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CONSIDERATION OF THE NEED FOR, AND MODALITIES OF, A PROTOCOL ON BIOSAFETY

Note by the Interim Secretariat

1. INTRODUCTION

1. Article 19, paragraph 3, of the Convention calls for 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 (LMO) resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity".

2. At the first session of the Intergovernmental Committee on the Convention on Biological Diversity, Working Group I heard presentations by representatives of a number of countries, the representative of UNIDO and representatives of various non-governmental organizations on action to enhance biosafety and on possible approaches to the development of a protocol on biosafety. There was a consensus on the need to enhance national capacities to deal with biosafety issues but not on the development of a protocol setting out procedures for the safe transfer, handling and use of LMOs resulting from biotechnology. The Chairperson of Working Group I noted that the discussion could be continued at the Committee's next session (see UNEP/CBD/IC/2/2, annex II, para. 18).

3. The purpose of the present note is to facilitate the continuation of the discussion begun in the first session by summarizing:

(a) The potential contributions and threats of biotechnology to the conservation and sustainable use of biological diversity; and

(b) The development of biotechnology regulations at the international level. The note also suggests steps that may be followed in preparing recommendations for submission to the Conference of the Parties.

4. The note draws upon chapter 16 (Environmentally sound management of biotechnology) of Agenda 21 and a number of documents issued by the United Nations Environment Programme (UNEP) during the negotiations of the Convention.

2. DEFINITION AND CONTRIBUTION OF BIOTECHNOLOGY TO THE OBJECTIVES OF THE CONVENTION

5. Article 2 of the Convention defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". Biotechnology is thus a continuum of technologies, ranging from long established and widely used technologies essentially based on the use of microorganisms, through to recombinant deoxyribonucleic acid (DNA) techniques.

6. The potential contributions of biotechnology to the conservation of biological diversity and sustainable use of its components are substantial. *In vitro* cell and tissue cultures in combination with lyophilization or storage at low temperatures can be used for *ex situ* preservation of various microbial, plant and animal resources. Genetic information from endangered species and other species that are difficult to conserve *in situ* may be stored this way in the form of an entire organism or parts of organisms.

7. *In vitro* cell and tissue cultures can also be used as means for rapid multiplication of organisms and to increase biological diversity. These techniques lead to somaclonal variations and may facilitate the selection of useful individuals resulting from natural or induced mutations. Protoplast fusions, embryo transfers and recombinant DNA techniques may enable researchers to move genetic information from one organism to another one. This is how genes of some threatened wild relatives have been preserved in domesticated relatives, as in the case of cattle used as surrogate mothers for banteng or gauer embryos. These techniques have also enabled scientists to enhance the ability of a number of crops and their products to adapt to biotic and abiotic stresses.

8. The main achievements in the area of genetic transformation include bacteria modified to protect crops from frost damage, to break down toxic pollutants, to increase biological nitrogen fixation in plants, or to aid in the recovery of ores; recombinant DNA vaccines against infectious diseases in animals; and disease and insect resistance, herbicide tolerance, increased products shelf-life in crops like corn (*Zea mays*), cotton (*Gossypium hirsutum*), potato (*Solanum tuberosum*), soybean (*Glycine max*), tobacco (*Nicotiana tabacum*) and tomato (*Lycopersicon esculentum*). The performance of crops genetically engineered for insect or disease resistance may be comparable to that of crops treated with chemical pesticides; engineered crops may thus be better suited to low-input and environmentally sound farming.

9. Biotechnology also offers new analytical tools for the identification and characterization of species, genetic resources and molecules that are important in food production, health care and in other industrial sectors.

10. Application of biotechnology has boosted the socio-economic development in industrialized countries by providing new opportunities for protecting the environment. Developing countries in general lag behind this development. Both access to and transfer of technology (including biotechnology) among Contracting Parties are essential elements for the implementation of the provisions of the Convention. Article 16, paragraph 1, of the Convention calls on each Contracting Party to provide and/or facilitate access for and transfer to other Contracting Parties of technologies like biotechnology relevant to the objectives of the Convention and that make use of genetic resources and do not cause significant damage to the environment. There are however some public concerns about the transfer, handling and use of products resulting from biotechnology.

3. POTENTIAL THREATS TO BIOLOGICAL DIVERSITY OF LIVING MODIFIED ORGANISMS RESULTING FROM BIOTECHNOLOGY

11. The following are the most often mentioned potential threats to conservation and sustainable use of biological diversity from the transfer, handling and use of living modified organisms (LMOs) resulting from biotechnology:

(a) Genetically engineered plants may become new weeds, i.e. invasive, by acquiring such traits as vigorous growth, production of large numbers of seeds that germinate readily, production of long-lived seeds, the capacity for either self- or cross-pollination, and mechanisms for rapid dispersal;

(b) The introduced genetic material may not be stably integrated into the organism's genome. This genetic material can then escape, be transferred accidentally to other organisms and amplify the adverse effects of weedy relatives or pathogens, or make non-pathogenic organisms virulent;

(c) Introduced genetic materials may cause the production of an infectious entity, or encode substances that are known to be or may be toxic to non-target organisms feeding or living on the genetically modified organism;

(d) LMOs may disrupt biotic communities and ecosystems processes; and

(e) LMOs may be so much preferred that natural resources may become neglected and lost.

