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Summary

Since the Convention on Biological Diversity was initiated in Rio de Janeiro, Brazil in 1992 the signatories to the Convention have been developing policies on biosafety in accordance with the requirements of Article 19.3 of the Convention. There have been a number of significant meetings of national experts leading to recommendations on biosafety. The latest such meeting occurred in Madrid in July 1995. The discussions had the aim of providing a basis for the Parties to the Convention to come to an informed decision as to "the need for and the modalities of a Protocol on Biosafety", when they meet at the 2nd Conference of the Parties in Jakarta, Indonesia, in November 1995. This report outlines the situation leading up to, and the developments at, the meeting in Madrid and provides the text of a document "Elements for the content of an international framework on
biosafety", produced at the meeting.

BACKGROUND

Article 19.3 of the Convention on Biological Diversity (CBD) (1) reads as follows

"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".

To develop the action programme required by other sections of Article 19, Expert Panel IV was established by UNEP and the secretariat prepared a guidance note (10). The 15 Panel members represented the seven UN geographical regions and they met three times between 1992 and 1993, publishing their final Report in April 1993 (2). In addition to Article 19.3, the Panel took into account Articles 6.b, 7.c, 8.g, 8.h, 14.1, 17.1, 18.3 and 19.4. Because they indicate the breadth of the approach taken to biosafety under the convention, the texts of these Articles are included in Annex 1. The report is divided into five chapters and several annexes. Chapter 2 deals with the need for a biosafety Protocol and includes both arguments for and against such a Protocol.

Subsequently, the Governing Council of UNEP set up an Intergovernmental Committee on the Convention on Biological Diversity (ICCBD) which held two sessions to consider various issues under the Convention among which was the need for a biosafety Protocol. It was agreed that there was a need for "adequate and transparent safety and border-control procedures aimed at controlling and managing risks associated with the use of living modified organisms (LMOs) and their release into the environment in addition to maximizing the benefit of biotechnology" (3). Annex 2 quotes relevant paragraphs from the discussions.

Following this, at the first Meeting of the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) in November 1994 in Nassau, Bahamas, an Open-ended Ad-hoc Group of Experts nominated by governments was set up to examine "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". Existing knowledge on experience and legislation in the field of biosafety, including the views of the Parties, subregional, regional and international organizations should be considered. A report should then be presented to the second meeting of the Conference of the Parties due to be held from 6 - 17 November 1995 in Jakarta, Indonesia, to enable the COP to reach an informed
decision as to the need for and the modalities of a biosafety Protocol.

To start the work and to lay out a more detailed basis, the COP also requested the Secretariat to establish a Panel of Experts on Biosafety, consisting of 15 government nominated experts, assisted by UNIDO (United Nations Industrial Development Organization), UNEP (United Nations Environment Programme), FAO (Food and Agriculture Organization of the United Nations) and WHO (World Health Organization) to prepare a background document to be submitted to the Open-ended Ad-hoc Group of Experts on Biosafety, in Madrid in July 1995 "based on considerations, as appropriate, of existing knowledge and experience on risk assessment and management, and guidelines and/or legislation already prepared". The secretariat of CBD provided a summary of existing knowledge and experience, provided by ca. 40 countries, the European Union and a number of United Nations bodies and specialised agencies (13). The Panel of Experts on Biosafety met in Cairo 1-5 May 1995 and produced and published their report (4), which was discussed at Madrid on 24-28 July, 1995.

MEETING OF THE OPEN-ENDED AD-HOC GROUP OF EXPERTS ON BIOSAFETY, MADRID 24-28 JULY, 1995:

Representatives of 83 countries and the European Community attended the meeting as well as 7 United Nations bodies and specialized agencies. Representatives of two intergovernmental and 22 non-governmental organizations were also present at the meeting.

The report of the Cairo meeting of the Panel of Experts on Biosafety was the basis of discussions. An Indicative List of Publications (5) and other documents (6, 7) describing existing knowledge and experience on assessment and management of risks that may be posed by living modified organisms resulting from biotechnology was provided.

There were three principal items for discussion arising from the report, which took place under items 3, 4, and 5 of the Agenda, as follows:

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

**Item 4:** Consideration of existing knowledge, experience and legislation in the field of biosafety.

**Item 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
Agenda Item 3

During discussions on Item 3 major concern was expressed by a number of participants with regard to the wording of some of the paragraphs of the report and especially 22 and 23. The texts were:

paragraph 22:

"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".

paragraph 23:

"In preparing this report, the Panel focused on the health and ecological concerns raised by the LMOs resulting from biotechnology. The Panel fully recognised the importance that the socio-economic effects of introducing these new technologies can have, inter alia, on decision making processes, but felt that the 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".

The term LMO, living modified organism, is used to include both GMOs and organisms derived from traditional methods. It was noted that this definition embraces a very broad range of organisms; of which those of relevance are those produced by modern biotechnological procedures; it was considered necessary to design a typology to divide up the field of LMOs in order to be able to give appropriate advice to the CBD.

Additionally it was discussed whether a possible international agreement on safety in biotechnology should take the form of a legally binding instrument (such as a Protocol to the Convention on Biological Diversity) or of a voluntary agreement (such as a code of conduct).

It was specifically noted that if transboundary movement (import/export) was not covered
by national law, which is often the case, then this should be an important subject of an agreed Protocol (whether legally binding or not). Additionally, the socio-economic considerations may not be national affairs but may need to be covered by international guidelines.

