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# ELABORATION OF THE TERMS OF REFERENCE FOR THE OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY

Note by the Secretariat

## INTRODUCTION

1. Pursuant to decision I/9 adopted by the Conference of Parties to the Convention on Biological Diversity at its first meeting, held in Nassau from 28 November to 9 December 1994, an Open-Ended Ad Hoc Group of Experts on Biosafety met in Madrid from 24 to 28 July 1995, at the invitation of the Government of Spain

2. Annex I to the report of the meeting of the Ad Hoc Group of Experts (UNEP/CBD/COP/2/7) contains elements for the content of an international framework on biosafety and is divided into five sections:

(a) Introduction to the elements,

(b) Aim of international action on biosafety;

(c) Suggested items to be considered in an international framework on biosafety, which provides a list of possible issues to be addressed, organized in terms of items which enjoyed consensus at the meeting of the Group of Experts (para 18 (a)) and issues which, though not enjoying consensus, were supported by many delegations (para 18 (b));

(d) Options for an international framework;

(e) Recommendations

3. The report of the Madrid meeting was examined by the Conference of the Parties at its second meeting, held in Jakarta from 6 to 17 November 1995 In paragraph 1 of its decision II/5, the Conference of the Parties decided to seek solutions to a number of concerns "through a negotiation process to develop, in the field of the safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focusing on transboundary movement, of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advanced informed agreement"

4. By paragraph 2 of the same decision, the Conference of the Parties established the present Open-ended Ad Hoc Working Group on Biosafety ("the Working Group"), to operate in accordance with the terms of reference annexed to the decision Paragraph 1 of those terms of reference specifies that the Working Group "should be composed of representatives, including experts, nominated by Governments and regional economic integration organizations"

5. The purpose of the present note is to assist the Working Group in considering its terms of reference and in developing a negotiation process for the protocol The note consists of nine sections, organized around the structure of the Working Group's terms of reference:

(a) Possible content of an "international framework on biosafety";

(b) Priority issues for developing a draft protocol;

(c) Effective functioning of the protocol;

(d) The protocol will take into account the Rio Declaration on Environment and Development;

(e) Application of the Convention's provisions to the protocol;

(f) Gaps in the existing legal framework identified through analysis of existing national and international legislation;

(g) Good faith and full participation;

(h) Best available scientific knowledge and experience as well as other relevant information; and

(i) Process of developing a protocol

## I POSSIBLE CONTENT OF AN "INTERNATIONAL FRAMEWORK ON BIOSAFETY"

### A Activities related to living modified organisms (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

6. The primary aspects which could be considered in relation to this issue include:

(a) To what organisms the protocol will apply;

(b) To which activities the protocol will apply; and

(c) Where the protocol will apply in relation to the activities and organisms

B 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

7. This item reflects three different aspects of transboundary movement as to the protocol's possible scope of application:

(a) The intentional transboundary movement of LMOs;

(b) The unintended movement of LMOs across national boundaries and their potential adverse effects; and

(c) Other issues related to transboundary movement of LMOs such as developing common understandings or working definitions for each aspect

8. Since transboundary movements are ultimately related to the protocol's scope, consideration could be given to:

(a) LMOs which should be addressed in the context of transboundary movement;

(b) Activities which should be addressed in the context of transboundary movement of LMOs; and

(c) The geographical context of transboundary movement relative to areas of national jurisdiction and beyond

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

9. The issue is whether the release of LMOs resulting from modern biotechnology in centres of origin and genetic diversity should be addressed by the protocol Further consideration of this question could include:

(a) Types of release to be addressed;

(b) Types of LMOs to be addressed; and

(c) The geographical context

10. Consideration could be given to developing working understandings or definitions for terms such as "release" and "centres of origin and genetic diversity" Consideration could also be given to whether the release in

centres of origin and genetic diversity needs to be distinguished for particular contexts such as:

(a) Transboundary and domestic activities;

(b) Intentional versus unintentional release;

(c) Terrestrial, aquatic and marine centres of origin and genetic diversity;

(d) Plants, animals and micro-organisms - whether wild, domesticated or cultivated; or

(e) Genetic resources used by humans or biological diversity in general

D Mechanisms for risk assessment and risk management

11. Consideration of whether the protocol should include mechanisms for risk assessment and management is closely linked to which LMOs and related activities the protocol will apply Consequently, it may be desirable to consider this issue in relation with other items