4. DEVELOPMENT OF BIOTECHNOLOGY REGULATIONS AT THE INTERNATIONAL LEVEL

12. The use and associated introduction into the environment of living modified microorganisms, plants and animals resulting from biotechnology have raised concerns about potential risks to public health and the environment. Cautionary measures about the use and release of LMOs resulting from biotechnology are therefore necessary. It is in this light that Article 8, subparagraph (g), and Article 19, paragraphs 3 and 4, of the Convention call on each Contracting Party to establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology.

13. To ensure the safe management of biotechnology, including research, development and commercial release of LMOs, it is generally agreed that countries need appropriate scientific and technical expertise; national assessment and decision-making structure(s), in particular for risk assessment and management; specific scientific advisory bodies; mechanisms to gather and provide relevant information *inter alia* to the public.

14. At the first session of the Intergovernmental Committee, Working Group I concurred on the need to enhance national capacities to deal with biosafety issues. In addition, all representatives who spoke on the biosafety issue recognized the need for international cooperation in exploring ways and means of enhancing biosafety (see UNEP/CBD/IC/2/2, annex II, para. 18).

15. Countries, particularly in the industrialized world, have developed guidelines designed to ensure environmentally safe applications of biotechnology. The guidelines have usually been built on existing regulatory experience such as the plant quarantine and environmental protection acts. In addition, a number of intergovernmental organizations have developed directives, guidelines and codes of conduct setting general frameworks for international harmonization of and cooperation on biosafety regulation. These guidelines and regulations have served as a basis for development of national biosafety systems and they take into account the potential transboundary impacts of LMOs.

16. Initiatives aimed at harmonizing biosafety approaches at a regional and global level include:

(a) The adoption of the European Council directives of 23 April 1990 on the contained use of genetically modified micro-organisms (90/219/EEC) and on the deliberate release of genetically modified organisms into the environment (90/220/EEC);

(b) The publication in 1991 by the Organisation for Economic Cooperation and Development (OECD) of Safety Considerations for the Use of Genetically Modified Organism: Elaboration of Criteria and Principles for Good Industrial Large-scale Practice (GILSP) and Good Development Principles (GDP), Guidance for the Design of Small-scale Field Research with Genetically Modified Plants and Micro-organisms;

(c) The publication in 1991 by the secretariat of the United Nations Industrial Development Organization (UNIDO) of the UNIDO/UNEP/WHO/FAO Voluntary Code of Conduct for the Release of Organisms into the Environment;

(d) The publication in 1991 by the International Office of Epizootics of the Organization of American States of the IICA (Inter-American Institute for Cooperation on Agriculture) Guidelines for the Release into the Environment of Genetically Modified Organisms, which presents a regional approach to biosafety.

In addition, the FAO International Code of Conduct on Plant Biotechnology as it affects the conservation and utilization of plant genetic resources is under preparation.

17. Harmonization of biotechnology regulations is conducive to international exchange and trade of biotechnology products. However, such harmonization may require some compromises between countries.

18. As familiarity with LMOs increases and experience accumulates on the use of biotechnology in the laboratory and in confined and small-scale field trials for agricultural and commercial purposes, the patterns of regulation will likely evolve from initial stringency to less stringent requirements. This development is leading to the formulation of regulation exemption for specific LMOs resulting from biotechnology. Nonetheless, the precautionary approach will always be necessary in view of the paucity of knowledge of ecosystems, particularly in developing countries which are coincidentally rich in biological diversity.

5. NEED FOR AND MODALITIES OF A PROTOCOL ON BIOSAFETY

19. As stated in paragraph 16.29 of Agenda 21, "only when adequate and transparent procedures for environmentally safe development and application of biotechnology are in place, will the community at large be able to derive maximum benefit from, and be in a much better position to accept the

potential benefits and risks of biotechnology". A number of regulatory instruments are currently in use at national and international levels. The Convention on Biological Diversity calls for the consideration of the need for and modalities of a protocol on biosafety. The Intergovernmental Committee may wish to define the term "protocol" as compared to other instruments regulating the transfer beyond national boundaries of LMOs resulting from biotechnology, and their handling and use. The Committee may then proceed to consider whether or not a protocol is needed; whether it is an immediate need or whether its development is envisaged for the future. The modalities of the protocol including appropriate procedures such as advance informed agreement between Contracting Parties could then be outlined taking into account the experience with modalities of existing national biosafety regulations.

20. If a protocol is not needed at all or if it is only needed in the future, the Committee may wish to consider whether other instruments such as voluntary codes of conduct and guidelines could be considered for setting the basis at the international level for the safe transfer, handling and use of LMOs resulting from biotechnology. The modalities of these instruments could also be outlined on the basis of, or designed independently from, existing regulatory instruments.

21. Whatever means are adopted, it should be borne in mind that international regulations can only be implemented in so far as national legislative and administrative structures are suitable. This consideration underscores the need to establish, maintain and enhance national capacities dealing with biotechnology risk assessment, management and oversight.
