution of the United Nations Recommendations on the Transport of Dangerous Goods to the implementation of the Protocol,

Recalling the support of the international community for Agenda 21 adopted by the 1992 United Nations Conference on Environment and Development and, in particular Chapter 16, which provides for the "Environmentally Sound Management of Biotechnology", and which further seeks to ensure safety in biotechnology development, application, exchange and transfer through international agreement,

Recognizing that, while properly addressing the risks from living modified organisms (LMOs) resulting from modern biotechnology the Protocol should avoid causing unnecessary delays, including through the creation of unwarranted administrative requirements for the transboundary transfer of LMOs for contained use,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on human or animal health, biological diversity, the environment, and social and economic welfare,

Aware also of the benefit that biotechnology can bring for health agriculture and the environment and mindful that unnecessary negative impacts on biotechnology research and development and on access to and transfer of technology should be avoided.

Concerned that significant gaps in scientific knowledge remain, specifically with regard to the interaction between the environment and living modified organisms (LMOs) resulting from modern biotechnology,

Noting that, in accordance with the precautionary principle, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize risk where such a risk is posed by living modified organisms (LMOs) resulting from biotechnology,

Recognizing also that, although considerable knowledge has accumulated, significant gaps in knowledge have been identified, specifically in the field of interaction between living modified organisms (LMOs) resulting from modern biotechnology and the environment, taking into account the relatively short period of experience with releases of such organisms, the relatively small number of species and traits used, and the lack of experience in the range of environments, specifically those in centres of origin and genetic diversity,

Determined to avoid and minimize the risks associated with the transfer, handling and use of living modified organisms (LMOs) through appropriate risk assessment and management techniques,

Recognizing the need to establish a minimum condition of safety and a procedure for the assessment and management of the potential risks arising from the development, use, release and transfer of living modified organisms (LMOs) and products thereof,

Recognizing that the socio-economic impacts of the introduction of LMOs and products thereof should be considered in risk assessment and management, taking particularly into account the needs and concerns of developing countries,

Affirming the need to provide adequate compensation for in the event of any damage caused by or arising from the handling, transfer and use of living modified organisms (LMOs),

Conscious of the need to promote and encourage public awareness of the safe use, handling and transfer of living modified organisms (LMOs) through the development and implementation of educational and public awareness programmes, and through public participation in risk assessment and management procedures,

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

Acknowledging the need for appropriate policies and measures to develop and strengthen human resources and institutional capacities in the safe handling, transfer and use of living modified organisms (LMOs), taking due account of the needs of developing countries,

Noting that the provisions of the Protocol should contribute to the field of biosafety, based on scientific risk assessment.

Have agreed as follows:

ARTICLE 28 - FINANCIAL MECHANISM AND RESOURCES

Option 1

1. The financial mechanism defined in Article 21 of the Convention, as well as the institutional structure carrying out its operation, shall serve as the financial mechanism and institutional structure of this Protocol.

2. The developed country Parties shall, in a predictable and timely manner, provide new and additional financial resources to the financial mechanism to enable developing countries to meet the agreed full incremental costs to them of implementing measures which will fulfil the obligations of this Protocol.

3. On matters related to activities under the provisions of this Protocol, the financial mechanism shall function under the authority and guidance of, and be accountable to, the Conference of the Parties serving as the meeting of the Parties to this Protocol.

4. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply mutatis mutandis to the provisions of this Article.

5. The developed country Parties may also provide, and developing country Parties avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Option 2

The developed country Parties may provide, and developing country Parties avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

ARTICLE 29 - CONFERENCE OF THE PARTIES

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

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from amongst the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

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

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

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

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 35 of this protocol and, as well, reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are determined necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied mutatis mutandis under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, which is qualified in matters covered by this Protocol and which has informed the Secretariat of its wish to be represented at a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

ARTICLE 30 - SUBSIDIARY BODIES AND MECHANISMS

1. Any subsidiary body established by or under the Convention may, upon a decision by the meeting of the Parties, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of a subsidiary body of the Protocol. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by the Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the Bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from amongst the Parties to this Protocol.

