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BACKGROUND DOCUMENT ON EXISTING INTERNATIONAL AGREEMENTS RELATED TO BIOSAFETY

Note by the Executive Secretary

1. This document provides an overview of selected international agreements with the potential to impact upon the transboundary movement of living modified organisms. Although any international agreement pertaining to biodiversity has the potential to affect such issues, for the purposes of this document a more selective list of agreements has been examined. As such, the agreements analyzed constitute a representative sample of technical, scientific and more general agreements which have the potential to impact on the work of the Ad Hoc Working Group on Biosafety (BSWG), rather than on biodiversity issues in general.

2. Part one of this document provides detailed descriptions of the agreements and analyzes their salient features. The agreements can be divided into three categories. First, those selected on the basis of their potential to act as models, particularly the UNEP International Technical Guidelines for Safety in Biotechnology, the notification system under the Office International des Epizooties (OIE) and the standards development structure under the Codex Alimentarius system. The second category concerns those agreements specifically targeted at genetically modified organisms (GMOs). These agreements highlight some of the difficulties involved in the regulation of such organisms and may also serve as models. Examples of this category include the UNIDO Code of Conduct for the Environmental Release of GMOs and the European Council directive on the deliberate release into the environment of genetically modified organisms. The third category consists of agreements such as the Prior Informed Consent (PIC) procedure developed by the Food and Agriculture Organization of the United Nations (FAO) and the UNEP/IRPTC and the Agreement on Sanitary and Phytosanitary measures. It should be noted that the vast majority of the agreements are voluntary in nature and therefore incorporation (by reference or approval) into a future biosafety protocol should not prove problematic.

3. Part two of this document focuses on six key issues which emerge from the analysis of the agreements. Success in tackling these issues will begin to provide an effective system capable of minimizing the adverse effects of biotechnology on the conservation and sustainable use of biodiversity.

CONTENTS

Part One

SELECTED INTERNATIONAL AGREEMENTS

I. CODEX ALIMENTARIUS

A. Purpose

1. 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".

2. The Codex was developed by the Codex Alimentarius Commission established following the recognition in 1962 by both the FAO and the World Health Organization (WHO) of the need for internationally agreed standards to guide the booming post-war food production industries. Since 1962, when the Commission began work, the Codex has grown to 28 volumes containing:

(a) Over 200 food commodity standards;

(b) Over 40 codes on hygiene and technological practice.

(c) Over 700 evaluations of food additives.

(d) Over 3200 maximum pesticide residue limits.

The food standards were developed in order "to improve the quality of world food supply and contain requirements for food aimed at ensuring the consumer a sound ... food product".

B. Operational structure

3. The Codex Alimentarius Commission meets biannually. It has a secretariat based in Rome. The policy directions of the Commission are determined by an Executive Committee, with input from regional coordinating committees ensuring adequate regional representation. The membership of the Executive Committee changes regularly and is geographically balanced.

4. Perhaps the most significant aspect of the Codex system is the method by which standards are developed. The Codex Alimentarius Commission has established 28 general subject and commodity specific committees, which draft standards and make recommendations to the Commission. Following a recommendation from these committees the Commission (if it deems this appropriate) will draft a standard. This standard will then be evaluated and reviewed by the Commission (twice), member Governments (twice) and other parties such as food manufacturers and trade and consumer advocates.

5. Following the adoption of an agreed standard, the Codex secretariat provides periodic lists of countries that have agreed to that standard ensuring that potential exporters of the product are aware of the regulatory framework in any potential markets.

6. It is this rigorous and wide-ranging process of consultation and information dissemination that is the most notable feature of the Codex Alimentarius system.

7. The Codex is not a mandatory system, thus member States are not obliged to adopt any standards developed by the Commission. One of the main purposes of the system was to provide a ready-made set of requirements in relation to food safety, particularly for developing countries which may not have had any food safety infrastructure in place. It is clear, however, that although voluntary, these requirements represent an agreed international standard.

C. Relevance for LMOs

8. The prime objective of the Codex is the protection of human health. As such, the Codex has at this stage little opportunity to address either the impact of LMOs on the environment or issues of biotechnology generally. In 1989, the Codex discussed the potential impact of biotechnology on food standards again with the sole purpose of addressing human health concerns. In 1995, the Codex discussed the implications of biotechnological advance for food-labelling requirements. Although it is possible that the Codex will begin to address biotechnology-related issues more regularly, it is unlikely that its competence will be extended to cover issues relating to the conservation and sustainable use of biodiversity.

9. It would be premature to conclude however, that the Codex has little to offer in relation to the development of a biosafety protocol. Although the Codex does not address issues of concern to the Ad Hoc Working Group on Biosafety (BSWG), the Committee system through which standards have been developed is an excellent model for the development of internationally agreed, scientifically sound standards. The success of this approach is evidenced by the specific mention of the Codex Alimentarius system in the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization (WTO).

II. EUROPEAN COMMUNITY INITIATIVES

10. In 1990, the European Council adopted two directives, relating to the contained use of genetically modified micro-organisms (Directive 90/219/EEC) and the deliberate release into the environment of genetically modified organisms (Directive 90/220/EEC). The Directives establish a comprehensive Community-wide system covering information exchange, approval of use of GMOs and the setting of standards.

A. Purpose

11. Directive 90/220/EEC recognises the ability of living organisms to reproduce and cross borders, thus creating the potential for irreversible environmental damage. It is designed to assist in controlling the risks associated with GMOs. The preamble sets as important the identification of the need to standardize/harmonize rules relating to GMOs across the Community to facilitate trade and competition.

12. The Directive also notes the vital role that efficient exchange of information plays in establishing an effective system to combat the potentially adverse environmental effects posed by certain GMOs. For the purposes of the Directive, a GMO is defined by article 2, paragraph 2, as: "an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".

