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BIOSAFETY IN THE PERSPECTIVE OF THE CONVENTION ON BIOLOGICAL DIVERSITY

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ABSTRACT

The field of biosafety is vast and complex. In order to reach international agreement, a sound scientific and technical basis is imperative in assessing the need for, and modalities of, an international biosafety framework. Needs assessment and descriptions of possible modalities have to be undertaken in the most rigorous, open and step-wise manner. The creation of a small panel of experts is a pre-statement to the Conference of the Parties' understanding of the importance of an objective technical assessment.

Key Words: **Biotechnology, genetic resources, UNEP**

RÉSUMÉ

Le domaine de la biotechnologie est vaste et complèxe. Afin d'arriver à quelques accords internationaux, une base scientifique et technique solide est nécessaire dans l'évaluation de besoins et des modalités d'une structure de biosécurité internationale. Des évaluations et descriptions des besoins de modalités possibles doivent être entreprises de manière rigoureuse, transparente, et graduelle. La création d'un Comité d'Experts est un préambule à la conférence des parties intéressées à l'importance d'une évaluation technique objective.

Mots Clés: **Biotechnologie, ressources génétiques, UNEP**

INTRODUCTION

Alarmed by the rapid erosion of the earth's biological diversity and its components, the world's nations met to negotiate a treaty to address the problem. After almost four years of discussions and negotiations, the Convention on Biological Diversity was adopted in May 1992, in Nairobi, Kenya. The Convention opened for signature in June 1992 at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, Brazil and entered into force on 29 December, 1993, less than 19 months after its opening, for signature. As of 5 April, 1995, 118 nations and the European Union had become parties to the Convention. The large and growing number of parties is a reflection of the world's commitment to achieving the objectives of the Convention. These objectives are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilisation of genetic

resources, including appropriate access to genetic resources, and transfer of relevant technologies and funding.

Access to and transfer of technology including biotechnology (Article 16 of the Convention) as well as technical and scientific cooperation (Article 18), are critical elements in benefiting the sharing arrangements and are, therefore, essential for the success of the Convention.

Biotechnology has the potential to make significant contributions to the eradication of poverty through, for example, the development of better health care and enhanced food security. However, if not properly handled, biotechnology may have adverse effects on biological diversity and human health. Biotechnology, in particular genetic engineering, is at the leading edge of scientific and technological development. Like any new technology, it raises concerns stemming mainly from uncertainties about the potential risks.

This paper elaborates on the views of the parties and other signatories to the Convention and outlines some future actions planned under the Convention to ensure safety in biotechnology. Development and application of safety measures are expected to promote maximum benefits from biotechnology and widespread public acceptance of this technology, especially in developing countries, without compromising the further development of such technology.

THE CONVENTION'S PROVISIONS RELATED TO BIOSAFETY

Articles 8(g) and 19, paragraphs 3 and 4 of the Convention explicitly refer to the issue of safety in the transfer, handling, release and use of any living modified organism (LMOs) resulting from biotechnology. Article 8 (g) states the obligations at national level 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". Article 19, paragraph 3 provides 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 effects on the conservation and sustainable use of biological diversity." Article 19, paragraph 4 complements Article 19, paragraph 3 by emphasising the need for provision of relevant information prior to the transfer of LMOs resulting from biotechnology. It states that "each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in Article 19, paragraph 3, 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 on the Contracting Party into which those organisms are to be introduced."

RELEVANT EVENTS PRECEDING THE FIRST MEETING OF THE CONFERENCE OF THE PARTIES

UNEP Expert Panel IV. In November, 1992, the Executive Director of UNEP established four panels to prepare specific advice on issues identified by Resolution 2 of the Nairobi Final Act adopted by the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity. Panel IV considered the need for, the elements for inclusion in, and the modalities of a protocol for transfer, handling and use of any LMO resulting from biotechnology. This mandate was derived from paragraph 2(c) of Resolution 2.