ARTICLE 31 - SECRETARIAT

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

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply mutatis mutandis to this Protocol.

3. [To the extent that these are distinct, the costs of the Secretariat services for this Protocol shall be met by the Parties hereto. [The Conference of the Parties to this Protocol shall decide at its first meeting the necessary financial arrangements to this end.]]

ARTICLE 32 - JURISDICTIONAL SCOPE

Deleted

ARTICLE 33 - RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol. 1/

ARTICLE 34 - RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS

Option zero

No provision necessary.

Option 1

The provisions of this Protocol shall not affect the rights and obligations of any Party to this Protocol deriving from any existing international agreement to which it is also a Party at the time that this Protocol enters into force for that Party.

Option 2

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

Option 3

In the event of any inconsistency between this Protocol and the obligations set out in:

(a) The Agreement on Technical Barriers to Trade;

(b) The Agreement on the Application of Sanitary and Phytosanitary Measures,

the Parties to this Protocol agree that this Protocol shall prevail to the extent of the inconsistency and waive to this extent their right to bring a complaint against any other Party under these agreements.

1/ It was noted that it may be necessary to revisit this provision in the light of the outcome of the discussions on substantive articles, which may have a bearing on issues such as settlement of disputes and adoption and amendment of annexes.

ARTICLE 35 - MONITORING AND REPORTING 2/

[1. Each Party shall monitor the implementation of its obligations under this Protocol and establish and/or maintain systems for this purpose.]

2. Each Party shall, at intervals to be determined by the meeting of the Parties to this Protocol, report to the meeting of the Parties to this Protocol on measures taken to implement this Protocol.

[ARTICLE 35 BIS - COMPLIANCE

Option zero

No provision.

Option 1

The Parties shall [at their first meeting] [consider and approve] [determine how to establish] [consider whether to establish] procedures and institutional mechanisms [for determining non-compliance with the provisions of this Protocol and] for the treatment of Parties found to be in non-compliance.]

[ARTICLE 36 - ASSESSMENT AND REVIEW OF PROCEDURES/ANNEXES]

Option zero

No provision necessary.

Option 1

Beginning in [ ], and at least every five years thereafter, the Parties shall assess the procedures and annexes provided in this Protocol on the basis of available scientific, environmental and technical information. At least one year before each assessment, the Parties shall [should consider the need to] convene an appropriate panel of experts and determine its composition and terms of reference. Within one year of being convened, the panels will report their conclusions, through the Secretariat, to the Parties.

Option 2

The Meeting of the Parties shall undertake [three] years after the entry into force of this Protocol, and at least every [six] years thereafter, an evaluation of its effectiveness.

ARTICLE 37 - SIGNATURE

This Protocol shall be open for signature at [ ] by all States and any regional economic integration organization from [ ] until [ ] , and at the United Nations Headquarters in New York from [ ] to [ ].

ARTICLE 38 - RATIFICATION, ACCEPTANCE, OR APPROVAL

Deleted

ARTICLE 39 - ACCESSION

Deleted

2/ The issue of information-sharing remains until further substantive issues from other articles of the Protocol are developed.

ARTICLE 40 - ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the [ ] instrument of ratification, acceptance, approval or accession. 3/

2. This Protocol shall enter into force for a Party that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that Party deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that Party, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

ARTICLE 41 - RESERVATIONS

Option zero

No provision necessary.

Option 1

No reservations may be made to this Protocol.

ARTICLE 42 - WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

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

ARTICLE 43 - AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

3/ One delegation indicated that they may want to revisit this article at a later stage.