B. Operational structure

13. A distinction is drawn under the Directive between those organisms intended for placement on the market and those intended for release for any other purpose (e.g. field trials and associated research and development activities). However, the Directive treats all GMOs in a similar fashion, irrespective of their intended use.

14. Under part B, relating to non-marketplace releases, a notification of a proposed release must be lodged with the relevant competent designated national authority, which must then examine the proposal to assess its compliance with the Directive and to evaluate the risks posed by the release. In addition, the authority must also forward a summary of each notification to the Commission within 30 days of the receipt of the application. The Commission (under the terms of article 9) must then forward all summaries to the other member States, who have 30 days to comment on the notification to the Commission or to the relevant national authority directly.

15. Following the completion of its review process and the consideration of any comments received from other member States, the competent national authority may then decide whether to approve the release.

16. If the GMO in question is intended for market release, the Directive sets additional requirements in addition to the formal consent of the competent national authority. First, the product must comply with relevant Community product legislation. Secondly, the product must comply with the procedure established in articles 11 to 18 of the Directive. More particularly, before a GMO may be placed on the market the manufacturer or importer of the product must submit a notification to the competent national authority of the member State where the product is to be placed on the market for the first time. This notification must contain a highly detailed dossier of information, the exact content of which is stipulated in annex II of the Directive.

17. Following receipt of this dossier the competent national authority must evaluate the notification to assess its compliance with the Directive. It must make a decision within 90 days and forward details of this decision, and the dossier, to the Commission. The Commission must then forward the dossier to all competent authorities in member States, who have 60 days to raise an objection to the decision. In the absence of such an objection, the competent authority must consent to the notification.

18. If an objection is received from a member State, it must be dealt with under the procedure contained in article 21 of the Directive, which, establishes a committee to assist the Commission. The committee contains a representative of each member State and is chaired by a representative of the Commission. The committee assesses a draft of the proposed measures to be

taken by the competent national authority and delivers its opinion to the Commission. The Commission may then either adopt the measures in accordance with the committee's opinion or, if the measures do not accord with the opinion of the committee, it must forward a proposal to the Council, which will make a final decision.

19. A noteworthy aspect of the Directive is article 6, paragraph 5, under which any competent national authority may apply to the Commission for a simplification of the above procedures if it considers that sufficient experience has been gained pertaining to the release of certain types of GMO. The Commission, in consultation with the committee established under article 21, may agree to this application and set down criteria for this simplified procedure, which must focus on environmental and health concerns.

20. In decision 93/584/EEC, the Commission noted that it was appropriate that different criteria be established for plants, animals and micro-organisms. Recognizing that a significant body of data had accumulated in relation to the release of genetically modified plants, a simplified notification procedure was instituted for the "group of GMOs with which most of the experience has been acquired to date".

21. The pivotal role played by the Commission in relation to information exchange and promulgation of standards cannot be underestimated. The performance of such clearing-house functions is a vital component of any dynamic and flexible regime for dealing with LMOs.

C. Relevance for LMOs

22. The Directive clearly applies to LMOs and contemplates their unintentional transboundary movement. However, article 1, paragraph 2, of the Directive categorically states that "this Directive shall not apply to the carriage of GMOs by rail, road, inland waterway, sea or air".

D. Current status

23. In December 1996, the Commission adopted a report by the Environment Commissioner on the operation of Directive 90/220/EEC. The report noted significant problems concerning risk assessment, the simplification of procedures and the role of independent scientific evidence. On the establishment of uniform procedures relating to non-marketplace GMO releases, the report commented:

> "At the time of the adoption of Directive 90/220/EEC, there had been very little experience, and it was considered, that all GMO releases would potentially present the same risks. Against this background one administrative procedure for research was adopted for research and development releases was foreseen. However, the experience gained on the basis of practices already implemented at industrial levels indicates that ... it is necessary to establish a classification commensurate with the identified risks involved in the release. Indeed, it is currently demonstrated that not all releases pose the same level of risk and, consequently, do not merit the same level of oversight."

24. In relation to the release of GMO-related products onto the open market, the report made similar comments:

> "The Directive foresees only one procedure which is indistinctly applied to all types of products, irrespective of the risk identified on whether similar products are already on the market. It has to be remembered that in this fast-moving, high-tech field ... both future and current notifications ... concern products which are similar to authorized ones in the EU, as well as products ... used elsewhere in the world and which have proven to be safe. There is therefore a need to provide for streamlined procedures for those products posing no, negligible or low risk. The establishment of categories according to the risk identified, ... without lowering the safety level, ... should be introduced."

25. The question of access to independent scientific advice to assist in dispute resolution was also raised:

> "Currently, the Directive does not provide the possibility to discuss, at Community level, scientific controversy within an independent scientific group, as is the case [in Community legislation dealing with marketing authorizations]. This leads to an anomalous situation where application controversy cannot be dealt with by an independent system of conflict resolution which would ... solve problems on a scientific basis."

26. The report concluded by recommending a review of the Directive be undertaken in 1997 with the aim of increasing the flexibility of the system while maintaining safeguards for the environment and human health.

III. UNEP INTERNATIONAL TECHNICAL GUIDELINES ON BIOSAFETY IN BIOTECHNOLOGY

A. Purpose

27. Adopted in 1995, 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.

B. Operational structure

28. According to paragraph 15 of the introduction, the Guidelines propose "mechanisms for evaluating biosafety, identifying measures to manage foreseeable risks and to facilitate processes such as monitoring, research and information exchange".

29. Paragraph 18 of the Guidelines recognizes that the safety of any technology is only adequately achieved by identifying, assessing and managing risks associated with the use of that technology. When this approach is applied to biotechnology, the key factors to be analysed are:

(a) The characteristics of the organism, including any newly introduced traits;

(b) The manner in which the organism is to be used;

(c) The characteristics of the potential receiving environment.