12. Further consideration could address:

(a) Assessment guidelines, harmonization of procedures and interpretation of risk;

(b) The nature or form of the assessment process;

(c) Institutional requirements; and

(d) Informational requirements and public involvement

13. Whether risk assessment and management provisions should be of a general or more specific nature may be related to the degree of harmonization the protocol may seek to promote, as well as the need to ensure flexibility in applying the protocol's requirements in the face of rapid technological change Such consideration could be guided by:

(a) The current state of science;

(b) Existing methodologies and guidelines;

(c) Capacities of Parties to the protocol; and

(d) The relationship between risk assessment/management mechanisms and other assessment mechanisms, such as environmental impact assessment and socio-economic assessment

E Procedure for the advanced informed agreement (AIA)

14. The advanced informed agreement (AIA) procedure has been closely associated with the intentional transboundary movement of LMOs Consequently, its consideration could be undertaken in parallel with the relevant aspects of the transboundary-movement issue As the Convention on Biological Diversity does not define AIA, it could be useful to develop a working understanding or definition of the term This could facilitate the consideration of the form and scope of AIA procedures, including:

(a) The procedure, its institutions and their responsibilities;

(b) Information requirements; and

(c) Monitoring and enforcement requirements

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

15. While the facilitation of information exchange is emphasized in the Convention, the purposes of information exchange in relation to protocol activities could be an issue For example, an AIA procedure implicitly requires information exchange In addition, a more general need for information exchange could be required, for instance, among Parties to the protocol Further consideration of means to facilitate information exchange could include, inter alia:

(a) Sources of information;

(b) The nature of information to be exchanged;

(c) Procedures for information exchange;

(d) Obstacles to information exchange; and

(e) Accessibility of information exchanged

16. Finally, Article 19, paragraph 4, of the Convention creates a bilateral information exchange requirement between Convention Parties with regard to the transfer of LMOs resulting from biotechnology This requirement would apply also to Convention Parties not party to the protocol The implications of this Article for transboundary movements of LMOs, as well as possible AIA procedures between Parties and non-Parties to the protocol, should be examined

G Capacity-building in all aspects required for biosafety

17. Capacity-building is closely related to the scope of the protocol The purpose of capacity-building, in an international instrument, is to increase a Party's ability to implement the instrument's provisions and, therefore, attain its objectives Developing countries have often been regarded as requiring capacity-building, but developed countries may also need capacity-

building in areas related to biosafety Capacity-building is usually described in terms of technical, financial and institutional factors Consideration of this issue could identify:

(a) Objectives of capacity-building in relation to biosafety;

(b) Areas or aspects of biosafety requiring capacity-building;

(c) Parties which may require capacity-building; and

(d) Mechanisms or modalities for increasing capacity

## H Implementation mechanisms

18. Implementation mechanisms can be broadly characterized with regard to:

(a) The instrument's structure and amendability;

(b) The institutions which administer the instrument or implement it;

(c) The provisions of the instrument for facilitating its implementation by Parties; and

(d) The regional and international cooperation

19. An instrument's structure and its ability to amend or supplement itself are subtle but important implementation means, particularly with respect to the level of harmonization sought by the protocol and its need to maintain flexibility; in other words, its long-term relevance in the context of rapid technological change This implies that early consideration could be given to the desirability of allocating provisions for annexes since annexes typically offer an expedient means to supplement an international legal instrument However, in its Article 30, paragraph 1, the Convention on Biological Diversity limits the subject matter of protocol annexes to procedural, scientific, technical and administrative matters

20. Institutions to administer the instrument can also be considered in the context of implementation mechanisms Institutions such as a Conference of the Parties, a secretariat, subsidiary bodies, financial mechanisms, clearing-houses and dispute-settlement mechanisms address particular aspects of an instrument's development and implementation Consideration could therefore be given to the desirability of establishing new institutions or sharing existing institutions with the Convention on Biological Diversity to facilitate the protocol's implementation

21. Provisions within the instrument itself may also facilitate its implementation They can focus on:

(a) General capacity-building;

(b) Technology transfer;

(c) Information exchange;

(d) Public education and awareness;

(e) Financial resources;

(f) Technical and scientific cooperation; and

(g) Other forms of cooperation between the parties to the instrument

22. Therefore, consideration could be given to these implementation mechanisms, or others, which may be appropriate for a protocol

23. Regional and international cooperation are part of the implementation mechanisms if their goal is to facilitate an instrument's implementation Consideration could be given as to how the protocol could facilitate existing and expanded regional and international cooperation among Parties to facilitate implementation