Annex IV

RESULTS OF THE WORK OF CONTACT GROUP 1

I. USE OF TERMS

LMO

LMO means any

[[biological] entity [or part thereof,] capable of [replication of [or [actively] transferring] its genetic material] [multiplication] [metabolic activity][natural propagation][reproduction of its specific genotype or whose genotype can be reproduced][,including viruses,]

[organism]

* that contains genetic material which has been [deliberately] modified
  - [by in vitro [gene] technologies]
  - [in a way that
    = [[does not][is not known to] occur naturally by reproduction or recombination]
    = [overcomes natural physiological reproduction or recombination barriers]]

[and

* of which the resulting [,expected or unexpected,] [genetic composition][genotype]
  - [contains [foreign][transgenic] genetic material]
  - [is unlikely to occur in nature,]]

[and] [or]

[would confer] [confers]
- [one or more novel traits]
- [traits novel to the species [in the receiving environment]].

Organism 1/

Organism means any [biological] entity [or part thereof,] capable of [replication of [or [actively] transferring] its genetic material] [multiplication] [metabolic activity][natural propagation][reproduction of its specific genotype or whose genotype can be reproduced][,including viruses].

Transboundary movement

Transboundary movement [of an LMO 2/] means any movement [of an LMO] from [an area under the jurisdiction][the territory] of one Party[/State] to [an area under the jurisdiction][the territory] of another Party[/State].

1/ One delegation noted a need to include entities, e.g. nucleic acid sequences and proteins, which can multiply inside organisms.

2/ At a later stage, Contact Group 2 will check the consistency of the use of the term "of an LMO" throughout the entire document.

Export

Export means the intentional movement [of an LMO] from [an area under the jurisdiction][the territory] of one Party[/State] into [an area under the jurisdiction][the territory] of another Party[/State][,but does not include transit through a third Party[/State]].

Import

Import means the intentional movement [of an LMO] into [an area under the jurisdiction][the territory] of one Party[/State] from [an area under the jurisdiction][the territory] of another Party[/State][,but does not include transit through a third Party[/State]].

Exporter

Exporter means any legal or natural person, under the jurisdiction of the Party[/State] of export, who [arranges][is responsible] for an LMO to be exported.

Importer

Importer means any legal or natural person, under the jurisdiction of the Party[/State] of import, who [arranges][is responsible] for an LMO to be imported.

Party of export

Party of export means a Party[/State] from which a [transboundary movement][export] [of an LMO] [is planned to be initiated or] is initiated.

Party of import

Party of import means a Party[/State] into which a [transboundary movement][import] [of an LMO] [is planned to be initiated or] is initiated.

II. REVISIONS TO ANNEX I CONTAINED IN THE APPENDIX TO THE ANNEX TO THE CONSOLIDATED TEXT CONTAINED IN UNEP/CBD/BSWG.3/6.

Annex I (REVISION)

INFORMATION REQUIRED IN NOTIFICATIONS FOR ADVANCE INFORMED AGREEMENT 3/

(a) Designation [and classification of biosafety levels] of LMO(s)[or products thereof].

(b) Name and address of the exporter.

(c) Name and address of the importer.

(d) Common name, taxonomic status, [source and characteristics] of recipient organism [and donor organism].

(e) Centre of origin/genetic diversity [if known] relevant to the organism that has been modified.

(f) Description of DNA/RNA fragment(s)/traits introduced or modified and resulting characteristics of the LMO [or products thereof].

(g) Intended use of the LMO [or products thereof][if known].

(h) Quantity of LMOs [or products thereof]to be transferred or volume and physical state of culture.

(i) A [known and available] risk assessment report [carried out on the LMO [or products thereof] in question] in accordance with the risk assessment parameters as stated in Annex II of the Protocol.

(j) Suggested methods to ensure safe handling, storage, transport and use, including packaging, [labelling,] documentation, disposal and contingency procedures.

(k) Intended date[s] of [first] [transfer] [movement].