30. The Guidelines focus on organisms with novel traits, referred to in paragraph 21 as "organisms whose make-up is unlikely to develop naturally". The Guidelines are designed to provide assistance in identifying those organisms with characteristics different from those of the parent organism. Paragraph 22 suggests that for these organisms "additional scrutiny might be appropriate", while paragraph 23 suggests that experience thus far indicates that even in cases involving organisms with novel traits, "in most cases, there will be low environmental risk".

31. Chapter III and IV of the Guidelines outline, respectively, the key parameters of a risk assessment of an organism with novel traits and the importance of establishing national authorities to organize and oversee risk-management procedures effectively.

32. For the purposes of the present report, however, the most relevant section of the Guidelines is chapter V, relating to the establishment of mechanisms at the international level, using information supply and exchange. In this regard, paragraph 40 makes several recommendations, including the need to designate national focal points and to foster cooperation with existing agencies and organizations. At a general level, the Guidelines also recommend the exchange of information about national biosafety mechanisms, approvals granted for the release of organisms with novel traits and adherence to Guidelines by individual national authorities. Paragraph 41 provides that this information should assist in the exchange of "mutually acceptable data and assessments".

33. In relation to the possible occurrence of transboundary environmental effects, the Guidelines set out model criteria for the exchange of information between the intending state of release and any states which may be affected. Paragraph 42 recommends that if the release of an organism represents a potential threat of a transboundary nature: "The potentially affected country should be given notice of the intended use and the opportunity to state whether particular measures will be needed to protect its interests, particularly its biodiversity."

34. In addition to this advance notification, the Guidelines recommend that: "The potentially affected country should be informed immediately in the event of an adverse effect of the use of an organism with novel traits which could affect it."

35. Paragraph 43 specifies the type of information which should be included in any notification carried out under Paragraph 42.

36. Paragraphs 44 to 52 constitute, for present purposes, the most significant section of the Guidelines in that they establish a system for the supply of information in relation to the transboundary transfer of organisms with novel traits. In this respect, they adopt the same approach as Directive 90/220/EEC, focusing on organisms transferred between countries for either research and development purposes or for placing on the market. They also recognize (as does the preamble to Directive 90/220/EEC) that the sophistication of information-exchange mechanisms and biosafety regulation will vary from country to country and provide a range of mechanisms which countries can adopt.

37. The mechanisms range from a simple system involving the provision of information from one user to another, to a sophisticated system of "advanced informed agreement (AIA)", which means that organisms with novel traits may be transferred only after the agreement of the receiving country has been obtained.

38. Paragraph 45 of the Guidelines stipulates that the key to the scheme is that a user who intends to transfer an organism from one country to another must provide relevant information to the user or appropriate focal points in the receiving country. The degree of specificity of information required will depend on the characteristics of the organism. The Guidelines also suggest that the information can be supplied at different stages depending on the intended use of the organism. The Guidelines stipulate three categories as follows:

(a) Organisms to be used in containment. In such situations, the information should be provided at the same time as the organisms are transferred. The information should be of a sufficient standard to enable the receiving country to perform a risk assessment;

(b) Organisms to be released into the environment or placed on the market. In such situations, information should be provided to the focal point in the receiving country prior to transfer under an advanced informed agreement. The AIA process may be dispensed with if the receiving country has sufficient familiarity with the organisms in question and has indicated that AIA is not required;

(c) Organisms to be used in containment but on an industrial scale. The Guidelines highlight that when used on an industrial scale, the possibility of routine or accidental escape of organisms with novel traits may pose a threat to the environment due to the quantities involved. In such situations, the Guidelines recommend that an AIA procedure be invoked.

39. The information which should be provided under AIA is catalogued in paragraph 47. It includes:

(a) Name and address of exporter and receiver;

(b) Origin, name and taxonomy of recipient organism;

(c) Description of novel traits introduced into organism;

(d) Characteristics of the organism;

(e) Summary of risk assessment;

(f) Intended date of transfer;

(g) Quantity of organism to be transferred;

(h) Any relevant safety requirements relating to handling and storage;

(i) Disposal and accident procedures;

(j) Intended use of the organism and any release history.

40. Under this system of AIA and information exchange, the role of national focal points is crucial. Paragraph 49 of the Guidelines provides that, the focal points make the final decision on transfer and may attach conditions on transfer and subsequent use. Paragraph 50 provides that, in a wider context, national focal points should provide relevant international databases and other focal points with their information requirements when conducting a transfer under an AIA procedure.

41. Finally, under paragraph 51, national focal points are encouraged to provide the maximum amount of information possible when answering general requests for information from other focal points and regional and international bodies. The Guidelines also recommend the regular and reciprocal exchange of information between regional groups.

42. Although the Guidelines represent the most modern and comprehensive existing agreement relating to the transboundary movement of LMOs, they are only guidelines and their application is purely optional.

IV. AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES

A. Purpose

43. The Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement) was completed as part of the suite of agreements establishing the World Trade Organization (WTO). Its purpose is to limit the trade-distorting aspects of sanitary and phytosanitary measures taken by States to protect human and environmental health. Such measures are deemed to be applied for the protection of human, animal and plant life or health in the WTO member State from the following threats:

(a) From the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease causing organisms;

(b) From risks arising from food additives, contaminants, toxins or disease-causing organisms in foods, beverages or foodstuffs;

(c) From risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests.

44. In addition, SPS measures may also be applied to prevent or limit other damage from the entry, establishment or spread of pests.

B. Operational structure

45. Article 2, paragraph 1, of the Agreement reaffirms the right of States to take SPS measures as long as they are consistent with the agreement. Article 2, paragraph 2, provides that any measures taken must be applied only to the extent necessary to protect human, animal or plant life and health and must be based on "scientific principles" and be maintained by scientific evidence. Paragraph 3 of the same article obliges States invoking SPS measures to ensure that those measures do not constitute a means of arbitrary or unjustifiable discrimination between WTO members and do not constitute a disguised restriction on international trade.