## I Definition of terms

24. Whether the protocol should include definition of terms may depend on the purposes these definitions would serve The primary purpose for the definition of terms in a legal instrument is to give an agreed, specific meaning to certain terms which may recur throughout the text

25. While most terms may not need to be defined, at least three scenarios can be envisaged in which such a need might exist:

(a) When the meaning of a particular term is unclear;

(b) When negotiators decide that the meaning should differ from normal usage; and

(c) When a term needs to be defined in order to define the instrument's scope

26. A definition of terms is usually undertaken in the later negotiation stages of a new international legal instrument However, to facilitate their work, negotiators may need to agree on working understandings or definitions for a handful of terms related to key issues These could be derived from existing instruments or created anew Therefore, in deciding whether to include definitions in the protocol, negotiators could also consider deferring an overall selection of terms to be defined, while selecting a limited number of key terms immediately in order to facilitate work This decision could take into consideration the relevancy of terms found in the Convention on Biological Diversity and other appropriate documents

## J Socio-economic considerations

27. With regard to whether socio-economic considerations should be addressed by the protocol, consideration could be given to which activities socio-economic considerations should apply Answers to this question may be linked to which organisms and activities the protocol will apply In this

regard, it may be desirable to develop a working understanding or definition of "socio-economic considerations" This could be facilitated by examining the relationship between socio-economic considerations and other assessment techniques such as risk and environmental impact assessment Further work might include determining:

(a) The state of science in assessing socio-economic impacts and their management in biosafety and other relevant areas, including existing methodologies and guidelines;

(b) The need for assessment guidelines, harmonized procedures and interpretation;

(c) The nature or form of the assessment process;

(d) Institutional requirements;

(e) Information requirements and mechanisms for public involvement; and

(f) Capacities of parties to the protocol

## K Liability and compensation

28. Whether the protocol should address liability and compensation is an issue closely related to the scope of the protocol Consequently, it may be desirable to consider this question in the context of the other items to be considered However, it would be useful to determine whether the protocol would address liability and compensation under international law, domestic law or both Additional considerations could include:

(a) The application to parties to the protocol and natural or legal persons;

(b) The nature or standard of liability;

(c) The nature of damage;

(d) The threshold of damage;

(e) The measurement and valuation of damage; and

(f) The entitlement of claim

## L Financial issues

29. Whether the protocol should include provisions for financing purposes could be considered by focusing on two aspects:

(a) To approach the issue in terms of financial implications for Parties implementing the protocol at the national level; and

(b) To approach it in terms of financial implications for any institution established under the protocol

In both cases, the protocol's scope and activities would be determinant

30. The financial implications of implementing the protocol at the national level could be related, in part, to developing and sustaining scientific, technical and institutional capacities Consequently, consideration could be given to estimating:

(a) Capacities needed at the national level;

(b) Parties' ability to assume the costs of implementation; and

(c) Possible modalities for covering all or a portion of these costs

31. The financial implications of the protocol's institutions could relate to:

(a) The number of institutions created;

(b) The number of people employed; and

(c) Their entrusted responsibilities

The financial implications of the protocol's institutions could be estimated *from the institutional costs of the Convention*

## II PRIORITY ISSUES FOR DEVELOPING A DRAFT PROTOCOL

### A Elaboration of key concepts and terms to be addressed in the process

32. Paragraph 3 (a) of the Working Group's terms of reference states that the development of the draft protocol shall, as a priority, elaborate the key concepts and terms that are to be addressed in the process Indeed, an early elaboration of key concepts and terms may facilitate the protocol's negotiation This may be especially true in those instances where the Convention neither provides key concepts relevant to the protocol nor defines key terms A threshold consideration is the protocol's scope Its delineation could facilitate the drawing of a list of key concepts and terms The list's elaboration could include determining whether they have already been elaborated in the Convention on Biological Diversity or other instruments Indeed, such instruments may offer a source of key concepts and terms which already reflect broad international consensus

### B Consideration of the form and scope of advanced informed agreement procedures

33. Paragraph 3 (b) of the terms of reference of the Working Group states that the development of the draft protocol shall, as a priority, include consideration of the form and scope of advanced informed consent (AIA) procedures AIA is often associated with the principles of prior informed

consent (PIC) PIC procedures have been established or referred to in other international instruments involving transboundary movements of biological and non-biological materials