(l) Declaration that the information is [factually] correct. 4/

3/ Contact Group 1 recognized that some items of information should be accessible through a Clearing-house Mechanism (CHM), the need for and status of which needs to be decided upon in another subsidiary of the Working Group. In particular, the following items of information may need to be reconsidered for inclusion in Annex I, depending on the outcome of deliberations on this issue:

> "The applicable laws, procedures and guidelines of the State of export and the stage reached in the testing and observation of the LMO according to the legal and administrative requirements of the State of export."
>
> "Available information about any notification to other Governments regarding the import or development of the LMO, and the purpose thereof."

4/ The responsibility for declaring the factual correctness of the information needs to be clarified.

III. REVISIONS TO THE ANNEX II CONTAINED IN THE APPENDIX TO THE ANNEX TO THE CONSOLIDATED TEXT CONTAINED IN UNEP/CBD/BSWG/3/6.

Annex II (Revision) 5/

Option 1

RISK ASSESSMENT FACTORS

1. The objective of risk assessment is to consider, as appropriate, the following points:

(a) Identification of any [hazardous] characteristics of the LMO [or products thereof] linked to the genetic modification [that may have adverse effects on the conservation and sustainable use of biological diversity [or] [taking also into account risks to] human health];

(b) The extent of the consequences of the [hazard][adverse effect] resulting from the genetic modification being realized;

(c) The likelihood of the [hazard][adverse effect] being realized;

(d) Estimation of the risk posed by each identified [hazard][adverse effect];

(e) Application of management strategies, when appropriate, for risks from the release of the LMO [or products thereof]. The management strategies should be commensurate with the results of the risk assessment;

(f) Determination of the overall risk of adverse effects.

2. Any new risks associated with the LMO [or products thereof] or its use should be considered in the context of the risks posed by using other organisms not subject to this risk assessment or risks that may be posed if the LMO [or products thereof] is not released.

3. Full regard should be paid to the experience gained and to the relevant literature and consultation with available experts and public authorities.

4. [The level of risk can be minimized either by applying risk-management strategies or by deciding not to proceed with the intended use of the LMO [or products thereof].]

5. The information required for a scientifically sound risk assessment could include the following, depending on the LMO [or products thereof], the application, the receiving environment and the interaction between the environment and the LMO [or products thereof], as appropriate. The application of this list may vary from LMO [or products thereof] to LMO [or products thereof]. Risk assessment may require more specific information about individual topics, which may be obtained during the assessment process, while other topics may not be relevant in some instances. Discussion of the scientific rationale for including particular data in particular instances is often appropriate in deciding how to conduct the assessment.

INFORMATION RELATING TO THE LMO [OR PRODUCTS THEREOF]

5/ The options set out here are not the only options and are not negotiating text, and will remain open for any additional options or alternative text.

A. Characteristics of the recipient organism

6. The relevant biological, physiological and genetic and environmental characteristics of the recipient/parental/host organism include, as appropriate:

(a) The name and identity of the organism;

(b) Pathogenicity and toxicity; 6/

(c) The natural habitat and the geographic origin of the organism, its distribution and its role in that habitat;

(d) Mechanisms by which the organism survives, multiplies and disseminates in the environment;

(e) Means for transfer of genetic material to other organisms.

B. Characteristics of the organism(s) from which the DNA/RNA fragment(s)[nucleic acid] are obtained (the donor)

7. The relevant characteristics include, in particular, pathogenicity and toxicity.

C. Characteristics of the vector

(a) Identity, origin, natural habitat, integrative properties and the relevant safety characteristics of the vector.

(b) The frequency at which the vector can be mobilized or can transfer itself to other organisms.

(c) Factors which would influence the ability of the vector to become established in other hosts.

D. Characteristics of the inserted DNA/RNA fragment(s)[nucleic acid](the insert)

(a) Functions as specified by the insert, including any residual vector.

(b) Information on the expression of the insert and the activity of the gene product(s).

E. Characteristics of the LMO [or products thereof]

8. The LMO [or products thereof] should be compared with the organism from which it is derived, examining, where relevant, the following points:

(a) Pathogenicity and toxicity to other organisms 6/;

(b) Survival, persistence, competitive abilities and dissemination in the environment or other relevant interactions;

(c) Capacity to transfer genetic material and the way in which this might occur;

(d) Functions which might affect its ecological range;

(e) Characterization of the product(s) of the inserted gene(s) and, where appropriate, the stability of the modification.