46. One notable feature of the SPS Agreement is that any SPS measures developed in conformity with its provisions are deemed to be General Agreement on Tariffs and Trade (GATT)/WTO-consistent. One way of achieving conformity is to apply "international standards, guidelines or recommendations". Annex A, paragraph 3, of the SPS Agreement specifically refers to the standards developed by the Office International Office des Epizooties (OIE), the Codex Alimentarius Commission, the International Plant Protection Convention (IPPC) and "other relevant organizations" open to all members of WTO. Higher standards than those developed by the named organizations are permitted under the Agreement as long as they are scientifically justified.

47. Article 5 of the Agreement requires WTO members to base any SPS measures on the results of risk assessments in relation to possible effects on human, animal and plant life or health. Again, specific reference is made to the procedures developed by OIE and IPPC. Any assessments should be based on available scientific evidence. Paragraph 3 of that article requires WTO members to take into account economic factors when performing risk assessments, in particular, the loss of production potentially caused by the entry, establishment or spread of a pest or disease and the costs of control or eradication in the importing member's territory. Members should also evaluate the cost-effectiveness of alternative risk-limitation procedures. The other function of article 5 is to ensure that the "appropriate" level of SPS protection is established. Article 5, paragraph 6, requires that WTO members must ensure that any SPS measures they adopt are "not more trade-restrictive than required to achieve the appropriate level of sanitary and phytosanitary protection".

48. Under annex B, paragraph 3 of the Agreement, WTO members must promptly publish all SPS measures they adopt to allow other members to become acquainted with the standards prevailing in potential importing countries. A further requirement is for each member to establish an enquiry point within its jurisdiction with the responsibility of providing information to other members.

49. Annex B, paragraph 5 also requires WTO members to comply with detailed notification procedures in a situation where a proposed SPS measure will apply to an area not covered by any international standard, guideline or recommendation. A similar duty exists when a proposed SPS regulation differs

substantially from an existing international standard, guideline or recommendation or may have a "significant effect on trade". Annex B, paragraph 6 provides a waiver of the aforementioned procedures where urgent problems of health protection arise. The member must notify other members immediately (via the secretariat) and provide details of the particular regulation adopted. The member must also allow other members to comment on the new regulation.

C. Relevance for LMOs

50. Any LMO which could be regarded as a threat to human, animal or plant life, and the SPS measures taken to regulate such organisms, will be covered by the SPS Agreement.

V. THE OFFICE INTERNATIONAL DES EPIZOOTIES (OIE)

A. Purpose

51. The Office International des Epizooties (OIE) was established in 1924. It is the pre-eminent world organization responsible for animal health and has three main objectives. Firstly, it aims to inform Governments of the occurrence and course of animal disease and of ways to control disease outbreaks. Secondly, it aims to coordinate international scientific research on the surveillance and control of animal disease. The other main objective of the organization is to facilitate the harmonization of regulations pertaining to trade in animals and animal products amongst its membership.

B. Operational structure

52. The most authoritative body within the OIE is the International Committee, comprised of permanent delegates elected by member States. This body effectively controls the Office. Secretariat services are provided by the Central Bureau which implements Committee resolutions with support from the elected commissions, namely, the Administrative Commission and the regional and specialist commissions.

53. The three main functions of OIE are of particular importance as a model in relation to the operation of a biosafety protocol. The three objectives will be considered in turn.

1. Information

54. The provision of information is seen as the priority function of OIE. More particularly, it must inform government veterinary services of the occurrence and course of disease outbreaks that could endanger animal or human health. The time-scale applicable to this notification depends on the classification of the disease. If a disease is classified as a List A disease, an affected country must inform the OIE Central Bureau within 24 hours of the first outbreak. The Bureau then immediately transmits information on the outbreak to the member countries that are directly at risk. All other countries are informed of List A outbreaks in Disease Information, a weekly OIE publication.

55. Apart from the emergency-notification procedures, OIE performs a clearing-house function. OIE receives and distributes information received from member countries on a regular basis via the OIE Bulletin, a monthly publication which also contains information on the epidemiology of certain diseases.

2. Research

56. The second function of OIE is to promote and coordinate research into the surveillance and control of animal diseases. This role falls to the specialist commissions and four working groups. The specialist commissions are the Foot and Mouth Disease and other Epizooties Commission, the Standards Commission, the Fish Diseases Commission and the International Animal Health Code Commission. These commissions meet on a regular basis and also convene important scientific meetings to further understanding of the issues under their respective jurisdictions.

3. Facilitating trade

57. By assisting in the promulgation of internationally developed and evaluated standards, OIE attempts to accomplish two objectives. First, it aims to prevent the spread of disease and, secondly, it aims to harmonize standards to avoid the establishment of unjustified trade restrictions.

C. Relevance for LMOs

58. Although OIE does not formally deal with LMOs, the categories of listed diseases are regularly updated. If LMOs were found to be causing diseases that constituted a threat to animal health, OIE could provide excellent clearing-house facilities. If this was not deemed appropriate, then a model similar to that of OIE should be given serious consideration in relation to notifications of emergencies involving the transboundary movement of LMOs.

VI. LONDON GUIDELINES FOR THE EXCHANGE OF INFORMATION ON CHEMICALS IN INTERNATIONAL TRADE

A. Purpose

59. The London Guidelines for the Exchange of Information on Chemicals in International Trade were adopted by the UNEP Governing Council in 1987. In 1989, they were amended to include the concept of Prior Informed Consent (PIC), which, according to the Guidelines, refers to "the principle that the international shipment of a chemical that is banned or severely restricted in order to protect human health or the environment should not proceed without the agreement, where such agreement exists, or contrary to the decision, of the designated national authority of the importing country".

