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BACKGROUND DOCUMENT ON EXISTING INTERNATIONAL AGREEMENTS RELATED TO BIOSAFETY

(This document is a revision of Document UNEP/CBD/BSWG/2/3)

Note by the Executive Secretary

1. The First Meeting of the Open-ended Ad hoc Working Group tasked the Secretariat to elaborate a document exploring the relevance of existing international agreements and instruments to a Biosafety Protocol. The Secretariat has prepared an initial background document (UNEP/CBD/BSWG/2/3) which provided an overview of selected international instruments to explore if overlap exists between those instruments and the proposed biosafety protocol as well as to investigate the potential impact of a Biosafety Protocol on existing agreements which may address Living Modified Organisms (LMOs).

2. The terms of reference for the preparation of this document, as stated in the First Meeting of the Open-ended Ad hoc Working Group, stipulated that the Secretariat seek responses from Secretariats of selected international agreements to the following questions:

(i) What is the objective of the international agreement?
(ii) To what extent, if any, does the international agreement cover LMOs resulting from modern biotechnology?

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(iii) Is the international agreement currently being applied, or could it be applied, to the oversight of LMOs resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity?

(iv) What obligations or disciplines contained in the international agreement could be assessed as being relevant to the Terms of Reference for the Biosafety Protocol negotiations?

(v) Is the international agreement currently being revised/re-negotiated, or when will the next revision/re-negotiation be undertaken? What is the expected timing for completing such revisions/re-negotiations? Is it expected that the next revised text of the international agreement will address the impact of LMOs resulting from modern biotechnology on the conservation and sustainable use of biological diversity?

3. The Secretariat has approached selected existing international institutions soliciting their views on how their instruments relate to a Biosafety Protocol. The first part of this document reflects responses received from these institutions. Part two of the document is a synopsis of the Secretariat's views on this matter.

Part I

SELECTED INTERNATIONAL AGREEMENTS

I. CODEX ALIMENTARIUS

4. The Codex Alimentarius (Codex) is an internationally developed code of food standards. The purpose of Codex is "to guide and promote the elaboration and establishment of definitions and requirements for foods, to assist in their harmonization and, in doing so, to facilitate international trade". The Codex is concerned with the protection of the health of consumers and the ensuring of fair practices in the food trade and as such does not address LMOs.

II. UNEP INTERNATIONAL TECHNICAL GUIDELINES FOR BIOSAFETY IN BIOTECHNOLOGY

5. The UNEP International Technical Guidelines for Safety in Biotechnology represent the most recent attempt to provide guidance on biotechnology-related safety issues. The preface of the Guidelines states that they are designed to act as an "interim mechanism during the development and implementation of a biosafety protocol and to complement it after its conclusion." The content of the Guidelines is derived from common elements and principles contained in existing national, regional and international instruments and regulations.

6. The most relevant section to a Biosafety Protocol of the Guidelines is chapter V, which relates to the

establishment of an information exchange mechanism at the international level, as well as the provision of guidance to national governments in developing their own legislation regarding biosafety.

7. It is worth stressing that the Guidelines are compatible with, as well as complementary and synergistic to, the on-going process by the Conference of the Parties to develop a Biosafety Protocol, as called for in Decision II/5 of the Second Meeting of the Conference of the Parties in Jakarta in November 1995.

III. AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES

8. The WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) is one of the agreements resulting from the Uruguay Round of Multilateral Trade Negotiations. The basic aim of the SPS Agreement is to maintain the sovereign right of any government to provide the level of health protection it deems appropriate, but to ensure that these sovereign rights are not misused for projectionist purposes and do no result in unnecessary barriers to international trade. The SPS Agreement requires that sanitary and phytosanitary measures be applied for no other purpose than that of ensuring food safety and animal and plant health. Measures to ensure food safety and to protect the health of animals and plants should be based as far as possible on the analysis and assessment of objective and accurate scientific data.

9. The scope of the SPS Agreement is limited to sanitary and phytosanitary measures, which it defines as follows:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or foodstuffs;
(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

10. Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.

11. The extent to which the SPS Agreement covers LMOs has not been the subject of consideration by WTO Members to date. The SPS Agreement provides, however, that WTO Members should review the operation and implementation of the Agreement three years after its entry into force, that is, in 1998, and thereafter as the need arises. It is not possible to estimate how much time any possible revisions could take. It follows that the extent to which the SPS Agreement relates to LMOs has not been the subject of consideration by WTO Members to date.

IV. THE OFFICE INTERNATIONAL DES EPIZOOTIES (OIE)

12. The three main objectives of the OIE are: (a) to inform Governments of the occurrence and course of animal diseases throughout the world, and of ways to control these diseases; (b) to co-ordinate, at the international level, studies devoted to the surveillance and control of animal disease; and (c) to harmonize regulations for trade in animals and animal products among Member Countries.