6/ Lists exist on the national level for plant and animal pathogens.

INFORMATION RELATING TO THE INTENDED USE

9. The amount of information required will vary with the characteristics of the LMO [or products thereof] and use, frequency and the scale of the intended use. Also consider possible new or changed use or practice, compared to traditional use or practice with similar non-modified organisms (for example, new or changed farming, forestry and aquaculture practice, etc. as a consequence of the living modified organism).

[10. For contained uses, this can include:

(a) Number or volume of LMO [or products thereof] to be used;

(b) Scale of the operation;

(c) Proposed containment measures, including the verification of their functioning;

(d) Training and supervision of personnel carrying out the work;

(e) Plans for waste management;

(f) Plans for safety of the health of personnel;

(g) Plans for handling accidents and unexpected events;

(h) Relevant information from previous uses.]

11. For deliberate releases, this can include:

(a) Purpose and scale of the release;

(b) Geographical description and location of the release;

(c) When relevant, proximity to residences and human activities;

(d) Method and frequency of release;

(e) As appropriate, training and supervision of personnel carrying out the work;

(f) Likelihood of unintended transboundary movement;

(g) Time and duration of the release;

(h) Expected environmental conditions during the release;

(i) As appropriate, proposed risk-management measures, including verification of their functioning;

(j) As appropriate, subsequent treatment of the site and plans for waste management;

(k) Plans for handling accidents and unexpected events;

(l) Relevant information from any previous releases.

CHARACTERISTICS OF THE POTENTIAL RECEIVING ENVIRONMENT

12. The potential for an organism to cause harm is related to the environment into which it may be released and its interaction with other organisms. Relevant information can include:

(a) The geographical location of the site, the identity and any special features of the receiving environments that expose them to damage;

(b) Where relevant, the proximity of the site to humans and to significant biota;

(c) Any flora, fauna and ecosystems that could be affected by the release, including keystone, rare, endangered or endemic species, potential competitive species and non-target organisms;

(d) The potential of any organism in the potential receiving environment to receive genes from the released LMO [or products thereof].

13. Note should be taken of any likely changes to interaction between the LMO [or products thereof] and non-target organisms, or between any target organisms of the LMO [or products thereof] and other organisms in the ecosystems.

Option 2

RISK-ASSESSMENT PARAMETERS

1. Prior to the use and release of living modified organisms an assessment as regards the risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies shall be performed. This assessment shall take the following parameters into consideration, including any other parameter deemed to be relevant.

A. General principles

2. The guiding principle of risk assessment is the precautionary approach. Where the transboundary movement, or use or handling of LMOs [or products thereof] may cause, or has the potential to cause harm to biodiversity, human or animal health, the lack of full scientific certainty or consensus regarding the level of risk should not be interpreted as the lack of risk, or as acceptable risk.

3. The risk assessment should, inter alia, take into account all relevant scientific evidence and experience, including previous risk assessments. This enables the risk assessment to evolve in the light of new evidence and knowledge; an LMO [or products thereof] previously considered acceptable may no longer be acceptable, and vice versa.

4. The risk assessment should, inter alia, take into account:

(a) All relevant scientific evidence and experience;

(b) The general characteristics of both the living modified organism and the parent organism(s), the vector(s) used, the genetic modification(s) and the novel trait(s), including marker trait(s) and other sequences even when not expressed;

(c) The native environments or host range of the recipient organism and donor organism(s);

(d) The intended use(s) of the living modified organism and the nature of the receiving and surrounding environments;

(e) Potential impact of the LMO [or products thereof] on the environment(s), including long-term ecological impacts, particularly on centers of origin and areas with high genetic diversity of taxa related to the living modified organism;

(f) Effects of the LMO [or products thereof] on human health and animals;

(g) Socio-economic impacts;

(h) Conformity with ethical norms of receiving party/State;

(i) Details of risk assessments completed elsewhere.

