CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/COP/2/7
3 August 1995

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSITY
Second meeting
Jakarta, 6-17 November 1995

REPORT OF THE OPEN-ENDED AD HOC GROUP OF EXPERTS ON BIOSAFETY

Introduction

1. In accordance with decision 1/9 of the first meeting of the Conference of the Parties to the Convention on Biological Diversity, held in Nassau, Bahamas, from 28 November to 9 December 1994, an Open-ended Ad Hoc Group of Experts on Biosafety was established with the following mandate: (a) to consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity; and (b) to consider existing knowledge, experience and legislation in the field of biosafety, including the views of the Parties, subregional, regional and international organizations, with a view to presenting a report for the consideration of the second meeting of the Conference of the Parties, so as to enable the Conference of the Parties to reach an informed decision as to the need for and modalities of a protocol. The meeting of the Open-ended Ad Hoc Group of Experts on Biosafety was hosted by the Government of Spain and convened at the Palacio de Congresos in Madrid from 24-28 July 1995.

2. The Conference of the Parties decided also to establish a panel of 15 Government-nominated experts to prepare a background document for consideration by the Open-ended Ad Hoc Group of Experts. The meeting of the Panel of Experts was held in Cairo from 1-5 May 1995.

UNEP

I. ORGANIZATION OF THE MEETING

A. Opening of the meeting

3. The meeting was opened by Mr. Veit Koester (Denmark) on behalf of Dr. Ivy Dumont (Bahamas), President of the Conference of the Parties to the Convention on Biological Diversity, in his capacity as Chairperson of the Committee of the Whole at the first meeting of the Conference of the Parties and Vice-President of the Conference of the Parties. He said that the present meeting of the Open-ended Ad Hoc Group of Experts on Biosafety was the second stage of a three-stage process established by the Conference of the Parties to tackle the issue of the need for and modalities of a protocol on biosafety. The Group of Experts was expected to consider existing knowledge, experience and legislation in the field of biosafety and to make recommendations on the need for and modalities of a protocol on biosafety to the second meeting of the Conference of the Parties, to be held in Jakarta, from 6-17 November 1995.

4. Mr. Carlos Tio, Secretary General of the Spanish Ministry of Agriculture, made an opening statement of welcome on behalf of the host country. He stressed the need for biosafety regulation to deal with the long-term effects of the application of biotechnology and drew attention to the ethical and socio-economic aspects of the issue.

5. Mr. Emilio Muñoz, Chairperson of the meeting, in his opening statement pointed to the concern and interest that existed with regard to the need for the safe transfer, handling and use of living modified organisms (LMOs) resulting from biotechnology to avoid adverse effects on the conservation of biological diversity and sustainable use of its components. He noted the work of the Panel of 15 Government-nominated experts, established by the Secretariat of the Convention to prepare a background document at its meeting in Cairo from 1-5 May 1995 for submission to the present meeting of the Ad Hoc Group of Experts.

6. Mr. Hans Alders, officer-in-charge of the Secretariat of the Convention on Biological Diversity, in his opening statement underscored the importance of the agenda of the present meeting. Two substantive items needed careful consideration. The first was the existing knowledge, experience and legislation in the field of biosafety. In accordance with the decision of the first meeting of the Conference of the Parties, the Secretariat had gathered responses from Governments and organizations concerning information related to biosafety guidelines and/or legislation. That information was contained in document CBD/Biosafety Expert Group/Inf.1. The second item involved the examination of the report submitted by the Panel of Experts on Biosafety, contained in document CBD/Biosafety Expert Group/2 (attached to the present report as annex IV), with a view to making recommendations on the need for and modalities of a protocol on biosafety which would set out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that could have adverse effect on the conservation and sustainable use of biological diversity.

B. Attendance

7. The meeting was attended by representatives of the following countries:

Argentina, Australia, Austria, Bahamas, Bangladesh, Barbados, Belarus, Benin, Brazil, Cameroon, Canada, Cape Verde, Central African Republic, Chile, China, Colombia, Cuba, Democratic People's Republic of Korea, Denmark, Ecuador, Egypt, Equatorial Guinea, Estonia,

Et
hiopia, Fiji, Finland, Georgia, Germany, Ghana, Guinea, Guyana, Hungary, Iceland, India, Indonesia, Italy, Japan, Jordan, Kazakhstan, Kenya, Malawi, Malaysia, Marshall Islands, Mauritius, Mexico, Micronesia (Federated States of), Myanmar, Nepal, Netherlands, New Zealand, Nigeria, Norway, Oman, Pakistan, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Republic of Korea, Romania, Russian Federation, Saudi Arabia, Senegal, Seychelles, Slovakia, South Africa, Spain, Swaziland, Sweden, Switzerland, Syrian Arab Republic, Thailand, Tunisia, Uganda, United Kingdom of Great Britain and Northern Ireland, United States of America, Uruguay, Venezuela, Viet Nam, Yugoslavia, Zambia.
The European Community was also represented.

The following United Nations bodies and specialized agencies were represented:

Food and Agriculture Organization of the United Nations (FAO), United Nations Conference on Trade and Development (UNCTAD), United Nations Educational, Scientific and Cultural Organization (UNESCO), United Nations Environment Programme (UNEP), United Nations Information Centre (UNIC), United Nations Industrial Development Organization (UNIDO), World Tourism Organization (WTO).

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

Centro Internacional de Agricultura Tropical (CIAT),
Organisation for Economic Co-operation and Development (OECD),
West Africa Rice Development Association (WARDA).

The following non-governmental organizations were represented:

Australian Gen-Ethics Network (AGE Net), Biotechnology Advisory Commission, Biotechnology Industry Organization (BIO), Biotechnology Working Group, Community Nutrition Institute, Cooperativa Tecnico Scientifica di Base (COBASE), Coordinadora de Organizaciones de Defensa Ambiental (CODA), Council for Responsible Genetics (CRG), ECOROPA-France, Fondo Patrimonio Natural Europeo, Forum on Environment and Development, Friends of the Earth International, German NGO Working Group on Biodiversity, Greenpeace International, World Conservation Union (IUCN), Novo Nordisk A/S, Senior Advisory Group on Biotechnology (SAGB), The Edmonds Institute, Third World Network, World Federation for Culture Collections (WFCC), World Wide Fund for Nature (WWF).

C. Election of officers

8. The Group at its 1st and 2nd sessions elected the following officers:

Chairperson:	Mr. Emilio Muñoz (Spain)
Vice-Chairperson:	Mr. Luiz Antonio Barreto de Castro (Brazil)
	Mr. Tewolde B.G. Egziabher (Ethiopia)
	Mr. Sugiono Moeljopawiro (Indonesia)
Rapporteur:	Mr. Ervin Balazs (Hungary)

D. Organization of the meeting

9. Following an amendment from the floor, the following agenda was adopted by the Group:

1. Opening of the meeting.

2. Organizational matters.

2.1 Election of officers;

2.2 Adoption of the agenda;

2.3 Organization of work.

3. Presentation of the background document prepared by the Panel of Experts on Biosafety.

4. Consideration of existing knowledge, experience and legislation in the field of biosafety, including the views of the Parties, subregional, regional and international organizations, with a view to presenting a report for the consideration of the second meeting of the Conference of the Parties, so as to enable the Conference of the Parties to reach an informed decision as to the need for and modalities of a protocol.

5. Consideration of the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

6. Adoption of the report.

7. Closure of the meeting.

10. At the 6th session, after the adoption of the section of the report on organization of the meeting, the representative of China stated that the organization of the meeting of the Open-ended Ad Hoc Group of Experts on Biosafety using only three of the official United Nations working languages should not be seen as a precedent for other future meetings of subsidiary bodies under the Conference of the Parties. His statement was supported by the representative of the Syrian Arab Republic, speaking on behalf of the Arab Group.

II. PRESENTATION OF THE BACKGROUND DOCUMENT PREPARED BY THE PANEL OF EXPERTS ON BIOSAFETY

11. At its 1st session, the Group took up its consideration of item 3 of its agenda. The Chairperson of the Panel of Experts on Biosafety informed the Group that the Panel, consisting of 15 Government-nominated experts established by the Secretariat of the Convention, had met in Cairo from 1-5 May 1995. He recalled that the mandate of the Panel was to prepare a background document for the present meeting of the Open-ended Ad Hoc Group of Experts, based on consideration of existing knowledge and experience of risk assessment and management and guidelines and/or legislation already

prepared by the Parties, other Governments and by national and competent subregional, regional and international organizations. The Chairperson of the Panel of Experts on Biosafety then introduced the report prepared by the Panel, contained in document CBD/Biosafety Expert Group/2. That document, he said, consisted of an introduction, a description of current approaches to risk assessment and management, a survey of existing national, regional and international guidelines/regulations, some recommendations on further action to be taken to improve safety in biotechnology and some conclusions. The Chairperson concluded that the Panel was of the opinion that the key issue of the next step to be taken would entail discussions and, preferably, clear options and/or recommendations for the Conference of the Parties about the type of framework that would ensure that the recommendations of the Panel were likely to be met.