60. The Guidelines' objective is to assist Governments in increasing chemical safety through the effective exchange of information on chemicals in international trade. The PIC procedure establishes special mechanisms for the exchange of information on banned or severely restricted chemicals in international trade.

61. In a parallel development, the FAO Conference in 1989 also included provisions for information exchange and prior informed consent into the International Code of Conduct on the Distribution and Use of Pesticides (see section VII below). Both the UNEP Governing Council and the FAO Conference decided that the operational responsibility for the PIC procedure should be shared between UNEP and FAO, and common elements implemented jointly. As a result, the FAO/UNEP Joint Programme on the implementation of the PIC procedure was established in 1990. The Plant Production and Protection Division is responsible for the PIC procedure within FAO and is the lead agency on pesticides, while UNEP Chemicals (IRPTC) is responsible for PIC within UNEP and is the lead agency for industrial and consumer chemicals.

B. Operational structure

1. Information exchange and export notification

62. Paragraph 5.4 of the Guidelines requires that each State designate a national authority or authorities to fulfil the administrative functions pertaining to the exchange of information and decisions regarding the importation of chemicals. This designated national authority should liaise with other designated national authorities and relevant international organizations to facilitate the exchange of information. Paragraph 5.9 (a) - (d) requires that this national authority should also be registered with the key organization in the London Guidelines structure, the International Register of Potentially Toxic Chemicals (IRPTC). */ IRPTC was given the following functions under the Guidelines:

(a) Coordinate the network of designated national authorities;

(b) Develop recommendations on practice and procedure;

(c) Liaise with concerned intergovernmental and non-governmental organizations;

(d) Continually review the implementation and effectiveness of the Guidelines.

63. Under paragraph 6 of the Guidelines, States should notify IRPTC of any control action taken. IRPTC must then disseminate this information to other countries in accordance with the provisions of Paragraph 9 of the Guidelines. Article 6 (c) requires that the notification should (as a minimum) include the chemical identification/specification of the chemical, summarize the nature of the control action taken and indicate where further information can be obtained in relation to the action. This information should be provided as soon as is practicable after the control action is taken. Paragraph 8 governs the control of information regarding exports. If a State exports a chemical that is severely restricted or banned within its jurisdiction, it must ensure that the designated national authority of the importing State is furnished with any relevant information. This information is to remind the

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*/ Now UNEP Chemicals.

importing State of the original control action taken and to ensure that it is aware of the import itself. States are encouraged to provide any information provided or received in implementing the Guidelines to IRPTC.

2. PIC procedure under the London Guidelines

(a) Aims

64. The PIC procedure is designed to assist participating countries in acquiring information about the characteristics of potentially hazardous chemicals. This information allows countries to decide whether to allow future imports of such chemicals. The procedure also facilitates the dissemination of information about such decisions to other participating countries.

(b) Scope of the PIC procedure

65. At the outset, it should be noted that States can participate in the aforementioned notification and exchange of export information schemes without participating in the PIC procedure. Participation in the PIC procedure is strongly encouraged in article 7.1 (c) of the Guidelines, but it remains voluntary. Nevertheless, this voluntary PIC procedure has been unanimously accepted by member countries of both FAO and UNEP.

66. Pesticides or industrial and consumer chemicals that have been banned or severely restricted for health or environmental reasons by participating countries are eligible for inclusion in the procedure. Acutely toxic pesticides presenting a hazard due to their manner of use in developing countries are also eligible.

3. Determining those chemicals to which the PIC procedure applies

67. Countries regularly notify IRPTC of any control actions taken to ban or severely restrict certain chemicals. Information on all control actions is stored on a database operated by IRPTC. Any chemical banned or severely restricted in at least one country after 1 January 1992 is eligible for inclusion in the PIC procedure. Chemicals banned or severely restricted prior to this date are eligible for inclusion if control actions have been taken against them in five or more States.

4. How PIC operates

68. For each chemical subject to the PIC procedure, a Decision Guidance Document (DGD) is developed and circulated to the designated national authorities. Annex III of the Guidelines stipulates the detailed content of a DGD. It should include a summary of the control action, detailed information on the chemical and a response form, providing a standardized method for importing countries to record their decisions with IRPTC. This standardized form is known as an Importing Country Response (ICR).

69. The DGD is a vital component of the PIC procedure in that it assists Governments in assessing the risks connected with the handling and use of the chemical concerned. It also enables them to make informed future decisions concerning the chemical. Following receipt of a DGD, the designated national authority completes an ICR and forwards it (within 90 days) to the UNEP/FAO

Secretariat which distributes a biannual summary of all import decisions to the national authorities.

5. Obligations of States under PIC

70. Importing States must ensure that all stakeholders are appraised of all notifications and responses received under the PIC procedure. Paragraph 7.3 (d) requires exporting States to ensure that a chemical is not exported without the consent of the importing State unless the product has been the subject of previous exports or the chemical is approved within the importing country. The exceptions only apply if the regulatory landscape in the importing country remains unchanged. Paragraph 7.4 (b) provides that exporting countries must also ensure that PIC decisions made by importing countries are communicated to industry.

C. Relevance for LMOs

71. The Guidelines apply to chemicals defined by paragraph 1 (a) as: "A chemical substance whether by itself or in a mixture or preparation, whether manufactured or obtained from nature and includes such substances used as industrial chemicals and pesticides."

72. From this definition, it is clear that the Guidelines have little scope in relation to controlling the transboundary movement of LMOs. However, the notification and exchange of export information procedures and the PIC procedure will be examined in part two of the present document with a view towards assessing their potential as model schemes for any future biosafety protocol.