5. The information required for risk assessment should include the following:

B. Specific information requirements

6. Characteristics of donor and recipient organisms or parental organisms:

(a) Scientific name and taxonomy;

(b) Strain, cultivar or other name;

(c) Species it is related to and degree of relatedness;

(d) The degree of relatedness between the donor and recipient organisms, or between the parental organisms;

(e) All sites from where the donor and recipient organisms or parental organisms were collected, if known;

(f) Information on the type of reproduction (sexual/asexual) and the length of reproductive cycle or generation time, as appropriate, as well as the formation of resting and survival stages;

(g) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;

(h) Phenotypic and genetic markers of interest;

(i) Description of identification and detection techniques for the organisms, and the sensitivities of these techniques;

(j) Geographic distribution and natural habitats of the organisms including information on natural predators, prey, parasites, competitors, symbionts and hosts;

(k) Climatic characteristics of original habitats;

(l) Ability of the organisms to survive and colonize the environment to which release is intended or otherwise;

(m) Genetic stability of the organisms, and factors affecting the stability;

(n) The presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability;

(o) The potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;

(p) Pathogenicity to humans or animals, if any;

(q) If pathogenic, their virulence, infectivity, toxicity and modes of transmission;

(r) Known allergenicity and/or toxicity of biochemical and metabolic products;

(s) Availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

7. Characteristics of the vector(s):

(a) Nature and source of the vector(s);

(b) Genetic map of the vector(s), position of the gene(s) inserted for the transfer, other coding and non-coding sequences affecting the expression of introduced gene(s), and marker gene(s);

(c) Ability of the vector(s) to mobilize and transfer genes by integration and methods for determining the presence of the vector(s);

(d) Complete nucleotide sequence of the vector(s);

(e) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;

(f) Potential for pathogenicity and virulence;

(g) Natural and host range of vectors;

(h) Natural habitat and geographic distribution of natural and potential hosts;

(i) Potential impacts on human and animal health and the environment;

(j) Measures for counteracting adverse impacts;

(k) Potential to survive and multiply in the environment, or to form genetic recombinants;

(l) Genetic stability of vector(s), such as hypermutability.

8. Characteristics of living modified organism:

(a) The description of the modifications made using gene technology;

(b) The function of the genetic modifications and/or the new insert, including any marker gene(s);

(c) Purpose of the modification and intended use in relation to need or benefit;

(d) Method of modification and, in case of transgenic organisms, the methods for constructing inserts and to introduce them into the recipient organism;

(e) Whether introduced gene(s) are integrated or extrachromosomal;

(f) Number of insert(s) and its/their structure(s), for example, the copy number whether in tandem or other types of repeats and the position of each insert;

(g) Nucleotide sequence of each insert, including at least one kilobase up and down stream from the insert;

(h) Product(s) of the transferred gene(s), levels of expression and methods for measuring expression;

(i) Stability of the introduced gene(s) in terms of expression and integration;

(j) Biochemical and metabolic differences of living modified organism compared with the unmodified organism;

(k) Probability of vertical or horizontal gene transfer to other species;

(l) Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;

(m) Allergenicities, toxicities, pathogenicities and unintended effects;

(n) Autecology of the living modified organism compared with that of the unmodified organism;

(o) Susceptibility of the living modified organism to diseases and pests compared with the unmodified organism;

(p) Detailed information on past uses including results on all experiments leading to previous releases.

9. Characteristics of resuscitated organism(s) and gene(s) and fossil DNA sequences:

Resuscitated organism

(a) Scientific name and taxonomy;

(b) Identity of nearest species and their characteristics which are of relevance to the intended use;

(c) Site at which it was found;

(d) Method used for resuscitation;

(e) Purpose of introducing the organism and benefits, if any;

(f) Impacts on human and animal health and the environment;

(g) Measures for counteracting adverse impacts;

(h) Length of time the organism has been in use;

(i) Genetic stability;

(j) Likelihood of gene transfer to other organisms;

(k) Fossil and living nearest relative species;

(l) Biological and biochemical differences from related living species;

(m) Information on previous uses since resuscitation.