UNEP (8) stressed that "regardless of the outcome of these considerations, which may take a number of years, there is an urgent need for rapid agreement on international technical guidelines, in order to provide a common framework for safety in biotechnology at the national, regional and international level. Further, if a binding agreement is adopted, there will be many countries, organizations and companies that will need technical guidance to fulfil the commitments of such an agreement."

Draft guidelines had been initially compiled by the Departments of Environment, UK and The Netherlands in collaboration with UNEP and other relevant institutions and subsequently reviewed in six regional and subregional consultations in close collaboration with the secretariat of the CBD. The guidelines (9) were presented to the meeting in Madrid and a workshop held to brief participants on the contents of the technical guidelines.

Agenda Item 4

With regard to Item 4 it was agreed that the evaluation carried out by the Secretariat (5-7) was sufficient and that therefore there was no need for the time being for 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. Governments which had not responded to the invitation of the Secretariat to provide relevant information were again encouraged to do so, in order to facilitate a more comprehensive overview.

Agenda Item 5

To work on Item 5 a smaller ad-hoc drafting group from the plenary was formed, including three representatives from each region, with a mandate to discuss the possible contents of an **International Protocol on Biosafety** and to prepare a draft to be presented to the second COP for consideration. The meeting stressed the immediate need for international action to achieve adequate safety in biotechnology that should be directed to ensure safety for human health and the conservation and sustainable use of biological diversity. 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 while taking into account the specific needs and circumstances of individual countries. In this context, it was
stated that 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.

The aims of such an international action, the suggested items to be considered in an international framework on biosafety, and the options for this international framework were compiled in the document "Elements for the content of an international framework of biosafety" (11). As these elements seem likely to form the basis of any framework agreed at the next meeting of the COP in November 1995, they are reproduced below.

A number of additional smaller group meetings and workshops were organized by various organizations to further supplement discussions on the different items. The final draft report of the Madrid meeting (12) was still to be finalised at the end of the meeting.

Convention on Biological Diversity
CBD/Biosafety Expert Group/L.2 28 July 1995
OPEN-ENDED AD HOC GROUP OF EXPERTS ON BIOSAFETY
Madrid, 24–28 July 1995

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 (1), the Open-ended Ad-Hoc Group of Experts on Biosafety stressed the immediate need for international action to achieve adequate safety of LMO's resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

   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".

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 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 GMOs resulting from modern biotechnology in centres of origin and genetic diversity.

(iv) National regulatory systems 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:

(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.

23. 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, these guidelines should not prejudice the decision of the Conference of the Parties to develop and adopt a Protocol.

ANNEX 1

ARTICLES OF THE BIODIVERSITY CONVENTION RELEVANT TO BIOSAFETY ADDITIONAL TO THOSE QUOTED IN THE BODY OF THIS PAPER.

Art. 6. (b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.

Art. 7. (c) Identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity, and monitor their effects through sampling and other techniques.

Art. 8. (g) 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;

Art. 8. (h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;

Art. 14. 1. Each Contracting Party, as far as possible and as appropriate, shall:

(a) Introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for
public participation in such procedures;

(b) Introduce appropriate arrangements to ensure that the environmental consequences of its programmes and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account;

(c) Promote, on the basis of reciprocity, notification, exchange of information and consultation on activities under their jurisdiction or control which are likely to significantly affect adversely the biological diversity of other States or areas beyond the limits of national jurisdiction, by encouraging the conclusion of bilateral, regional or multilateral arrangements, as appropriate;

(d) In the case of imminent or grave danger or damage, originating under its jurisdiction or control, to biological diversity within the area under jurisdiction of other States or in areas beyond the limits of national jurisdiction, notify immediately the potentially affected States of such danger or damage, as well as initiate action to prevent or minimize such danger or damage; and

(e) Promote national arrangements for emergency responses to activities or events, whether caused naturally or otherwise, which present a grave and imminent danger to biological diversity and encourage international cooperation to supplement such national efforts and, where appropriate and agreed by the States or regional economic integration organizations concerned, to establish joint contingency plans.

Art. 17. 1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.

Art. 18. 3. The Conference of the Parties, at its first meeting, shall determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.

Art. 19. 4. 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.

ANNEX 2

Paragraphs 15, 16, and 17 of CBD/Biosafety Expert Group/Inf.2, cited from
UNEPCBD/COP/1/4.

15. With regard to the need for and modalities of a Protocol, a significant number of representatives expressed support for immediate work on a Protocol, while others expressed support for the COP's establishment of a step-by-step process to consider the need for and modalities of a Protocol. Several representatives stated that any consideration of the need for a Protocol under the Convention should be based on existing scientific work undertaken by bodies such as the Food and Agriculture Organization of the United Nations (FAO), the United Nations Industrial Development Organization (UNIDO) and the Organization for Economic Cooperation and Development (OECD). It was also noted that the clearing house mechanism to be established within the framework of the Convention could facilitate exchange of information relating to the safe transfer, handling and use of LMO's resulting from biotechnology.

16. Several representatives expressed the view that there should be a process through which technical guidelines on safety in biotechnology should be developed rapidly without prejudging the need for a Protocol so as to enable experience to be gained with the application of such guidelines. The development of national biosafety capacities was identified as one of the most pressing needs, especially within developing countries.

17. Representatives of three non-governmental organizations advocated the need for the introduction of a legally binding international biosafety Protocol as a matter of urgency in order to combat risks inherent in applying biotechnology without safeguards, especially in developing countries. They also asked that the serious destabilizing socio-economic aspects of biosafety form part of such a Protocol.

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