12. The representatives of the following countries voiced general comments on the report of the Panel of Experts: Argentina; Australia; Austria; Chile; China; Colombia; Cuba; Ecuador; Fiji; Finland; India; Indonesia; Japan; Kenya; Malaysia; Malawi; Mauritius; New Zealand; Norway; Peru; Republic of Korea; Senegal; Spain, on behalf of he European Union; Sweden; Switzerland; United States of America; and Zambia. Statements were also made by the representatives of Greenpeace International and of Third World Network.

13. Many representatives agreed that the report prepared by the Panel of Experts on Biosafety was a suitable background document for discussion at the meeting. Several representatives noted the possibility of also considering additional background material contained in other reports.

14. The representative of UNEP made a statement on behalf of the Executive Director. At the request of the delegates, the representative of UNEP also introduced the report on UNEP-sponsored world-wide consultations on international technical guidelines for safety in biotechnology and related capacity-building requirements, contained in document Biosafety Guidelines/Inf.1.

III. CONSIDERATION OF EXISTING KNOWLEDGE, EXPERIENCE AND LEGISLATION IN THE FIELD OF BIOSAFETY, INCLUDING THE VIEWS OF THE PARTIES, SUBREGIONAL, REGIONAL AND INTERNATIONAL ORGANIZATIONS, WITH A VIEW TO PRESENTING A REPORT FOR THE CONSIDERATION OF THE SECOND MEETING OF THE CONFERENCE OF THE PARTIES, SO AS TO ENABLE THE CONFERENCE OF THE PARTIES TO REACH AN INFORMED DECISION AS TO THE NEED FOR AND MODALITIES OF A PROTOCOL

15. At its 2nd session, the Group took up its consideration of item 4 of its agenda. In its deliberations, the Group referred to sections 2, 3 and 4 of the report of the Panel of Experts on Biosafety, contained in document CBD/Biosafety Expert Group/2, attached to the present report as annex IV.

16. Statements were made by representatives of the following countries: Australia, Austria, Brazil, Cameroon, China, Denmark, Ethiopia, Germany, India, Kenya, Malawi, Malaysia, New Zealand, Norway, Philippines, Republic of Korea, Senegal, Slovakia, Syrian Arab Republic, Sweden, Thailand, United States of America and Zambia. The following NGOs also presented their views on the agenda item: Australian Gen-Ethics Network, Council for Responsible Genetics, Edmonds Institute, German NGO Working Group on Biodiversity and Open University.

17. The representative of FAO recalled the work of the Intergovernmental Commission on Plant Genetic Resources on safety of agrobiotechnologies in the context of the draft International Code of

Conduct on Plant Biotechnology and informed the Group of the Commission's decision to submit this work to the Conference of Parties to the Convention on Biological Diversity as a contribution by FAO to the possible elaboration of a framework for safety of biotechnologies, to be decided within the context of the Convention. He also referred to other recent FAO activities and publications in connection with the safety of biotechnologies of interest to agriculture and foodstuffs.

18. At its 4th session, the Group of Experts established an open-ended drafting group chaired by Mr. Luiz Antonio Barreto de Castro, Vice-President. The open-ended drafting group was composed of a core group of three representatives from each regional group, as follows:

African Group: Ethiopia, Kenya, Malawi
Latin American and Caribbean Group: Argentina, Bahamas, Colombia
Asian Group: Malaysia, Republic of Korea, Syrian Arab Republic
Western Europe and Others Group: Australia, Norway, United Kingdom
East European Group: Belarus, Hungary, Slovakia.

19. The Bureau of the Open-ended Ad Hoc Group decided that the mandate of the open-ended drafting group was to prepare, for the consideration of the meeting of the Group of Experts on Biosafety, draft recommendations, if necessary including alternatives, to be transmitted to the second meeting of the Conference of the Parties on agenda items 4 and 5.

20. At its 6th session, the Group considered the paper prepared by the Secretariat entitled "Consideration of existing knowledge, experience and legislation in the field of biosafety, including the views of the Parties, subregional, regional and international organizations, with a view to presenting a report for the consideration of the second meeting of the Conference of the Parties, so as to enable the Conference of the Parties to reach an informed decision as to the need for and modalities of a protocol", contained in document CBD/Biosafety Expert Group/L.3.

21. After the adoption of some amendments from the floor, the Group adopted the following conclusion under agenda item 4:

CONCLUSION OF THE MEETING UNDER AGENDA ITEM 4

(a) The consideration, by the Open-ended ad hoc Group of Experts, of agenda item 4 "consideration of existing knowledge, experience and legislation in the field of biosafety, including the views of the Parties, subregional, regional and international organizations, with a view to presenting a report to the second meeting of the Conference of the Parties, to enable the Conference of the Parties to reach an informed decision as to the need for and modalities of a protocol", was based on Section III of the Report of the Panel of Experts on Biosafety (CBD/Biosafety Expert Group/2) contained in the annex to this report. There was consensus that this document was the designated background document for the meeting and that other documents with potentially relevant information should be considered in this context.

(b) The meeting considered elements of information contained in paragraphs 48 to 62 of the Report of the Panel of Experts as providing a good general overview of the existing knowledge, experience and legislation in the field of biosafety. A number of participants noted also that some of the information contained in the UNEP Expert Panel IV report on "Consideration of the need for and modalities of a protocol setting out appropriate procedures including, in particular, advance informed agreement in the field of the safe transfer, handling and use of any living modified organism resulting

from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity" was also relevant to the discussion.

(c) Some representatives felt that an evaluation of the adequacy of existing mechanisms and legislation on biosafety was desirable in identifying the need for any additional action to ensure safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

(d) In this regard, the meeting noted that the assessment provided in the Report of the Panel of Experts on Biosafety drew on the responses of Governments and international organizations submitted to the Secretariat in accordance with decision I/9 of the first meeting of the Conference of the Parties. The meeting agreed that the evaluation carried out is sufficient and that therefore there was no need for the time being of an additional survey of existing national, regional and international regulations and agreements of relevance to the impact of living modified organisms (LMOs) resulting from modern biotechnology on the conservation and sustainable use of biological diversity. It was also noted that only a limited number of countries had responded to the Secretariat's survey. Therefore, the meeting invited Governments that did not provide information to do so, in order to facilitate a more comprehensive overview. The meeting also agreed that there was a need for further analysis of existing national, regional and international regulations and agreements of relevance to the impact of LMOs on the conservation and sustainable use of biological diversity. Some participants stated that the publication by the Secretariat of that survey and analysis would be useful.

(e) A number of participants stated also that the experience gained so far, although substantial and important, could not constitute a complete understanding of the interactions between all LMOs in all different environments. They also noted the need to take into account the different climatic and environmental conditions between temperate countries, where most of the releases of LMOs have taken place, and tropical countries.

(f) The meeting considered that lack of technical, financial and institutional capacity in many developing countries is an impediment in addressing biosafety. It was noted that an effective implementation of Articles 16 to 19 of the Convention on Biological Diversity is important for the acquirement and/or development of relevant biotechnology, and its proper management, as well as the building up of local, technological and institutional competence, thereby contributing to the distribution of the benefits from the potentials of biotechnology while avoiding possible negative impacts. Accordingly, the meeting stressed the urgent need to address capacity-building requirements of developing countries for the effectiveness of any international framework to deal with biosafety. In this context, the meeting recommended that the draft UNEP International Technical Guidelines be completed urgently because of their potential contribution to capacity-building, stressing at the same time that completion and implementation of these guidelines should not prejudice the decision of the Conference of the Parties to develop and adopt a protocol.

(g) The meeting noted that existing international and regional guidelines/agreements on biosafety have served and may serve as a basis for the development of some national biosafety regulatory systems. For example, the OECD principles were found very useful for OECD countries and it was suggested (by some delegations) that they could be used as model in other countries. Considering the large number of international agencies dealing with biosafety regulations, the meeting invited these agencies to coordinate and harmonize their efforts.

(h) The meeting also noted that while some efforts at regional harmonization of existing legislation/guidelines on biosafety have been undertaken or are underway, such harmonization is not

occurring on a global basis. The meeting also underlined that existing international legislation does not specifically address the transboundary movements of LMOs or other related cross-border issues and their effects on conservation and sustainable use of biological diversity. Neither do they address on a global level the specific concerns expressed in Article 19, paragraph 3 and other considerations such as socio-economic and ethical aspects pertaining to LMOs.

22. In connection with paragraph (h) of the above-adopted conclusion, the representative of the United States of America referred to current efforts within the North American region aimed at ensuring a regional harmonization of existing national legislation/guidelines on biosafety, as well as efforts in a number of international organizations.