A majority of the panel members concluded that existing international agreements and instruments did not adequately address biosafety concerns under the Convention and, hence, a protocol was needed. In considering the possible scope of a protocol, a majority of the panel members recommended that, if a protocol was to be developed, it should cover only genetically modified organisms, i.e., "organisms in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination" (UNEP, 1993). The panel agreed

that alien species, organisms modified by traditional breeding techniques and human health (in its broad sense, i.e., including worker protection and food safety) should not be covered by such a protocol.

In discussing a procedure for advance informed agreements, the panel concluded that the procedure might include information relating to the organism, information on prior related releases of the organism, regulations concerning the organism's safe handling and use in the exporting country, a preliminary risk assessment, a risk management procedure, information and assessment of the socio-economic implications, and practical information concerning transfer.

The Inter-governmental Committee on the Convention on Biological Diversity. At the time of the adoption of the Convention, governments recognised that action to halt the erosion of the world's biological diversity should not wait for the Convention's entry into force. Accordingly, the Conference for the Adoption of the Agreed Text of the Convention adopted a resolution which, among other things, called upon the United Nations Environment Programme (UNEP) to establish an Inter-governmental Committee on the Convention on Biological Diversity (ICCBD) to consider critical identified issues in preparation for the first meeting of the Conference of the Parties. The UNEP Governing Council established the ICCBD and the Executive Director of UNEP convened two meetings of the ICCBD from 11 to 15 October 1993 in Geneva, Switzerland and from 20 June to 1 July 1994 in Nairobi, Kenya. Among the issues identified by the resolution as requiring urgent attention was, "the 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 an adverse effect on the conservation and sustainable use of biological diversity."

The Committee generally agreed on the need for early establishment of adequate and transparent safety and border-control procedures to manage and control the risks associated with the use and release of LMOs resulting from biotechnology; and, development and strengthening of national capacities to deal with safety issues (UNEP, 1994). This need was identified as one of the most pressing, especially in developing countries, and is also emphasised by the fact that international regulations can only be implemented in so far as suitable national structures exist. Biotechnology is evolving rapidly without an equivalent evolution of national capacities for risk assessment, management and oversight, especially in developing countries.

The possibility of including the following in the scope of the regulatory instrument was also considered: (a) ethical considerations and socio-economic concerns raised by the development of modern biotechnology; (b) the question of accountability in the case of local or national disaster; and, (c) harmful and invasive alien species.

Several representatives suggested the initiation of a process through which technical guidelines on safety in biotechnology could be rapidly developed, without prejudging the need for a protocol, to enable experience to be gained with the application of such guidelines.

ACTIONS DECIDED BY THE CONFERENCE OF THE PARTIES AT ITS FIRST MEETING

At its first meeting held in Nassau, the Bahamas, from 28th November to 9th December, 1994, the Conference of the Parties expressed deep concern and interest about the need for the safe transfer, handling and use of all LMOs resulting from biotechnology to avoid adverse effects on the conservation and sustainable use of biological diversity (UNEP, 1995).

Accordingly, the Conference of the Parties decided to establish an open-ended *ad hoc* group of experts nominated by governments with the following mandate: (a) to consider, as stated in Article 19, paragraph 3 of the Convention, the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of safe transfer, handling and use of any LMO resulting from biotechnology that may have adverse effects 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, sub-regional, regional and international organisations, 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 a decision as to the need for and modalities of a protocol.

In order to prepare for the work of the open-ended *ad hoc* group of experts on biosafety, the Conference of the Parties requested the Secretariat to establish a panel of 15 government-nominated experts, assisted by the United Nations Industry Development Organisation, UNEP, the Food and Agricultural Organisation of the United Nations (FAO), the World Health Organisation, to prepare a background document to be submitted to the open-ended *ad hoc* group of experts based on a 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 organisations.

The meeting of the Panel of Experts on Biosafety took place from 1 to 5 May, 1995 in Cairo, Egypt; the meeting of the open-ended *ad hoc* group of experts from 24 to 28 July, 1995, in Madrid, Spain; and the Conference of the Parties from 6 to 17 November, 1995 in Indonesia.