34. To facilitate consideration of this issue, other international instruments which rely on PIC could be used to develop such an understanding, for instance: the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal; the London Guidelines for the Exchange of Information on Chemicals in International Trade; the FAO International Code of Conduct on the Distribution and Use of Pesticides; the UNEP International Technical Guidelines for Safety in Biotechnology; and the FAO Code of Conduct for the Import and Release of Exotic Biological Control Agents

### C Identification of relevant categories of LMOs resulting from modern biotechnology

35. Paragraph 3 (c) of the Working Group's terms of reference states that the development of the draft protocol shall, as a priority, identify relevant categories of LMOs resulting from modern biotechnology Such an identification relates to the protocol's scope of application and, therefore, to which organisms and activities it will apply To facilitate identification, consideration could be given to the activities which the protocol will apply as one criterion for establishing relevancy Other criteria could also be selected

## III EFFECTIVE FUNCTIONING OF THE PROTOCOL

36. Paragraph 4 of the Working Group's terms of reference states that the effective functioning of the protocol requires that Parties establish or maintain national measures, but the absence of such national measures should not prejudice the development, implementation and scope of the protocol

37. The relationship between an international legal instrument and its implementation at the national level, usually requires the establishment or maintenance of national measures in the form of legislation and relevant machinery The establishment or maintenance of national measures is related to technical, financial and institutional capacities In the biosafety area, a number of States have national legislation and machinery The absence of national measures should not prejudice the development, implementation and scope of an international instrument since the instrument itself could be designed to support the development of necessary capacities to facilitate its implementation

## IV THE PROTOCOL WILL TAKE INTO ACCOUNT THE RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT

### A Principles of the Rio Declaration

38. Paragraph 5 of the terms of reference provides that the protocol will take into account the principles enshrined in the Rio Declaration on Environment and Development and, in particular, the precautionary approach contained in Principle 15 Consideration could be given to other principles which are relevant to the draft protocol's elaboration

### B The protocol will not exceed the scope of the Convention

39. Paragraph 5 (a) of the Working Group's terms of reference states that the protocol will not exceed the scope of the Convention In general, "scope" refers to an instrument's scope of application In the context of an international legal instrument this could be characterized as the domain of the protocol's application; and its geographical coverage

40. The Convention's scope of application is defined in its Article 4 (Jurisdictional scope) and Article 5 (Cooperation)

### C The protocol will not override or duplicate any other international legal instrument in this area

41. Paragraph 5 (b) of the terms of reference states that the protocol will not override or duplicate any other international legal instrument in this area Fulfilling this mandate is related to the protocol's scope Defining the protocol's scope therefore could take into consideration relevant international legal instruments in order to avoid their being overridden or duplicated by the protocol In this regard, consideration could be given to the relevant passages of the report of the Panel of Experts on Biosafety and the report of the Open-ended Ad Hoc Group of Experts on Biosafety

42. In its report, the Panel of Experts on Biosafety reviewed, inter alia, existing international guidelines/agreements on biosafety (CBD/Biosafety Expert Group/2 and UNEP/CBD/COP2/7, annex IV) In annex II of its report, the Panel of Experts provided a list of relevant international instruments which required a more detailed review for a comprehensive analysis of relevant international instruments In paragraph 78 of its report, it also expressed the view that "immediate action is necessary to assess regulatory systems (be they national, regional or international) ability to address the movement of LMOs across national boundaries"

43. The Open-ended Ad Hoc Group of Experts on Biosafety considered that paragraphs 48 to 62 of the report of the Panel of Experts on Biosafety provided a good general overview of existing knowledge, experience and legislation in the field of biosafety, and that for the time being there was no need for an additional survey of existing international regulations and agreements (UNEP/CBD/COP/2/7, para 21 (b)) The Group agreed that there was a need for further analysis of existing regional and international regulations

and agreements relevant to the impact of LMOs on the conservation and sustainable use of biological diversity (UNEP/CBD/COP/2/7, para 21 (d))

44. The Open-ended Ad Hoc Group of Experts on Biosafety, however, 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 Nor do they address on a global level the specific concerns expressed in Article 19, paragraph 3, of the Convention and other considerations such as socio-economic and ethical aspects pertaining to LMOs (UNEP/CBD/COP/2/7, para 21 (h))

### D The protocol will provide for a review mechanism

45. Paragraph 5 (c) of the Working Group's terms of reference states that the protocol will provide for a review mechanism Such a mechanism should enable the instrument's implementation to be assessed Consideration could be given to the form and scope for such a review mechanism