D. Current status

73. In November 1994, the FAO Council determined that the FAO secretariat should proceed with the preparation of a draft PIC convention as part of the FAO/UNEP programme on prior informed consent. In May 1995, the Governing Council of UNEP authorized the Executive Director to convene, together with FAO, an intergovernmental negotiating committee (INC), mandated to prepare an international legally binding instrument for the application of the PIC procedure to certain hazardous chemicals in international trade. FAO and UNEP have jointly organized two INC sessions. The third session is scheduled for May 1997. At its second meeting, in Nairobi in September 1996, it was reported that discussions were progressing swiftly and if Governments retained the level of commitment demonstrated to date, they would meet their target of a legally binding treaty in 1997.

VII. FAO INTERNATIONAL CODE OF CONDUCT ON THE DISTRIBUTION AND USE OF PESTICIDES

A. Purpose

74. The FAO International Code of Conduct on the Distribution and Use of Pesticides was developed to assist countries (particularly those which do not yet possess adequate pesticide registration and control schemes) to control the use of pesticides. The preamble to the Code acknowledges that

"pesticides can be hazardous to humans and the environment and that immediate action must be taken ... to eliminate, as far as possible ... unreasonable risks not only in the country of origin but also in the countries to which pesticides may be exported".

75. The FAO Code also recognizes that pesticides will be an essential part of attaining increased food production. All FAO members are recommended to promote the use of the Code in the interests of safe and efficient pesticide use.

76. The objectives of the FAO Code are set out in its article 1. In particular, it aims to delineate the responsibilities and establish voluntary standards of conduct for all public and private entities involved in the regulation or actual distribution and use of pesticides. Emphasis is also placed on the need for cooperation between Governments. The Code aims to:

(a) Encourage responsible trade practices;

(b) Assist countries to regulate the quality and suitability of pesticides and to address the safe handling and use of such products;

(c) Promote the safe use of pesticides, including minimizing adverse effects on humans and the environment; and

(d) Ensure that pesticides are used effectively for the improvement of agricultural production and human, animal and plant health.

B. Operational structure

77. Articles 3 and 4 of the FAO Code set out criteria for the management and testing of pesticides, delineating the respective responsibilities of industry and government. Governments are to introduce pesticide regulation and control schemes based on the suggestions made in article 6 of the Code. Article 8.1.1 requires industry to test all pesticide products and assess their safety prior to marketing. Results of any tests should be forwarded to the local responsible authority for independent evaluation.

78. For the purposes of the present document, the most relevant aspect of the FAO Code are the provisions of article 9, relating to information exchange and PIC. The system adopted is essentially similar to that adopted under the London Guidelines: Governments must inform FAO of any control actions taken and FAO must disseminate this information to other Governments. If a pesticide is banned or severely restricted on health or environmental grounds it is subject to the PIC procedure outlined above.

C. Relevance for LMOs

79. The FAO Code was developed to regulate pesticides which it defines as "any substance or mixture of substances intended for preventing, destroying or controlling any pest". If an LMO is developed for the purpose of pest control, it could arguably come under the rubric of the Code. However, the preamble notes that "growth in pesticide use is likely to take place in spite of necessary intensive parallel efforts to introduce biological and

integrated pest control systems". This may well indicate that biological pest control systems (such as those developed using LMOs) fall outside the scope of the Code.

VIII. FAO CODE OF CONDUCT ON BIOTECHNOLOGY

A. Purpose

80. Article 1.1 of the FAO draft Code of Conduct on Biotechnology states that the aims are to promote the use of biotechnologies for the "conservation and sustainable utilization of plant genetic resources", while simultaneously providing recommendations for their "safe, responsible and equitable use". The Code also aims to ensure that "the environmental impact of innovations in biotechnology in the agriculture and food industry are fully assessed and measures taken to minimize and mitigate them".

81. The FAO draft Code limits its operation to:

(a) Biotechnologies affecting the conservation and utilization of plant genetic resources;

(b) Those biotechnologies used to exploit and modify living organisms so as to produce new tools, goods and products.

82. Article 4 is significant in that it lists those existing international agreements in harmony with which the code is to be implemented. The Convention on Biological Diversity and the International Plant Protection Convention are named specifically, while there is a third residual category of: "other international agreements and understandings setting biosafety standard for the release, import and export of genetically modified plants and micro-organisms; and for protecting biological diversity and plant genetic resources".

83. Article 4 is also significant in that it emphasizes the voluntary nature of the draft Code. Chapter II sets out the operational methods to be adopted in achieving the goals of the Code. In particular, it emphasizes the importance of the development and transfer of appropriate technologies to developing countries. Governments are singled out for particular attention and should endeavour to establish committees focusing on research, education and the assessment of the benefits and impacts of the "new" biotechnologies. Article 8 requires both Governments and international organizations to develop systems to monitor and assess the "possible negative long-term environmental effects of biotechnologies".

B. Biosafety issues

84. The provisions of the FAO draft Biotechnology Code most pertinent to the work of the Ad Hoc Working Group on Biosafety are contained in articles 11 to 15, which deal with environmental risk, international cooperation, risk assessment, risk management and AIA respectively. In relation to the environmental risks associated with plant biotechnologies, Governments are requested to, inter alia, establish national committees on biosafety, develop biosafety laws and disseminate pertinent environmental data. Recognizing the

ability of plants and other organisms (including GMOs) to move across borders, article 12 recommends that Governments cooperate in order to reduce the "risks associated with the application of biotechnologies ... and the deliberate release of transgenic plants and other organisms which could adversely effect plant genetic resources".

85. In relation to risk assessment, the draft Code adopts a similar system to Directive 90/220/EEC, including the adoption of a "step-by-step" approach to risk assessment. Of some significance is the suggestion in article 13.9 that "liability for eventual environmental damages due to the deliberate release ... should be specified in the authorization by the national competent authority".