IV. CONSIDERATION OF THE NEED FOR AND MODALITIES OF A PROTOCOL SETTING OUT APPROPRIATE PROCEDURES, INCLUDING, IN PARTICULAR, ADVANCE INFORMED AGREEMENT, IN THE FIELD OF THE SAFE TRANSFER, HANDLING AND USE OF ANY LIVING MODIFIED ORGANISM RESULTING FROM BIOTECHNOLOGY THAT MAY HAVE ADVERSE EFFECT ON THE CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY

23. At its 3rd and 4th sessions, the Group considered item 5 of its agenda. The representatives of the following countries made statements: Australia; Austria; Bangladesh; Brazil; Canada; Chile; China; Cuba; Democtractic People’s Republic of Korea; Denmark; Ecuador; Egypt; Ethiopia, on behalf of the African Group; Germany; India; Japan; Kenya; Malawi; Malaysia; Mauritius; Myanmar; Netherlands; New Zealand; Norway; Peru; Philippines, on behalf of the Group of 77 and China; Republic of Korea; Senegal; Spain, on behalf of the European Union and on its own behalf; Sweden; Switzerland; Syrian Arab Republic; Tunisia; Uganda; United Kingdom; United States of America, and Viet Nam. The representative of the European Community also made a statement. The representatives of the following two NGOs also made statements: Edmonds Institute and German NGO Working Group on Biodiversity.

24. With reference to Articles 28 and 32 of the Convention, the officer-in-charge of the Secretariat of the Convention clarified the meaning of "protocol" within the context of the Convention. He also made reference to document UNEP/CBD/IC/1/5, "The further development of Legal Regimes under Multilateral Treaties", which was subsequently distributed.

25. At the 5th session of the Group, the chairman of the open-ended drafting group reported back to the plenary session on the "Elements for the content of an international framework on biosafety" prepared by the drafting group.

26. Following an exchange of views and the proposal of amendments from the floor, it was agreed that the "Elements for the content of an international framework on biosafety", as amended, would be forwarded to the Group at its 6th session for discussion and adoption.

27. At its 6th session, the Group considered the "Elements", as contained in document CBD/Biosafety Expert Group/L.2. After the adoption of several amendments from the floor, the meeting adopted the text of the "Elements for the Content of an International Framework for Biosafety", as contained in Annex 1 to the present report.

28. After the adoption of the text, the representative of the Philippines, speaking on behalf of the

Group of 77 and China, requested that the following statement be recorded in the report of the meeting:

> "The Group of 77 and China:
>
> Acknowledging the mandate contained in decision I/9 of the first meeting of the Conference of the Parties to the Convention on Biological Diversity;
>
> Considering all the views expressed in the plenary session of the Open-ended Ad Hoc Group of Experts in Madrid on the issue of biosafety;
>
> Taking into account that existing regulations do not address the issue of transboundary movements of LMOs or other related cross-border issues and their efforts on the conservation and sustainable use of biological diversity, nor that they address the specific concerns expressed in Article 19, paragraph 3, of the Convention on Biological Diversity; and
>
> Recognizing that biotechnology has great potential for human well-being if developed with adequate safety measures with due concern for the environment and human health;
>
> Concluded and agreed to strongly recommend that a protocol on biosafety under the Convention be established."

29. The representative of Japan requested that the following statement be recorded in the report of the meeting:

> "It has been widely considered that recombinant DNA techniques are an extension of conventional genetic procedures and that organisms produced by this technology present risks that are the same in kind as those posed by any other organism."

30. The representative of India said that, with regard to the substance of the statement made by the representative of Japan, a number of representatives at the present meeting had expressed views that disagreed with that statement.

31. The representative of Chile, speaking on behalf of the Latin American and Caribbean Group, requested the inclusion in the report of a statement on behalf of that Group. The statement is attached as annex II.

32. The representative of OECD, in her statement, informed the meeting that, in the spirit of international cooperation and coordination, OECD would like to make available to the Secretariat of the Convention on Biological Diversity documents which they had developed in the area of biosafety, including comprehensive surveys on comparisons of regulatory systems for plants and micro-organisms. OECD would also keep the Secretariat informed of its efforts on harmonization which entail development of consensus documents and BIOTRACK, a database with information on field testing. The Third World Network also made a statement.

V. ADOPTION OF THE REPORT

33. At its 6th session, the Group adopted its report on the basis of documents CBD/Biosfety Expert Group/L.1-3. It was agreed that the Secretariat and the Rapporteur would be entrusted with the finalization of the report to include the last part of the session.

VI. CLOSURE OF THE MEETING

34. The closing ceremony took place with the participation of Ms. Cristina Narbona, Secretary of State for the Environment of the Government of Spain, who made a closing statement.

35. Mr. J.G.M. Alders, Officer-in-charge of the Secretariat also made a closing statement.

36. At the same session, the representative of the Philippines, speaking also on behalf of the Group of 77 and China, proposed the adoption of a resolution paying tribute to the Government of Spain.

37. The resolution was adopted by acclamation. The text of the resolution is attached to the present report as annex III.

38. After the usual exchange of courtesies, at 6 p.m. on Friday 28 July 1995 the Chairman declared the meeting formally closed.

Annex I

ELEMENTS FOR THE CONTENT OF AN INTERNATIONAL FRAMEWORK ON BIOSAFETY

1. Pursuant to its mandate as contained in decision I/9 of the first meeting of the Conference of the Parties to the Convention on Biological Diversity, the Open-ended Ad-Hoc Group of Experts on Biosafety stressed the immediate need for international action to achieve adequate safety of LMOs* resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

I. INTRODUCTION

2. In addressing its mandate, the Open-ended Group was guided by the provision of Article 19, paragraph 3 of the Convention on Biological Diversity, which states that:

> "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity".

3. In addition, the Group noted the particular relevance of two other provisions of the Convention. Article 19, paragraph 4, provides:

> "Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced".

Furthermore, Article 8 (g) requires that:

> "Each Contracting Party shall, as far as possible and as appropriate:
>
> Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health".

---

* This understanding of LMOs applies throughout the text.

4. The meeting considered that these provisions needed to be borne in mind in addressing the implementation of Article 19, paragraph 3 of the Convention.

5. The meeting also considered that international action on safety in biotechnology should be directed to ensure safety for human health and the conservation and sustainable use of biological diversity.

6. International action should lead to a framework for safety in biotechnology which could include legally binding instruments, voluntary agreements, bilateral and multilateral arrangements and actions by national, regional and international bodies.

7. The meeting also stressed that the international action on safety in biotechnology should be based on the principles enshrined in the Rio Declaration on Environment and Development and, in particular, the precautionary approach contained in Principle 15.

8. The international action should also take into account specific needs and circumstances of all countries and, in particular, the developing countries, including small island developing States.

9. The meeting also stressed the importance of taking into account the scientific considerations underlying the need for international action.

10. In this context, a reason for giving attention to LMOs resulting from modern biotechnology that may have adverse effects on biodiversity is that there may be a lack of familiarity with these organisms and, under these circumstances, it is not possible to assess and evaluate the impacts fully. Appropriate risk assessment and risk management reflect the application of the precautionary approach.

11. Significant gaps in knowledge have been identified, specifically in the field of interaction between 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 a range of environments, specifically those in centres of origin and genetic diversity.

12. International action will need to address the different behaviour of LMOs in different ecosystems and geographical areas. The potential risks posed by LMOs are often environment-dependent and ecosystems and living organisms vary geographically and climatically. As a result, an organism that is safe in one country is not necessarily safe in another country.

13. In the light of the complexity of this issue, the meeting stressed that, under the framework on biosafety, principles for risk assessment and risk management should be applied within a well-defined technical/scientific methodology for safety in biotechnology including a step-wise and case-by-case approach.

14. The framework should be flexible and encourage development of knowledge and provisions for adjustment to new knowledge.

15. The framework should take into account other related instruments to ensure most efficient and effective coordination.

II. AIM

16. The international action on biosafety should offer an efficient and effective framework for the development of international cooperation aimed at ensuring safety in biotechnology through effective risk assessment and risk management for the transfer, handling and use of any LMO resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking also into account Articles 8 (g) and 19 (4).

III. SUGGESTED ITEMS TO BE CONSIDERED IN AN INTERNATIONAL FRAMEWORK ON BIOSAFETY

17. The international framework should be guided by the principles contained in section I above.

18. Possible issues to be addressed within the international framework on biosafety:

(a) Consensus was reached on the following items:

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

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

(iii) The release of LMOs resulting from modern biotechnology in centres of origin and genetic diversity.

(iv) Mechanisms for risk assessment and risk management.

(v) Procedure for advance informed agreement.

(vi) Facilitation of exchange of information from all publicly available sources, including to local communities.

(vii) Capacity-building in all the aspects required for biosafety.

(viii) Implementation mechanisms.

(ix) Definition of terms.

(b) The following issues, though not enjoying consensus, were supported by many delegations:

(i) Socio economic considerations.