13. Under OIE, LMOs along with other products of biotechnology are considered a part of animal disease diagnosis prevention and control technology and are included in the work of the OIE. Numerous recommendations and guidelines regarding their use have been approved by the Official Veterinary Services comprising the governing body of the OIE under the terms of reference of the agreement.

14. OIE recommendations and guidelines apply among other matters to the import and export of animals and products including biological products primarily for animal (including aquatic animal) disease prevention. They thus have significant impact on biodiversity of domestic and wild animal populations. Regarding LMOS, in addition to disease prevention, there have been recommendations about vaccine vectored immunocontraceptives for wildlife.

15. Reference is made to the periodically revised OIE *Internal Animal Health Code* and the *Manual of Standards for Diagnostic Test and Vaccines*, containing internationally agreed chapters on a great variety of matters which could apply to LMOs.

16. The basic agreement is not being considered for revision. However, the OIE International Committee convenes and adopts a series of resolutions each year, which are recognized as international recommendations.

V. THE INTERNATIONAL PLANT PROTECTION CONVENTION (IPPC)

17. The International Plant Protection Convention (IPPC) was established to maintain and increase international co-operation in controlling pests and diseases affecting plants and plant products. As such, the IPPC secures common and effective action to prevent the spread and introduction of pests of plants and plant

products and to promote measures for their control. A new amendment to the IPPC shall be adopted by the FAO Conference in November 1997, whereby the Commission on Phytosanitary Measures becomes the supreme body for the Convention.

18. In so far as they are pests, pests being any species, strain or biotype of plant, animal or pathogenic agent, injurious to plants or plant products, IPPC may cover Living Modified Organisms (LMOs). IPPC deals mainly with quarantine pests and non-regulated non-quarantine pests. Under IPPC, there is an obligation to perform a pest risk analysis.

VI. UNIDO VOLUNATARY CODE OF CONDUCT FOR THE RELEASE OF ORGANISMS INTO THE ENVIRONMENT

19. The UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment was developed following requests of developing countries for advice and technical assistance in determining policies with regard to research and commercial activities involving the use of Genetically Modified Organisms (GMOs). Existing national biotechnology related regulations/guidelines were reviewed with the purpose of identifying common elements and differences. The position of other international organizations, NGOs and industry associations were also taken into account. The Code of Conduct for the Release of Organisms into the Environment was designed as a coherent compilation of points that met a consensus among the different interest groups. Contentious elements and points of disagreement were omitted.

20. The Code of Conduct covers exclusively GMOs resulting from modern biotechnology. However, it only provides guidance to governments to develop and apply regulatory policy with regard to the development, handling and commercialization of GMOs and products thereof. As such, it is particularly relevant to article 8(g) of the Convention on Biological Diversity. The Code of Conduct is voluntary. It does not include provisions for mandatory obligations or disciplines.

VII. UNITED NATIONS RECOMMENDATIONS ON THE TRANSPORT OF DANGEROUS GOODS

21. The United Nations Recommendations on The Transport of Dangerous Goods have been developed by the United Nations Committee of Experts on the Transport of Dangerous Goods in light of technical progress, the advent of new substances and materials, the exigencies of modern transport systems and, above all, the requirement to ensure the safety of people, property and the environment. Among other aspects, the Recommendations cover principles of classification and definition of classes, listing of the principal dangerous goods, general packing requirements, testing procedures, marking, labeling or placarding, and transport documents. They do not apply to dangerous goods in bulk. The Recommendations aim at presenting a basic scheme of provisions that will allow uniform development of national and international regulations governing the various modes of transport; yet they remain flexible enough to accommodate any special requirements that might have to be met.

22. The Recommendations cover the carriage of infectious substances and Genetically Modified Organisms (GMOs) if they are capable of spreading disease upon exposure. Furthermore, according to the Recommendations, Genetically Modified Organisms (GMOs) so long as they are "known or suspected to be dangerous to humans, animals or the environment". The Recommendations stipulate that micro-organisms that are unlikely to cause human or animal disease are not considered infectious.

23. The Recommendation's Manual of Tests and Criteria presents the United Nations schemes for the classification of certain types of dangerous goods and gives descriptions of the test methods and procedures, considered to be the most useful, for providing competent authorities with the necessary information to arrive at a proper classification of substances and articles for transport. It should be noted, however, that the Manual is not a concise formulation of testing procedures that will unerringly lead to a proper classification of products. Therefore, it assumes competence on the part of the testing authority and leaves responsibility for classification with them.

24. It is expected that governments, intergovernmental organizations and other international organizations, when revising or developing regulations for which they are responsible, will conform to the principles stipulated in the Recommendations, thus contributing to worldwide harmonization in this field.