DNA sequences from fossils or from resuscitated organism

(a) Scientific name and taxonomy of the species whether resuscitated or a fossil;

(b) Site of origin of the fossil;

(c) Site of the gene in the resuscitated genome, if known;

(d) Base sequence of the extracted gene;

(e) Method used in extracting the gene;

(f) Function of gene, if known;

(g) Purpose of use and benefits, if any

(h) Environment in which it lived before fossilization;

(i) Fossil species related to the species from which the gene was taken;

(j) Living species related to the species from which the gene was taken.

10. Safety considerations for human and animal health:

Information on the living modified organism and when it is genetically engineered, information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled, regarding:

(a) Capacity for colonization;

(b) If the living modified organism is pathogenic to humans or animals the following information is required:

(i) Diseases caused and mechanism of pathogenicity, including invasiveness and virulence, and property of virulence;

(ii) Communicability;

(iii) Infective dose;

(iv) Host range and possibilities of alteration;

(v) Ability to survive outside of the human or animal host;

(vi) The existence of vectors or other means of transmission;

(vii) Biological stability;

(viii) Allergenicity;

(ix) Availability of appropriate therapies.

11. Environmental considerations:

Information on the living modified organism and, when it is genetically engineered, information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled, regarding:

(a) Factors affecting the survival, reproduction and spread of the living modified organism in the environment;

(b) Available techniques for detection, identification and monitoring of the living modified organism;

(c) Available techniques for detecting transmission of genes from the living modified organism to other organisms;

(d) Known and predicted habitats of the living modified organism;

(e) Description of the ecosystems which could be affected by accidental release of the living modified organism;

(f) Possible interactions between the living modified organism and other organisms in the ecosystem which might be affected by accidental release;

(g) Known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, being a vector of pathogens, allergenicity, and colonization;

(h) Possible involvement in biogeochemical processes;

(i) Availability of methods for decontamination of the area in case of accidental releases;

(j) Effects on agricultural practices with possible undesirable impacts on the environment.

12. Socio-economic considerations:

(a) Anticipated changes in the existing social and economic patterns resulting from the introduction of the living modified organism or product thereof;

(b) Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture;

(c) Impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agro-climatic zones;

(d) Anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and, in general, means of livelihood of the communities likely to be affected by the introduction of the living modified organisms or products thereof;

(e) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare;

(f) Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the living modified organism [or the product thereof].

Annex V

LIST OF ANNEXES TO THE DRAFT PROTOCOL

1. Consolidated text from Contact Group I

Annex I: Information required in notifications for Advance Informed Agreement.
Annex II: Risk assessment.

2. Annexes in government submissions

(a) Risk management;

(b) Function of focal points/competent authorities;

(c) Information to be provided to the Secretariat under information-sharing/clearing house;

(d) (i) Contained use of the living modified organism;

(ii) Requirements/guidelines for the use of LMOs in contained facilities;

(e) Information requirements for unintentional release/transboundary movement;

(f) Information requirements for notifications;

(g) Lists of, and criteria for, LMOs, genes/traits and activities with LMOs to which the Protocol shall not apply;

(h) Relevant information on LMOs (in relation to the European Union submission for Article 4, paragraph 4);

(i) Cases of explicit consent;

(j) Information requirements for simplified procedures.

3. Annexes referred to in the consolidated text of the sub-working groups

(a) LMOs not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 3);

(b) Criteria for LMOs to be included in the AIA procedure (Article 3);

(c) Cases of transboundary movement subject to explicit consent (Article 6);

(d) LMOs to be exempted from AIA procedure (Article 9 (cf. Article 3));

(e) Information required in the notification of transboundary movement (Article 9);

(f) Information required for the transfer of LMOs (Article 17).