### E The protocol will be efficient and effective and seek to minimize unnecessary negative impacts on biotechnology research and development and not hinder unduly access to and transfer of technology

46. Paragraph 5 (d) of the terms of reference states that the protocol will: (i) be efficient and effective; (ii) seek to minimize unnecessary negative impacts on biotechnology research and development; and (iii) not hinder unduly access to and transfer of technology

47. Fulfilling this mandate is closely associated with the protocol's scope A clear definition of the scope could provide the basis for periodically identifying: possible inefficiencies; and possible negative impacts on biotechnology research and development as well as the commercialization of new biotechnology products and possible hindrances to access to and transfer of technology as well as the associated financial resources Consideration could be given as to how a protocol review mechanism could function in this regard

## V APPLICATION OF THE CONVENTION'S PROVISIONS TO THE PROTOCOL

48. Paragraph 6 of the Working Group's terms of reference states that the provisions of the Convention will apply to the protocol Such an application offers the possibility of avoiding duplication between the two instruments in terms of text (for example, the use of terms) or implementation mechanisms, such as institutions

## VI GAPS IN THE EXISTING LEGAL FRAMEWORK IDENTIFIED THROUGH ANALYSIS OF EXISTING NATIONAL AND INTERNATIONAL LEGISLATION

49. Paragraph 7 of the terms of reference states that the development of a protocol shall take full account of gaps in the existing legal framework identified through analysis of existing national and international legislation

50. While this mandate focuses on the national and international legal framework, paragraph 5 (b) of the terms of reference is its partial complement since it strives to avoid duplication with existing international instruments The reports of the Panel of Experts on Biosafety and the Open-Ended Ad Hoc Group of Experts on Biosafety could be used in this regard

51. In its report, the Panel of Experts identified trends and characteristics of national guidelines/legislation and 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" (CBD/Biosafety Expert Group/2 and UNEP/CBD/COP2/7, annex IV, para 78) Among other things, the Panel felt that immediate action was necessary to assess regulatory systems in terms of their ability to address the movement of LMOs across national boundaries

52. In its report, the Open-ended Ad Hoc Group of Experts 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 (UNEP/CBD/COP/2/7, para 21 (d)) In addition, it underlined that existing international legislation does not specifically address transboundary movements of LMOs or other related cross-border issues and their effects on conservation and sustainable use of biological diversity Nor do they address, on a global level, the specific concerns expressed in article 19, paragraph 3, of the Convention and other considerations such as socio-economic and ethical aspects pertaining to LMOs (para 21 (h))

## VII GOOD FAITH AND FULL PARTICIPATION

53. Paragraph 8 of the terms of reference states that the process shall be guided by the need for all Parties to cooperate in good faith and to participate fully, with a view to have the largest possible number of Parties to the Convention ratifying the protocol Cooperation in good faith is a guiding principle of international law and thus intergovernmental negotiations The full participation of all Parties to the Convention on Biological Diversity is needed to ensure that the protocol is widely ratified Consideration could be given on how to ensure full participation in the protocol's development process

## VIII BEST AVAILABLE SCIENTIFIC KNOWLEDGE AND EXPERIENCE AS WELL AS OTHER RELEVANT INFORMATION

54. Paragraph 9 of the terms of reference states that the process will be carried out on the basis of the best scientific knowledge and experience, as well as other relevant information

55. Consideration could be given to the desirability of compiling an assessment of scientific knowledge and experience in selected areas, as well as other relevant information to identify gaps to support the protocol's development A non-exhaustive indicative list of possible areas, which could be considered and elaborated upon, includes defining centres of origin/genetic diversity; ecosystem and climatic aspects of risk assessment/management; capacity-building; socio-economics; and liability and compensation for damage to biological diversity

## IX PROCESS OF DEVELOPING A PROTOCOL

56. Paragraph 10 of the terms of reference states that the process of developing a protocol should be conducted as a matter of urgency by an open-ended ad hoc group, which will report on progress to each subsequent meeting of the Conference of the Parties The Open-ended Ad Hoc Working Group should endeavour to complete its work in 1998

57. The terms of reference provide a broad framework to the Working Group The elaboration of a protocol could be guided by a number of considerations including, inter alia: structuring the work of the Working Group, in particular the need for establishing sub-working groups assigned to particular tasks; scheduling meetings; assessing the required secretariat support; and financial implications

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