86. Under article 14, Governments and national authorities are required to inform countries which may be affected by an impending deliberate release. In its article 15, the draft addresses issues pertaining to the import and export of products and AIA. It is significant to note that the draft regards AIA and PIC as synonymous. Article 3, note 11 states that: "Advanced Informed Agreement is the term used in the Convention on Biological Diversity; it refers to the same concept as Prior Informed Consent". Article 15.2 of the Code emphasizes that:

> "No ... organisms that could adversely affect plant genetic resources intended for release should be imported into a country without that country's Advance Informed Agreement. The Advance Informed Agreement procedure should apply ... independently of the risk assessment and authorization for release in the exporting country."

87. The draft concludes by outlining policies for reporting, monitoring and updating. Of particular importance are the obligations provided by article 17.1, which requires Governments to inform the Commission on Plant Genetic Resources (CPGR) of any measures taken in relation to the implementation of the Code and the requirement to notify the CPGR of non-observance of the Code by industry or research providers. Finally, article 18 suggests that national and international bodies undertake periodic reviews of the code to maintain the contemporary nature of its provisions and to ensure that:

> "The Code ... be considered as a dynamic text that may be brought up to date as required, to take into account technical, economic, social, ecological, ethical and legal developments and constraints."

IX. THE INTERNATIONAL PLANT PROTECTION CONVENTION (IPPC)

A. Purpose

88. The International Plant Protection Convention (IPPC) was established to maintain and increase international cooperation in controlling pests and diseases affecting plants and plant products. The Convention pays particular attention to preventing the spread of pests across national boundaries. Contracting Governments are to develop their own phytosanitary standards and furnish other contracting Governments with details of them.

B. Operational structure

89. Under article IV, paragraph 1, of the Convention, each contracting Government is required to make provision for an official plant protection organization. This organization is responsible for:

(a) Inspecting crops or international shipments of plants for the presence of pests and/or diseases;

(b) Issuing certificates relating to the phytosanitary condition and origin of plants and plant products;

(c) Conducting research into methods of plant protection.

90. The official plant protection organizations are also required to communicate with each other and engage in the exchange of relevant information including data on the standards applied within their respective jurisdictions.

91. Under article VI of IPPC, importing States are authorized to regulate the transfer of pests, which in some cases may well include "prohibitions, inspections and destruction of consignments". Any such measures taken are subject to the following conditions aimed at "minimizing interference with international trade".

(a) They must be necessary for phytosanitary reasons;

(b) Details of the measures must be published and forwarded to other contracting Governments and FAO;

(c) Inspections must be performed promptly and exporting States should be informed if a consignment breaches the terms of the Convention;

(d) States should reduce to a minimum the number of cases in which a phytosanitary certificate is required, without prejudice to their own plant production.

C. Relevance for LMOs

92. As stated previously, the focus of IPPC is "pests", defined in article II, paragraph 2, of the amended Conventions as "any form of plant or animal life, or any pathogenic agent, injurious and potentially injurious to plants or plant products". Clearly any LMO which presented a threat to plant life will be covered by IPPC. However, the Convention was developed in 1951, well before the advent of LMOs, and the implications of biotechnology have not been formally discussed within the framework of the Convention. At the last IPPC meeting, in Rome in January 1997, biotechnology and GMOs were on the agenda, but were not discussed.

X. UNIDO VOLUNTARY CODE OF CONDUCT FOR THE RELEASE OF ORGANISMS INTO THE ENVIRONMENT

A. Purpose

93. The main aims of the UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment are to establish a general framework and guidelines which will ensure safety in the research, development, trade and use of GMOs. The Code also aims to provide assistance to Governments in developing their own regulatory infrastructure and standards relating to GMOs. Article 1.3 states that the Code does not "call for a change in national regulatory provisions. It is intended as a general model that could be adopted in countries that have no regulations at present. It aims to draw on existing experiences rather than to frame new principles".

B. Operational structure

94. The Code of Conduct applies to GMOs at all stages of research, development, trade, use and disposal but its primary focus is on the release of GMOs into the environment. Article 1.4 of the Code explicitly recognizes the potential of newly introduced organisms to cause transfrontier impacts and recommends that risk assessment and regulations should focus on the characteristics of the GMO rather than the techniques by which it was created. Article 4.3 requires that the level of potential risk identified should determine the level of information required by any researcher.

95. Article 4.8 of the Code recommends that any risk assessment be based on scientific evidence. Governments complying with Code have several responsibilities (including):

(a) They must designate a national authority;

(b) As a starting point, they should perform a review of their own domestic procedures pertaining to GMOs;

(c) National authorities should facilitate the collection, storage and dissemination of data;

(d) When informed of an potential threat to public health or the environment occurring during the release of a GMO, they must inform other national authorities.

XI. OECD SAFETY CONSIDERATIONS FOR BIOTECHNOLOGY

A. Purpose

96. The OECD Safety Considerations For Biotechnology were published in 1992. They were developed by the Group of National Experts established by the OECD Committee for Scientific and Technological Policy in 1983. The preface states that "the report sets out general principles and criteria for safe large-scale production and small-scale experimental field research in biotechnology".

97. The report is divided into two sections, the first develops criteria for large scale industrial practice and reviews the fundamental principles applicable to the handling of low risk recombinant DNA organisms in industrial production. The second section "provides guidance on the design of low or negligible risk field research involving genetically modified plants and organisms".

B. Relevance for LMOs

98. Although the OECD report is directly related to the development of safe practices for the environmental release of GMOs, it does not deal with transboundary issues and as such is of little value in relation to the work of the Ad Hoc Working Group on Biosafety. It does, however, provide useful guidance in relation to procedures which may be adopted or recommended in any protocol on biosafety as representing "scientific best practice".