VIII. WHO REQUIREMENTS AND GUIDELINES FOR BIOLOGICAL SUBSTANCES USED IN MEDICINE AND OTHER SETS OF RECOMMENDATIONS

25. The WHO Requirements and Guidelines for Biological Substances Used in Medicine are scientific and advisory in nature. However, they are printed in the form of requirements so that, if a national control authority so desires, the Requirements and Guidelines may be adopted as they stand as the basis of national requirements. The Requirements and sets of recommendations concerned with biological medicines are formulated by international groups of experts and, following extensive global consultations, considered and approved by the WHO Expert Committee on Biological Standardization.

26. The WHO Requirements and Guidelines assure the safety and quality of biological medicines by providing guidance for national control authorities on the production and quality control of specific biological and international reference material for ensuring comparability of their activities world-wide.

27. As the WHO Requirements and Guidelines are concerned with assuring the quality and safety of all biological medicines, whether produced by traditional or novel biotechnologies, they would also cover LMOs which might be developed as live vaccines or gene therapy products.

28. The WHO Requirements and Guidelines serve as reference to national control authorities who should ensure that all biological products are produced under appropriate Good Manufacturing Practices.

PART II

Synopsis

29. Various voluntary codes/guidelines, regional and international agreements have been analyzed with the aim of identifying gaps in the existing system. However, the existence of gaps pre-supposes the existence of a "system" which could address the transfer and handling of LMOs. A cursory reading of this document indicates that no such system exists. The range of international agreements provide excellent models and techniques with the potential to be of use in developing a Biosafety Protocol, but they do not form a comprehensive system for the control of transboundary movements of LMOs, nor do they provide international legally-binding instruments for handling biosafety matters.

30. In the major international agreements studied, such as the OIE, IPPC and Codex, any coverage of LMOs is purely incidental to their main purpose. Consequently, any attempt at filling in gaps is highly problematic. The closest instrument to the scope and objectives of a Biosafety Protocol is Directive 90/219/EEC and Directive 90/220/EEC which relate to the Contained Use of Genetically Modified Micro-organisms and the Deliberate Release into the Environment of Genetically Modified Organisms respectively. These EC Directives clearly apply to LMOs and contemplate their unintentional transboundary movement. However, Article 1 (2) of the Directive 90/220/EEC categorically states that "this Directive shall not apply to the carriage of GMOs by rail, road, inland waterway, sea or air." Another significant factor is the limited scope (in a global sense) of the application of the Directive. The Directives apply only to the 15 EC Member States and relies heavily on the enforcement mechanisms established by the Community to ensure adherence to its terms. In the wider global community, no such enforcement mechanism exists, and therefore Directive 90/220/EEC must be seen as a valuable model rather than as an exact blueprint.

31. Although the UNEP Guidelines represent the most modern and comprehensive existing agreement relating to national procedures for assessing impacts of LMOs, including those that might be imported, they are only Guidelines and are purely optional. However, they contain several features which could act as models in the drafting of a protocol. The intent of the Guidelines is such that application to national systems can result in widely variable national systems. As such, the Guidelines although a valuable tool that has achieved international consensus on "approaches", do not address the transboundary/precautionary and transparent regulatory system envisaged under a Biosafety Protocol.

32. If attempts were made to cover biosafety through these and other agreements, they would inevitably be piecemeal and would fail to provide a rational legal structure capable of resolving biosafety matters. The confusion would benefit no-one, and would be likely to disadvantage developing countries in particular. On the other hand, a Protocol on Biosafety would require all countries to institute national biosafety laws, thereby harmonizing the standards and practices internationally as well as domestically.

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33. Most of the other instruments and guidelines lack clear provision for monitoring the effects of LMOs releases and omit a crucial factor in the evaluation of the assumptions used in risk assessment. They do not provide a basis for long-term ecological surveillance which is essential for assessing the environmental effects of LMOs releases. Nor do they provide a basis for legal redress.

34. It is therefore our recommendation that a protocol on biosafety be negotiated in order to address biosafety issues generally, and the release of LMOs into the environment in particular, based on the Precautionary Principle. Such a Protocol should set stringent international standards and clear procedures covering all aspects of transboundary, handling, release and use of LMOs and their products.

Conclusion

35. While there is a plethora of guidelines, regional and international instruments that either directly (as in the case of the EC Directives) or obliquely address the subject of transboundary movement of LMOs, none of these instruments may substitute for a Biosafety Protocol. This is because they either have a limited scope (as compared with the proposed Biosafety Protocol) and/or fail to adequately address the transboundary movement and handling of LMOs. Further, the vast majority of existing instruments are merely guidelines and accordingly not legally binding. Attempts to revise or amend the existing instruments is certain to be a complicated and difficult task.

36. On the other hand, and in view of the fast development in biotechnology, a Biosafety Protocol is bound to capture and encompass biosafety related issues concerning the transboundary movement, risk assessment and management and safe handling of LMOs. Such a Protocol would supersede existing instruments and agreements that deal with the same subject. Therefore, it may safely be concluded that a Biosafety Protocol will serve as an appropriate binding instrument to cover the tranboundary release, risk assessment and management, and handling of LMOs.

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