(ii) Liability and compensation.

(iii) Financial issues.

IV. OPTIONS FOR AN INTERNATIONAL FRAMEWORK

19. The following options for an international framework are relevant for the Conference of the Parties in its consideration of the need for a protocol.

In addressing the question of the need for and modalities of a protocol on the safe transfer, handling and use of LMOs resulting from modern biotechnology, the Expert Group reviewed the following points:

(a) Coordination and strengthening of existing arrangements.

This option would be based on existing arrangements, including strengthening cooperation among relevant national, regional and international regulations, mechanisms, guidelines, legislation, agreements and activities as directed by member Governments. Opportunity for greater coordination and strengthening of existing arrangements could include:

(i) Improvements to international arrangements for and approaches to risk assessment and management:

(ii) Further elaboration of capacity-building requirements and strategies for their implementation;

(iii) Further efforts to coordinate existing guidelines/regulations and agreements;

(iv) Improved information exchange and dissemination on existing regulatory systems through established mechanisms.

(b) Establish new voluntary international arrangements.

Any such arrangements could be established within the framework of the Convention or outside the Convention. One example of this option could be the further development of the draft international technical guidelines for safety in biotechnology currently being prepared by UNEP.

(c) New legally binding instrument (protocol) under the Convention.

(d) A combination of some of the above.

V. RECOMMENDATIONS

20. The large majority of delegations favoured the development, within the context of the international framework outlined in section III, of a protocol under the Convention on Biological Diversity and that the second meeting of the Conference of the Parties may consider the establishment of an open-ended working group under the Conference of the Parties for that mandate.

- Some delegations wanted immediate action on this process.

- Some favoured a step-wise approach to the development of such a protocol.

21. Those delegations who did not yet have a position on whether there is a need for a protocol or not, recommended that the second meeting of the Conference of the Parties should consider the options in section IV above.

22. All delegations highlighted the urgent need to give attention to the issue of transboundary movement of LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

23. In addition, the Group endorsed UNEP's efforts to finalize its International Technical Guidelines on Safety in Biotechnology and start the capacity-building programme as soon as possible. However, this should not prejudice the decision of the Conference of the Parties to develop and adopt a protocol.

Annex II

STATEMENT BY THE MEMBERS OF THE GROUP OF LATIN AMERICAN AND CARIBBEAN STATES (GRULAC)

The Members of the Group of Latin American and Caribbean States (GRULAC),

Considering that the Convention on Biological Diversity has now entered into force;

Considering that the Parties to the Convention have adopted decision 1/9, and particularly paragraphs 2 to 6;

Bearing in mind the principles of the Rio Declaration on Environment and Sustainable Development;

Reiterating the need to adopt a legally binding instrument on the safety of biotechnologies within the framework of the dispositions contained in the Convention on Biological Diversity;

Recalling the mandate conferred on the Parties under Article 19, paragraph 3 of the Convention on Biological Diversity, which states that: "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity";

Conscious of the need to decide on steps towards the elaboration of a protocol;

Suggest that a protocol on safety of biotechnologies should take account of the following aspects:

Proposed structure

- **Principles**

  The protocol on safety of biotechnologies should be based on the Principles of the Rio Declaration.

- **Objective/scope**

  The main objective/scope of the protocol is to establish adequate procedures for the safe transboundary transfer of any genetically modified organisms that may have adverse effect on the conservation and sustainable use of biological diversity.

- **Proposed content**

  Mechanisms for risk evaluation and management;

  Mechanisms for application of advance informed agreement;

Public information mechanisms;

Technical information network;

Transboundary movement of genetically modified organisms;

Release of genetically modified organisms in centres of origin and/or centres of genetic diversity;

Financial mechanism;

Mechanism for the transfer of appropriate technology;

Capacity-building;

Relationship with other international instruments;

Liability and compensation;

Settlement of disputes;

Definitions.

- **Immediate measures**

National regulations based on existing guidelines;

Capacity-building;

Information network.

Annex III

TRIBUTE TO THE GOVERNMENT OF SPAIN

The Open-ended Ad Hoc Group of Experts on Biosafety, having met in Madrid, Spain, from 24 to 28 July 1995

Deeply appreciated the warm hospitality and the quality of services offered to the members of the Open-ended Ad Hoc Group of Experts on Biosafety by the Spanish authorities;

Expressed its sincere gratitude to the Government of Spain for hosting the meeting of the Open-ended Ad Hoc Group of Experts on Biosafety.

Annex IV

REPORT OF THE PANEL OF EXPERTS ON BIOSAFETY
(originally issued as document CBD/Biosafety Expert Group/2)

1. OPENING OF THE MEETING

1. The meeting of the Panel of Experts on Biosafety was opened on 1 May 1995 by Ms. Angela Cropper, Executive Secretary of the Convention on Biological Diversity. She welcomed the participants to the meeting and expressed on behalf of the Secretariat her gratitude to the Egyptian authorities for hosting the meeting and for the generous hospitality extended to all participants.

2. The Executive Secretary introduced the background document prepared by the Secretariat to facilitate the work of the Panel and noted with appreciation the support of international organizations in its finalization (*see* CBD/Biosafety Expert Group/Inf.2). She reviewed the context for the work of the Panel of Experts contained in the introduction to the Secretariat's Note.

3. At its first meeting held in Nassau, The Bahamas, from 28 November to 9 December 1994, the Conference of the Parties (COP) expressed deep concern and interest about the need for the safe transfer, handling and use of all living modified organisms (LMOs) resulting from biotechnology to avoid adverse effect on the conservation and sustainable use of biological diversity.

4. Accordingly, the COP decided to establish an open-ended ad hoc group of experts nominated by Governments with the following terms of reference:

(a) to consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity; and

(b) to consider, as appropriate, existing knowledge, experience and legislation in the field of biosafety, including the views of the Parties, subregional, regional and international organizations, with a view to presenting a report for the consideration of the second meeting of the Conference of the Parties, so as to enable the Conference of the Parties to reach an informed decision as to the need for and modalities of a protocol.

5. In order to prepare for the work of the open-ended ad hoc group of experts on biosafety, the COP requested the Secretariat to establish a panel of 15 government-nominated experts, assisted by UNIDO, UNEP, FAO and WHO, to prepare a background document to be submitted to the open-ended ad hoc group of experts based on consideration, as appropriate, of existing knowledge and experience on risk assessment and management, and guidelines and/or legislation already prepared by the Parties, other governments and by national and competent subregional, regional and international organizations.

6. The Executive Secretary emphasized that the work of the Panel of Experts is the first stage of a three-stage process designed to facilitate a decision by the second meeting of the Conference of the Parties on how to proceed under Article 19, paragraph 3, of the Convention on Biological Diversity on the need for and modalities of a protocol on biosafety.

7. At the kind invitation of the Government of the Arab Republic of Egypt, the meeting of the Panel of Experts on Biosafety was held in Cairo, Egypt, from 1 to 5 May 1995.

8. The meeting was attended by the following 15 experts nominated by their governments after consultations with their respective regional group: Mr. Ivan Rodrigo Artunduaga Salas (Colombia), Mr. Ervin Balazs (Hungary), Mr. V.L. Chopra (India), Ms. Dhurata Frasheri (Albania), Mr. Zhu Guangqing (China), Mr. Ken-ichi Hayashi (Japan), Mr. John Hoffmann (South Africa), Mr. Gabriel Macaya (Costa Rica), Mr. Magdy Madkour (Egypt), Ms. Helen Marquard (United Kingdom), Mr. Terry Medley (United States of America), Mr. Eduardo Trigo (Argentina), Mr. Albert S. Welinder (Denmark), Mr. A.P. Yermishin (Belarus) and Mr. Roger G. Zangre (Burkina Faso).

9. The meeting was also attended by representatives of the United Nations Environment Programme and the Food and Agriculture Organization of the United Nations.

2. ORGANIZATIONAL MATTERS

2.1 Election of officers

10. At its first session, the Panel of Experts unanimously elected Mr. Magdy Madkour as Chairman.

11. At the same session, the Panel of Experts unanimously elected Mr. Albert Welinder, as Rapporteur.

2.2 Adoption of the agenda

12. At its first session, the Panel of Experts adopted the following agenda:

1. Opening of the meeting.

2. Organizational matters:

   2.1 Election of officers;
   2.2 Adoption of the agenda;
   2.3 Organization of work

3. Preparation of a background document for the meeting of the open-ended ad hoc group of experts:

   3.1 Consideration of existing knowledge and experience on risk assessment and management including guidelines and/or legislation already prepared by the Parties, other Governments and by national and competent subregional, regional and international organizations.

   3.2 Options and recommendations on the need for and modalities of a protocol on biosafety for consideration by the open-ended ad hoc group of experts on biosafety.