POSSIBLE PROCESS FOR CONSIDERATION OF THE NEED FOR AND MODALITIES OF A PROTOCOL

In order 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, it may be useful to describe first the scope of a biosafety framework in accordance with Article 19, paragraph 3. This includes: (a) the scope of LMOs to be addressed, e.g. should all types of living modified organisms be covered or only certain categories? If only certain types by what criteria will they be determined?; (b) the scope of operations related to LMOs to be addressed; e.g., should the entire scale of operations related to LMOs, their domestic and international transfer, handling and use be covered or only particular aspects? If only particular aspects of the operations are to be covered, how will these aspects be defined?; (c) the types of effects being controlled e.g. should the scope of a biosafety framework under the Convention be limited to controlling the adverse effects on the conservation and sustainable use of biological diversity?

Examination of experience on risk assessment and management, including existing national, regional and international guidelines and/or legislation, will facilitate the description of the scope of a biosafety framework under the Convention and may indicate whether current practices are adequate or present gaps that additional regulatory measures such as a protocol can fill.

Modalities of a protocol on biosafety consist of elements and procedures that will make the protocol operational. They should include the advance informed agreement procedure and provisions *inter alia* for information exchange, capacity building, and international cooperation. They may also include some guidelines for the establishment of national regulatory instruments and structures in countries lacking expertise in biosafety and the necessary infrastructure.

PRELIMINARY IDENTIFICATION OF AND POSSIBLE RESPONSE TO GAPS IN EXISTING BIOSAFETY REGULATIONS

A survey of national and international biosafety regulations, (e.g., Commercialisations of agricultural products derived through modern biotechnology: Society Results, OECD Environment Monograph No 99; and, Analysis of information elements used in the assessment of certain products of modern biotechnology). OECD Environment Monograph No. 100 (OECD, 1995 a,b), shows that: (a) a large number of countries have no national safety frameworks regulating LMOs resulting from biotechnology, (b) existing national biosafety regulations address activities relating to domestic handling and use of LMOs,

(c) efforts at promoting international agreements on biosafety often address issues from a perspective different from that of the Convention on Biological Diversity, and, (d) international agreements currently under consideration are limited in scope. For example, the FAO *International Code of Conduct on Plant Biotechnology as it Affects the Conservation and Utilisation of Plant Genetic Resources* which is under preparation, covers only plant genetic resources, but could be used as a starting point for the development of a comprehensive biosafety framework addressing transfer of any LMO resulting from biotechnology.

A biosafety framework under the Convention may, therefore: (a) cover issues pertaining to the transboundary movement of LMOs in a comprehensive manner; (b) establish an agreed framework of international cooperation; and, (c) develop and strengthen national capacity for risk assessment and management. International agreements can be implemented only if the existing national structures are adequate.

In principle, a new framework under the Convention should be flexible, credible, transparent and predictable to be effective. Flexibility implies that the framework should be responsive to the rapid advances in biotechnology while avoiding any undue burdens that may hamper biotechnology development. The framework should evolve following two dynamics: relaxation and/or deregulation when experience gained confirms a status of low- or no-risk, respectively, and expansion when new risks are identified. Rigid regulations tend to paralyse the development of biotechnology and prevent potential users from deriving the benefits that may arise from the utilisation of LMOs. Flexible approaches stimulate innovation. To be credible, a biosafety framework should be based on science, the foundation upon which users of LMOs and regulatory authorities should design their risk assessment strategies and rational risk management measures. Transparency will be ensured if the process of developing the agreement/regulation and the process of implementing the agreement is known to all parties involved. In addition, because public acceptance of applications of biotechnology is a prerequisite for technology transfer, commercialisation and utilisation of the products of biotechnology, regulatory systems should include procedures that ensure meaningful public information and participation in decision making. Transparency will reinforce credibility. For predictability, the framework should lead to consistent and planned results.

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