4. Adoption of the report.

5. Closure of the meeting.

2.3 Organization of work

13. At its first session, the Panel of Experts adopted its organization of work as contained in document CBD/Biosafety Panel/1/Add.2.

14. At its second session, the Panel of Experts established open-ended drafting groups on specific issues under the coordination of the Rapporteur.

3. PREPARATION OF A BACKGROUND DOCUMENT FOR THE MEETING OF THE OPEN-ENDED AD HOC GROUP OF EXPERTS

15. The Panel noted that the recommendation on structure of the Panel's report in the Secretariat Note was an effective way to begin the discharge of its mandate. Accordingly, the Panel agreed to proceed with agenda item 3 by considering approaches to risk assessment and risk management, and existing national, regional and international guidelines, regulations and agreements. The Panel then chose to identify additional needs for action before reaching its main conclusions.

4. ADOPTION OF THE REPORT

16. The consideration of agenda item 3 led to the Panel report to be submitted to the open-ended ad hoc group of experts to be held in Madrid, Spain, from 24 to 28 July 1995. The Panel also adopted its background document and included it as the following paragraphs 18-84 of this report.

5. CLOSURE OF THE MEETING

17. At its final session, the Panel paid tribute to the Government of the Arab Republic of Egypt, the text of which is attached as annex I to this report. The Chairman then closed the meeting.

1. INTRODUCTION

18. Initially, the Panel reaffirmed that direction for its deliberations was provided by Article 19, paragraph 3 of the Convention on Biological Diversity which states that:

"The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity".

19. However, the Panel noted the particular relevance of two other provisions of the Convention. Article 19, paragraph 4, provides:

"Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced".

20. In addition, Article 8(g) requires that:

"Each Contracting Party shall, as far as possible and as appropriate:

Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health".

21. The Panel felt these provisions needed to be borne in mind during its review of existing documentation on risk assessment and risk management and of the existing guidelines and regulations relevant to biosafety.

22. The Panel noted that the term "living modified organisms" (LMOs) covers a wide range of organisms but that the LMOs of concern were those with the potential to adversely affect the conservation and sustainable use of biodiversity. The Panel acknowledged that these LMOs would cover a range of organisms with different usages and different associated risks. A typology for dividing up the field of LMOs of relevance to the Convention is necessary if the Parties decide to develop an international framework for safety in biotechnology.

23. LMOs were considered to be all organisms produced through the use of recombinant DNA technology, but the Panel was of the view that a wider range of modifying technologies is relevant when considering living modified prokaryotes and yeast. The definition was used only to distinguish modern from traditional biotechnologies and does not imply any greater risk attached to products from modern biotechnologies vis-a-vis those arising from traditional ones. In order further to establish a common understanding about the framework for discussion, the Panel carefully considered its understanding of key terms not defined in the Convention itself. These are explained as appropriate as footnotes in the body of this report.

24. In preparing this report, the Panel focused on the health and ecological concerns raised by

LMOs resulting from biotechnology. The Panel fully recognized the importance that the socio-economic effects of introducing these new technologies can have, inter alia, on decision-making processes, but felt that risk assessment should be restricted to the basis of objective parameters. Socio-economic aspects bring value judgements into the analysis which inevitably vary among countries and communities and from case to case depending on considerations other than the nature of the technologies themselves.

25. The perception of risk posed by LMOs varies in form and intensity among different organizations and groups of people. Some, as a matter of faith, often see biotechnology as a great evil, while others proclaim biotechnology products to be as safe as those created by traditional methods. One result of this is that the general public is confused by two conflicting positions. The Panel therefore felt it was important to attempt to give a balanced perspective on biosafety based on factual and valid criteria.

26. Since the advent of recombinant deoxyribonucleic acid (DNA) technology, many of the initial concerns and fears have been allayed as experience and knowledge has accumulated. Experience has led to the relaxation in the rigidity of operational guidelines where it has shown that this is appropriate. It is not, however, prudent to abandon all caution and extrapolate beyond what is warranted by experience and experimental design. The Panel noted the potential and the desirability of its playing an educative role and infusing balance into the discussion among non-specialists.

27. In looking ahead to its review of existing guidelines and legislation relevant to the impact of LMOs on the conservation and sustainable use of biological diversity, the Panel noted that there are other important international instruments of relevance. The Panel did not take these into detailed consideration in preparing its report, but it recognized that any further development of its work would need to be seen in the context of these instruments.

28. The Panel noted that Agenda 21, agreed at the United Nations Conference on Environment and Development (UNCED, Rio de Janeiro, June 1992), makes specific provision for the "Environmentally Sound Management of Biotechnology". The introduction in chapter 16 of Agenda 21 recognizes that although biotechnology cannot provide solutions to all problems, it could contribute substantially to sustainable development by improvements in food and feed supply, health care, and environmental protection.

29. Agenda 21 also recognizes that the community at large can only benefit maximally from biotechnology if it is developed and applied judiciously. Therefore it seeks to ensure safety in biotechnology development, application, exchange and transfer through international agreement on principles to be applied on risk assessment and management.

30. The contribution that safety in biotechnology can make to the successful global development of the technology depends on the extent of international information exchange, cooperation, harmonization, and agreement, and on the extent to which countries are able to take advantage of mechanisms for safety.

31. The development of new techniques of genetic modification in the early 1970s prompted a thorough discussion on safety in biotechnology which resulted in a number of national and international recommendations, guidelines and legislation. By the mid-1980s it was widely considered that recombinant DNA techniques were an extension of conventional genetic procedures and that organisms produced by this technology present risks that can be the same in kind as those posed by any other organism. It was also recognized that the potential benefits of biotechnology were increased because

the new molecular techniques allowed a greater diversity of genes to be introduced into organisms. However, it was considered that it would be appropriate to develop the application of the technology in a precautionary manner.

32. Modern biotechnology has now been developed and applied for over 20 years under contained conditions and over eight years for applications in the environment. Given the rapid development of the use of this technology and taking into account the knowledge and experience gained so far, an international framework to provide for safety in biotechnology, as called for in Agenda 21, is now opportune.

33. The Panel considered that adequate mechanisms for risk assessment and risk management, the exchange of information, and capacity building at national, regional and international levels, can contribute significantly to safety in biotechnology.

34. Equally, the Panel was of the view that adequate safety mechanisms can contribute to the sustainable development of biotechnology, as foreseen in the Convention, and to the international trade in biotechnological products.

35. The adoption of an international framework, such as guidelines, regulations, codes of conduct, or a protocol, does not of itself ensure safety. Rather, it must provide a mechanism for evaluating safety, identifying measures to manage foreseeable risks and facilitating processes such as appropriate monitoring, research and information exchange, all of which improve the safe application of the technology.

2. APPROACHES TAKEN TO RISK ASSESSMENT AND RISK MANAGEMENT OF RELEVANCE TO THE IMPACT OF LMOs ON THE CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY BY REFERENCE TO NATIONAL, REGIONAL AND INTERNATIONAL DOCUMENTATION

2.1 Introduction

36. The Panel, in keeping with its mandate, considered existing knowledge and experience on risk assessment and management as used to ensure as far as possible that LMOs resulting from biotechnology will not have an adverse effect on the conservation and sustainable use of biological diversity. Such safe application of LMOs is achieved by the appropriate application of risk assessment and risk management.

37. While this approach is generally used the Panel in its work considered this process in close relation to the Convention on Biological Diversity and in particular the safe transfer, handling and use of LMOs[1].

[1] As referred to in Article 19, paragraph 3, of the Convention, the Panel considers the terms "transfer, handling and use" taken as a whole to cover all possible activities involving a LMO. For its work the Panel did not see the need to define the terms individually. The Panel is of the opinion that this would require a full, detailed analysis. In addition, the Panel considers that in Article 8(g) the terms "use" and "release" might be understood to have the usual meanings attached to the terms "contained use" and "deliberate release" respectively.

2.2 Risk assessment

38. Risk assessment is the use of scientific data to identify and characterize the nature and magnitude of hazards, if any, and the likelihood of hazards being realized. Risk assessment may, subsequently, serve as a basis for decision-making by authorities if the operation to which it refers initiates regulatory requirements.

39. It was recognized that:

(a) risk assessment is based on the characteristics of the organisms, the introduced trait, the environment into which the organism is introduced, the interactions between these, and the intended application. Knowledge of and experience with any or all of these provides familiarity which plays an important role in the risk assessment;

(b) risk assessment is conducted prior to an intended action and is typically a routine on-going component of research, development and testing of new LMOs, whether performed in a laboratory or a field setting. It can range from judgements by the researcher (as an implicit part of good experimental practices) to adherence to wide-ranging and detailed formalized procedures.

40. From the perspective of the Convention on Biological Diversity, the issues raised by LMOs resulting from biotechnology cover a wide range. These include, *inter alia,* issues of the stability of the inserted genes, environmental impact on non-target species, adverse effects on ecosystem processes, potential for weediness of genetically modified crops; issues of genetic alteration, regulation of gene expression and intended and unintended changes; and issues of phenotypic properties of the donor organisms, such as competitiveness, pathogenicity and virulence.

41. With regard to these issues, assessment is linked to gathering and generation of scientific data on potential adverse effects, in particular data indicating a cause/effect relationship.

42. The Panel felt that risk assessment of LMOs with the potential to adversely affect the conservation and sustainable use of biological diversity might best be approached on a case-by-case basis[2]. The case-by-case approach involves assessing organisms or category of organisms. It involves first considering key issues, for example the potential to transfer genetic material. If such potential exists the approach proceeds to assess the risk of an adverse effect consequent to gene transfer and then, if appropriate, proceeds to risk management.

43. Systematic risk assessment is based on the following set of elements:

(a) the characteristics of the donor, the recipient or, where appropriate, the parental organism(s);

(b) the characteristics and intended utilization of the modified organism including the scale and frequency; and

(c) environmental and health considerations.

---

[2] Case-by-case means that each proposal is reviewed individually. This does not imply that every case requires review by national or other authority since various classes of proposals may be excluded.

44. A review of existing guidelines and legislation on safety in biotechnology highlights the following fundamental principles of risk assessment:

(a) a primary consideration of the characteristics of the organism and the potential receiving environment;

(b) familiarity[3] with LMOs as a key feature in risk assessment; and

(c) a general distinction between contained use and release into the environment.

45. These principles may best be applied within a well-defined framework for safety in biotechnology. Within this framework, there is need for a case-by-case approach and for reliable information, derived from the stepwise development.

2.3 Risk Management

46. In this report the term risk management is the implementation of the most appropriate measures to minimize the identified risks and mitigate their effects while achieving the anticipated results. Under certain legislative mandates, risk management procedures may depend on comparisons of potential risks and benefits, including economic considerations.

47. Risk management is implemented during the development and evaluation of an organism in a systematic and stepwise fashion, through an appropriate continuum, for example from the laboratory, through steps of field testing, to final application, e.g., commercial. The number and modalities of the stages to be included in this continuum are not fixed, but depend on the outcome of the risk assessment at each step. Progression through successive steps generally entails a reduction in control measures whilst often increasing scale in order to gain knowledge, or for functional purposes. Any particular developmental stage begins after incorporating information and experience from an earlier stage, or other appropriate information.

3. EXISTING NATIONAL, REGIONAL AND INTERNATIONAL GUIDELINES, REGULATIONS AND AGREEMENTS OF RELEVANCE TO THE IMPACT OF LMOs ON THE CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY

48. The Panel felt that an evaluation of the adequacy of existing guidelines and legislation on biosafety would enable it to identify any additional needs for action to ensure an appropriate safety framework for LMOs. The identification of such needs was deemed essential prior to discussion of the need for establishment of appropriate frameworks. In its review of the existing guidelines and legislation, common elements or characteristics of appropriate mechanisms emerged. For example, it was of paramount importance that oversight mechanisms for LMOs clearly delineate the respective responsibilities of the applicant/user of the LMO and the relevant authority or authorities responsible for oversight. It was also clear that although the initial trigger for risk assessment might differ amongst national authorities, such risk assessment uses scientific principles to evaluate agreed upon common sets of elements such as the characteristics of the donor, the recipient and where appropriate, the vector; the

[3] Familiarity means having enough information to be able to judge the safety or risks of an LMO. It can be used to indicate ways of handling risks. It is not synonymous with safety. Relatively low degree of familiarity may be compensated for by appropriate management practices. Familiarity can be increased as a result of trial or experiment. This increased familiarity can then form a basis for future risk assessment.

intended utilization of the modified organism and its interaction with the environment; and where appropriate human health considerations.

49. Further, in an effort to have safety frameworks that are adaptive and adjusted based upon experience, there is a development trend to identify low risk categories of LMOs and to simplify administrative requirements for such organisms. This has led to development of simplified notification procedures for certain groups of modified plants.

3.1 National guidelines/legislation

50. In accordance with its mandate, the Panel considered available information on national guidelines and/or legislation on biosafety. The Panel noted with appreciation the response of governments to the Secretariat's request for information on national regulatory systems. Based on the expertise of the Panel members and the limited number of replies, the Panel conducted only a preliminary analysis of the trends and general characteristics of national instruments. This analysis also forms the basis for the discussion of additional needs for action in section 4. For a comprehensive analysis, an additional detailed survey would be needed.

3.1.1 Trends

51. The scope of coverage of national regulations for biosafety range from those that address only organisms developed through recombinant DNA techniques to those that include other modification techniques such as micro-injection, cell fusion, etc. In addition, under these different national regulations, the specific taxa of organisms covered range from, for instance, micro-organisms, plants or animals to some combination of these e.g. plants and micro-organisms or plants; micro-organisms and animals. There are even those national regulations that address specific groups of organisms such as bioremediation agents.

52. In addition to the type of organisms covered, the particular stages of development of the different types of LMOs are also covered. Research and development, particularly in contained conditions, as well as small-scale and large-scale experimental releases, and commercialization are included in the scope of existing regulations. A new trend is that, except where pathogens are involved, separate regulation of genetically modified organisms (GMOs) in contained use may become unnecessary over and above current good laboratory practice. Domestic transportation is included in national guidelines, but only a small number of them cover transport across boundaries.

53. In general, protection of the environment and public and worker health are primary objectives of many biosafety regulations. Parameters to consider as part of risk assessment and management in order to characterize the environment and public health are listed in the annexes to regulations. They present many common elements and a few differences. The importance of socio-economic aspects is highlighted in the preamble of some guidelines and regulations.

3.1.2 Characteristics

54. A number of countries have derived their biosafety framework from existing regulations, especially in the area of plant protection. Under this approach, countries use existing administrative structures to implement the requirements of these regulations; however, adaptation of existing regulations to cover potential risks posed by LMOs might not always be transparent.

55. Some other countries use as a basis the US National Institute of Health (NIH) guidelines for

contained use and the Inter-American Institute for Cooperation on Agriculture (IICA) guidelines for contained use and deliberate release of LMOs to the environment, and/or the OECD Good Industrial Large-Scale Practice and Good Development Principles. Although guidelines are followed on a voluntary basis, indirect pressure may ensure compliance. For example, compliance with guidelines may be a condition for receipt of government grants.

56. In several countries, LMOs can be subject to regulatory oversight under the ambit of other broader legislation e.g., legislation concerned with new chemicals/substances, environmental protection, or pollution control. The implications and degree of overlap with other forms of regulatory oversight should be assessed.

57. The triggers which initiate regulatory requirements under national frameworks differ among countries. Some are triggered by the type of products and resulting risks and others are triggered by the general definition of the type of organisms covered.

58. In general, countries that developed their framework from existing regulations have biosafety regulations that are administered in a decentralized manner, i.e. by more than one national authority. This decentralized manner also holds true in countries that have developed new guidelines and regulations. For countries that are developing new guidelines or legislation, it appears that the tendency is for a centralized administration of the biosafety framework i.e. one national authority. In the case of such new guidelines, a national biosafety committee usually has responsibility for formulating biosafety policy and procedures and providing technical advice. Under either a centralized or decentralized approach, past experience emphasizes the need for public consultation and transparency.

3.2 International and regional guidelines/agreements on biosafety

59. A number of intergovernmental organizations have developed directives, guidelines and codes of conduct setting out general frameworks for international harmonization of and cooperation on biosafety regulations. These guidelines and regulations have and may serve as a basis for development of some national biosafety systems. Those that are the result of a political process and have been formally adopted by the organization overseeing their development include:

(a) Recombinant DNA Safety Considerations, OECD, Paris, 1986.

This document, also referred to as the "Blue Book" sets out the first international safety guidelines for biotechnology applications in industry, agriculture and the environment. This document was followed up by "Safety Considerations for Biotechnology" in 1992.

(b) Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms. Official Journal of the European Communities No. L117, Vol. 33 of 8 May 1990, pages 1-14.

The objective of this Directive is to provide a harmonized regulatory framework for all contained uses of genetically modified micro-organisms in order to provide for the protection of human health and the environment. The Directive does not cover contained uses of higher organisms as such, although in most cases the work with higher organisms will be covered since it will be preceded by modification work at the micro-organism or cell culture level. A provision is made to allow Member States to maintain flexibility in conformity with the Community treaty and relevant legislation and to adopt national measures, in conformity with the Community treaty and relevant legislation, regarding

the contained use of those genetically modified micro-organisms to which this Directive does not apply. For flexibility, the Directive contains a provision whereby criteria for classifying genetically modified micro-organisms, safety assessment parameters, containment measures, and other information required can be amended.

(c) Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms. Official Journal of the European Communities No. L117, Vol. 33 of 8 May 1990, pages 15-27.

This Directive covers all GMOs i.e. "organisms in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural combination", except those organisms produced by mutagenesis and through cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods. Unlike the contained use Directive (see (b) above), this Directive does not apply to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air.

(d) Safety Considerations for Biotechnology, OECD, Paris, 1992.

This report is a follow-up to the 1986 publication. The report consists of two parts: Part One further develops the Good Industrial Large-Scale Practice criteria and reviews the fundamental principles, identified in the 1986 report, for the handling of low-risk recombinant DNA organisms in industrial production; Part Two provides guidance on the design of low or negligible risk (small-scale) field research with genetically modified plants and micro-organisms. It introduces general principles for such research, or "Good Development Principles" (GDP) applicable to the continuum of testing from laboratory to production release. The application of GDP should ensure the safety of small-scale field research with genetically modified organisms by providing guidance to researchers on selecting organisms, choosing the research site, and designing appropriate experimental conditions. It should assist in the review of proposals for small-scale field trials, which in turn should provide data to predict the safety of large-scale trials as part of the step-by-step process.

60. Those that are the result of an international technical discussion but not formally adopted include:

(a) Guidelines for the use and safety of genetic engineering techniques or recombinant DNA technology, Washington DC, The Inter-American Institute for Cooperation on Agriculture (IICA), 1988.

"These guidelines provide safety assurance and regulatory guidance on a range of biotechnology issues including research done in laboratories or contained facilities, as well as research involving products intended for release. They give some specific attention to the needs and constraints faced by Latin American countries, including advice on how national and institutional review bodies might be established, where they do not exist".

(b) Guidelines for the release into the environment of genetically modified organisms. Organization of American States, International Office of Epizootics. The Inter-American Institute for Cooperation on Agriculture (IICA), 1991.

Because genetic engineering activities done in the laboratory or in contained conditions are regulated in many Latin American and Caribbean countries by a voluntary notification to some competent authority at the organization or national level, and activities with GMOs in non-contained

conditions are regulated in some countries by legally competent institutions under existing laws and in a few instances under special laws, Latin American and Caribbean countries found it appropriate to develop guidelines for regulating biotechnology products at the regional level instead of proposing new legislation.

(c) Voluntary Code of Conduct for the Release of Organisms into the Environment. UNIDO Secretariat, July l991.

The Code suggests that regulation of GMOs should build on existing mechanisms such as quarantine procedures or similar mechanisms for managing the import of new plants, animals or micro-organisms. To ensure the safe management of research, development, use and associated environmental releases of GMOs, the Code emphasizes the need for and formulates suggestions on establishment of appropriate scientific and technical expertise; national assessment and decision-making structure(s); specific scientific advisory bodies; mechanisms to gather information on local agronomic and environmental conditions; systems for the provision of information to and education of the public; and mechanisms for cooperation and consultation among governments in compliance with international transport laws, and movement of biotechnology products in trade.

61. Two are currently in process and may be adopted by the organization under whose auspices they are being developed. They are:

(a) The FAO International Code of Conduct for Plant Biotechnology as it affects the Conservation and Utilization of Plant Genetic Resources is under preparation (FAO, 1993).

The draft Code consists of elements for a preamble and four chapters on : (i) objectives, scope, definitions, nature of the code, and its relationship with other legal provisions; (ii) promoting the use of biotechnology for the conservation and sustainable use of plant genetic resources; (iii) biosafety and other environmental concerns; and (iv) reporting, monitoring and updating.

(b) Draft International Technical Guidelines for Safety in Biotechnology (UNEP, 1995).

The draft Guidelines have been developed on the basis of common elements and principles derived from relevant national, regional and international guidelines and instruments and draw upon experience already gained through their preparation and implementation. The Guidelines suggest a mechanism for prior informed agreement for some cases of transfer of novel organisms. The Guidelines recognize that adequate mechanisms for risk assessment, risk management, exchange of information, and capacity building at national, regional and international levels can contribute significantly to safety in biotechnology.

62. In reviewing existing guidelines and legislation, the Panel also identified the need to include in its review other relevant instruments that are being applied or could be applied to the oversight of LMOs. It was recognized that in response to the Secretariat's survey of national guidelines/legislation some national authorities use existing legislation to implement mechanisms for oversight of LMOs. These national authorities reasoned, from a scientific perspective, since the potential risks associated with LMOs can be the same in-kind as those associated with conventially produced organisms, using existing legislation was justified. Therefore, it followed that existing international instruments such as the International Plant Protection Convention (IPPC), Codex Alimentarius, London Guidelines for the Exchange of Information on Chemicals in International Trade and the International Office of Epizootic (OIE) should be considered (see annex II for a listing of those instruments identified by the Panel). For

a comprehensive analysis a more detailed review of such instruments is needed.

4. NEED FOR ADDITIONAL ACTION

63. On the basis of the foregoing analysis of risk assessment/management and of existing legislation and guidelines, the Panel identified needs for additional actions in a number of areas. In the following subsections these needs are discussed for three main areas of consideration: risk assessment and management, capacity building requirements and guidelines/regulations/agreements.

4.1 Risk assessment and risk management:

64. The Panel felt it was important to highlight that the assessment and management of risks arising from the development and use of LMOs resulting from biotechnology is not fundamentally different from that used in other technologies. The Panel recognized that methodologies for risk assessment are well defined and therefore can be, and are, applied to the use and release of LMOs. Considerable international documentation on risk assessment and risk management has been produced by intergovernmental, international and other bodies. The Panel noted, however, that such documentation was often restricted to a small number of languages. The introduction of appropriate risk assessment and risk management in all countries would be facilitated by making such information available in more languages. Furthermore, such documentation often does not take account of the full range of environmental and climatic conditions throughout the world. It cannot, therefore, always constitute a comprehensive source of advice applicable to all countries. Some international organizations have undertaken to meet this need, but such action in this area is relatively limited.

65. The Panel noted that in some countries the trigger for regulation of LMOs is the type of product, such as a microbial pesticide, whereas in other countries the trigger is the modern techniques of molecular biology used to produce the LMO. However, the Panel felt that regardless of the trigger, the data and considerations required to make an assessment of the risk are essentially the same.

66. The Panel considered that the nature of hazards associated with LMOs produced by biotechnology can usually be well characterized, although this is less so in the area of aquatic systems and soil microbiology. The Panel also noted that in some cases it is difficult to estimate the magnitude and likelihood of the effects were the hazards to be realized. The Panel felt it would be helpful to distinguish between potential primary or secondary effects and potential indirect effects. Potential primary effects are those that might result directly from the transfer of genetic material from the LMO to other organisms and from the LMO itself on other organisms. Potential secondary effects are those effects that might arise from primary effects. Potential indirect effects include the broader cultural and socio-economic transformations that may be triggered by the adoption of new technologies. The Panel recognized the importance of indirect effects but reiterated its decision not to consider them in its work.

67. With regard to primary and secondary effects, the Panel noted that in order to achieve a sound assessment of the risks associated with the use and release of LMOs relevant expert advice on the potential environmental effects of such use and release is necessary.

68. The Panel was firmly of the view that it was not necessary to apply risk management measures to all uses and releases of LMOs solely because the organisms were produced using modern biotechnological techniques, but that risk management should be applied in order to minimize any identified risks or to take account of uncertainties. The Panel reiterated that biotechnology does not differ from other technologies: uncertainties or lack of knowledge about any particular LMO does not mean that the LMO should not be used. It means that in accordance with a precautionary approach

great care should be taken to achieve a balance between the use of risk management measures to control any risks and to ensure safety as far as possible, noting that the acquisition of information will reduce the degree of uncertainty and thereby increase familiarity. The Panel accepted that as a result of the experience and knowledge gained over the past 20 years, it has been appropriate to relax some of the risk management measures that were initially applied. However, the Panel felt that such measures would not have been appropriate without the benefit of such experience.

69. The Panel considered that as a result of the progressive development of an LMO, there would in many cases be sufficient information at the time of commercialization to allow the removal of any distinction between LMOs and organisms produced by traditional methods. This would mean that there would be no need to require certain procedures, such as monitoring, as the safety of the product would have been demonstrated by the end of the development phase. However, when an LMO product has been developed for certain specialized uses or is to be transferred to a different environment, the use of appropriate risk management measures always needs to be considered.

4.2 Capacity Building Requirements

70. The Panel identified that in many developing countries the absence of an adequate biosafety regulatory framework is mainly due to the lack of minimal research and development capacities in the biotechnology field. This is not only limiting to domestic technology development but also inhibits the flow of technologies of relevance to some of the Convention's objectives. Furthermore, because of the lack of adequate financial and human resources, moving forward in the development and implementation of biosafety regulations will bring up a clear conflict of interest between the use of scarce resources to access and benefit from the technologies on the one side, and the scientific and technical support needs of biosafety regulation on the other.

71. Countries will benefit from the potential of biotechnology while avoiding possible negative impacts only if they have appropriate infrastructure and resources that permit them to acquire and/or develop and apply relevant biotechnology, to manage it properly, and to build up local scientific, technological and administrative competence. Consequently, there is an urgent need to build up biosafety frameworks and related human and physical resources and institutional capacities at the national, regional and international levels to ensure the safe development and application of biotechnology.

72. Such action should include:

(a) Development of technical guidelines or regulations to provide a common framework which will help in evaluating safety and identifying and implementing measures to manage foreseeable risks and facilitate regional and international cooperation.

(b) Human resource development;

(c) Information exchange at the national and international levels;

(d) Active participation and contribution of all sectors involved in the handling and use of the technologies;

(e) Strengthen regional and international cooperation because cooperation is a key factor in implementing biosafety frameworks.

73. Proper consideration of these aspects will ensure that scientists and organizations using LMOs are aware of any risks with LMOs and that regulatory bodies are able to undertake informed decisions to achieve safety when LMOs are to be developed, transferred, handled and used in their countries.

74. Over the last few years a number of important initiatives have been taken by countries, international and intergovernmental organizations to address these needs. Worth noting among them are the efforts of the Inter-American Institute for Cooperation on Agriculture (IICA) in providing technical assistance and training for biosafety development at the national level in Latin America, the ICGEB of UNIDO work in the development of research and development capacities at the national level, the action of the Biotechnology Commission created by the Stockholm Environmental Institute to handle specific risk assessment requests from developing countries, and the current work of UNEP to develop a set of international technical guidelines and a capacity building programme of work to support their implementation. A number of countries have also hosted regional workshops to promote exchange of experience and information.

75. All these efforts, however, have been seriously limited by resource constraints. In the judgment of the Panel, it is clear that on the basis of these experiences plus those accumulated by the developed countries, a capacity building programme could be rapidly put in place if enough resources are made available to mobilize the technical and training support capabilities already in existence at the regional and international levels.

4.3 National, Regional, International Guidelines, Regulations and Agreements

76. As noted in section 2 above, there is wide variation among national governments in the degree and method of regulation of LMOs. Some governments have adopted guidelines or legislation which specifically address biosafety considerations. Others have not promulgated specific regulations but use existing legislation in areas such as plants, vaccines, environmental/human health and pesticides to address biosafety considerations. There are, however, countries which have not adopted specific regulations for biosafety nor have they used existing legislation to promulgate regulations for biosafety. The Panel felt that immediate action is needed for countries to utilize some mechanism for oversight of LMOs.

77. The Panel also felt that there was a need to evaluate the efficacy and appropriateness of the system in use for LMOs irrespective of whether the system is biosafety-specific or uses existing regulations. The flexibility of the national system to be adjusted, based upon experience gained and its ability to address the public understanding of biosafety should also be considered.

78. The Panel noted that even effective national systems are not sufficient if they do not contain procedures for dealing with living organisms which do not necessarily stop at national borders. The question becomes what needs to be done to address transboundary issues. The Panel felt that immediate action is needed to: (i) assess regulatory systems (be they national, regional or international) ability to address the movement of LMOs across national boundaries; (ii) address transboundary issues whether in national, regional or international systems; and (iii) establish at the international level an accepted standard of care for control of transboundary movements of LMOs such as that contained in the draft International Guidelines for Safety in Biotechnology being developed under UNEP's auspices and the draft International Code of Conduct for Plant Biotechnology as it affects the Conservation and Utilization of Plant Genetic Resources under preparation by FAO.

79. The Panel noted that while some efforts at regional harmonization have been undertaken or are underway, such regional harmonization was not occurring on a global basis. The Panel felt that action

should be initiated in those regions where it has not yet begun.

5. CONCLUSIONS

80. As the basis of action to enhance biosafety at the international level, chapter 16, paragraph 29 of Agenda 21 highlights a number of fundamental principles underlying many of the existing safety procedures:

> including primary consideration of the organism, building on the principle of familiarity, applied in a flexible framework, taking into account national requirements, and recognizing that the logical progression is to start with a step-by-step and case-by-case approach, but also recognizing that experience has shown that in many instances, a more comprehensive approach should be used, based on the experiences of the first period, leading *inter alia*, to streamlining and categorizing; complementary consideration of the risk assessment and management; and classification into contained use or release to the environment.

81. Among the activities to be conducted to reach the goals set, Agenda 21 recommends the compilation, updating and development of compatible safety procedures into a framework of internationally agreed principles as a basis for guidelines to be applied on safety in biotechnology.

82. In the perspective of the Convention on Biological Diversity, the Panel, in accordance with its mandate, made the following observations during the consideration of the need for an international framework on biosafety:

(a) Ecological effects and geographic ranges of LMOs transcend political boundaries;

(b) The potential risks posed by LMOs are often environment-dependent and ecosystems and living organisms vary geographically and climatically. As a result, an organism that is safe in one country is not necessarily safe in another country. The commercial import and export and the inadvertent dissemination of LMOs and their genetic material across political boundaries may raise special concerns which require international cooperation and coordination;

(c) Some products of biotechnology are on the market and many more are expected to be commercially available soon. Lack of harmony among national regulatory systems may create non-tariff trade barriers in international trade.

83. As a first step the Panel analyzed existing methods for and practices of risk assessment and management. On the basis of this analysis, the Panel identified need for additional action in three areas of work: risk assessment and management, capacity building and guidelines/regulations/ agreements. The full set of needs identified is presented in section 4 of this report. From this set of needs, the Panel drew the following main conclusions:

(a) The Panel finds that methods for risk assessment and management are well-defined and are not fundamentally different from those in other technologies. The wide application of such methods would be facilitated by making information available in more languages and by taking account of the different environmental conditions throughout the world. The Panel recognizes that in some cases it can be difficult to estimate magnitudes and likelihoods of effects were the hazards to be realized.

(b) The Panel underlines the need to use expert advice in order to assess fully the effects and to apply risk management methods in order to minimize identified risks and take account of uncertainties. The Panel accepts that it has been appropriate to relax some risk management standards as a result of experience gained. Finally, the Panel stresses that it is always necessary to consider appropriate risk management measures when a LMO is transferred to a different environment.

(c) The Panel strongly believes that capacity building is essential to ensure adequate capacities to implement effectively biosafety regulations at the national level in a way which also promotes safe development in the field of biotechnology.

(d) The Panel also strongly believes that immediate action is needed to assess existing biosafety frameworks including their ability to address the movement of LMOs across national boundaries and to address other related transboundary issues. The Panel finds that such issues are best addressed by an appropriate international framework.

84. The Panel concluded that the form and content of such an international framework must ensure that the additional needs identified by the Panel are fully addressed and met.

ANNEX I

Tribute to the Government of the Arab Republic of Egypt

The Panel of Experts having met in Cairo, Egypt, from 1 to 5 May 1995

Deeply appreciated the warm hospitality and the quality of the services offered to the members of the Panel by the Egyptian authorities;

Expressed its sincere gratitude to the Government of the Arab Republic of Egypt and in particular the Ministry of Agriculture and Land Reclamation and the Agricultural Genetic Engineering Research Institute for hosting the meeting of the Panel of Experts.

ANNEX II
Examples of Existing International Agreements and their Relevance to Biosafety

Instrument	Relevance to Biosafety
International Plan Protection Convention (IPPC)/FAO	Addresses the plant pest risks associated with plants and plants parts including seeds, fruits, tubers, etc. and products which are based on organisms that could be plant pests (e.g., organisms injurious or potentially injurious to plants)
International Office of Epizootics (OIE)	Addresses communicable disease risks posed by animals (including bees), animal biologics and vaccines, animal parts (e.g., meat, dairy products, leather, fur, wool, embryos, semen, etc.)
International Code of Conduct on the Distribution and Use of Pesticides (FAO)	The concern is the exporting of pesticides to countries that do not have infrastructures to assess and control pesticides to ensure their safe and appropriate use. Concern addressed by a "Prior Informed Consent" program for banned or severely restricted pesticides.
UN Committee of Experts on the Transport of Dangerous Goods	The concern is proper containment. These recommendations provide requirements for proper packaging and shipment of living organisms.
WHO Certification Scheme for the Quality Assurance of Pharmaceutical in International Commerce	Product safety is certified through a detailed scheme. Certificates are required for trade.
London Guidelines for the Exchange of Information on Chemicals in International Trade (UNEP)	The concern is the exporting of hazardous chemicals to countries that do not have infrastructures to assess and control them to ensure their safe use. Concern is addressed by "Prior Informed Consent" program for banned or severely restricted chemicals.
Codex Alimentarius Commission (FAO and WHO)	Concerned, in addition to other goals, with protecting the health of consumers and food quality
WHO Expert Committee on Biological Standardization	Study aspects of standardization, production, quality control of sera and vaccines
Pharmaceutical Inspection Convention	Safety is analyzed, scheme for the mutual recognition of evaluation reports on pharmaceutical products, designed to facilitate trade in drugs between participants