XII. UNITED NATIONS RECOMMENDATIONS ON THE TRANSPORT OF DANGEROUS GOODS

A. Purpose

99. The United Nations recommendations on the Transport of Dangerous Goods are designed to present a core set of provision which should "allow for the uniform development of national and international regulations governing the various modes of transport". They are designed to assist Governments and international organizations dealing with the regulation and transport of dangerous goods. Areas covered include:

(a) Classification of goods;

(b) Packing requirements;

(c) Labelling;

(d) Testing;

(e) Documentation requirements.

100. The standardization of international transport regulations is also a key goal. As stated in paragraph 1.2 of the Recommendations:

> "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 laid down in these Recommendations, thus contributing to worldwide harmonization in this field".

101. The Recommendations assert that harmonization would minimize the difficulties faced by exporters when goods cross borders, and would ease the task of inspecting authorities.

B. Operational structure

102. The Recommendations adopt a system which categorizes goods by the types of risk associated with their transportation. Again, one of the main reasons for this system is to provide a common pattern of treatment for similar goods, products and organisms.

C. Relevance for LMOs

103. Division 6.2 of the classifications system relates to infectious substances, defined as substances known or reasonably expected to contain pathogens, which are defined as micro-organisms or recombinant micro-organisms, that are known or reasonably expected to cause infectious diseases in humans or animals. Such substances fall into risk categories developed by the World Health Organization (WHO), the most significant of which are:

(a) Risk group, 4 relating to pathogens that cause serious disease in human or animal recipients. These pathogens are highly contagious and effective treatment and prevention methods are not readily available. They present high risks to both individuals and communities;

(b) Risk group 3 pathogens cause serious diseases in humans and animals but are not readily transmitted. Effective treatment and prevention methods are generally available. They represent a high individual risk, but a low community risk.

104. Different standards apply to the transportation of infectious substances depending on their inclusion in one of the WHO risk groups.

105. GMOs are specifically referred to in paragraph 6.9.3 which states:

> "Genetically modified micro-organisms and organisms are organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally."

106. It should be noted that the Recommendations do not apply to all GMOs. Only those GMOs (or animals containing or contaminated with GMOs) that meet the definition of infectious substance are covered. However, the Recommendations provide little guidance on methods of safe transportation of such products or organisms which present a danger to the environment. Paragraph 6.9.3 (b) states that "genetically modified organisms, which are known or suspected to be dangerous to humans, animals or the environment, should be transported in accordance with conditions specified by the competent authorities".

Part Two

ISSUES OF CONCERN FOR A BIOSAFETY PROTOCOL

107. The terms of reference provided to the Secretariat by the Working Group at its first meeting indicate that the aforementioned agreements should be analysed with the aim of identifying gaps in the existing system. However, the existence of gaps presupposes the existence of a "system". A cursory reading of part one of the present document indicates that no such system exists. The range of international agreements provide some 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. In the major international agreements studied, such as the OIE, IPPC and the Codex Alimentarius, any coverage of LMOs is purely incidental to their main purpose. Therefore, part two will analyse those areas of concern identified by the terms of reference, such as Advanced Informed Agreement/notification procedures, liability and compensation and WTO-related issues.

108. The agreements can be divided into two basic categories: those which provide incidental coverage of LMOs and those which focus specifically on issues pertaining to GMOs and LMOs. Generally, those agreements in the former category are older, wider in their application and have more established administrative systems. Agreements in the latter category tend to be newer and predominantly voluntary in nature. The task, therefore, is to design an agreement which has the administrative capacity and membership of one of the more established agreements and the specific focus on LMOs lacking in the majority of those agreements.

A. Advanced Informed Agreement and Prior Informed Consent

109. The work of UNEP/FAO Intergovernmental Negotiating Committee, the UNEP Guidelines for Safety in Biotechnology and the FAO Biotechnology Code are all relevant in an analysis of those agreements containing AIA (and by association PIC) procedures. AIA (and PIC) refers to the notion that a product or organism will only be transferred after the agreement of the receiving State has been obtained. Any effective AIA system relies on the early transfer of quality information, thus allowing any potential receivers to make a fully informed decision on the acceptability of importing the product or organism concerned. An effective AIA procedure must be included in any biosafety protocol.

110. The work of the UNEP/FAO Intergovernmental Negotiating Committee indicates that work on a binding international instrument for the application of the PIC procedure may be concluded in 1997. Essentially the PIC procedure is designed to deal with highly hazardous substances. Certain LMOs may fall into such a category from time to time. The European Community experience suggests of the need for a differentiated system of regulation, more attuned to the probable risks posed by a particular product or organism. It is significant to note that the FAO Biotechnology Code recommends that any AIA procedure should operate independently of the risk-assessment procedure. Also noteworthy is in the UNEP Guidelines recommendation that the need for AIA is determined by the end-use of the organism.

111. In addition to AIA and PIC, there is a demonstrable need for a notification procedure in instances of the unplanned release or escape of potentially hazardous LMOs. OIE's notification procedure provides an excellent model in this regard.

B. World Trade Organization (WTO) related issues

1. The compatibility problem

112. One of the most complex problems facing international environmental law concerns the potential conflicting obligations upon States that are parties to both the WTO and certain multilateral environmental agreements (MEAs). In its 1996 report, the WTO Committee on Trade and the Environment (CTE) noted the:

> "Doubts expressed by some WTO Members about the WTO consistency of certain trade measures applied pursuant to some MEAs, in particular discriminatory trade restrictions. For some, the uncertainty these doubts create for WTO Members and for the negotiators of MEA's make clarification of the relationship between WTO provisions and these trade measures desirable".

113. Any agreement designed to regulate the intentional transboundary movement of LMOs will impact upon the global trading system. The international and national safety requirements being proposed for including in a possible biosafety protocol have the potential to become trade-related environmental measures (TREMs), in that they may create a restriction on trade with the aim of protecting the environment and/or humans from potential harm. More particularly, any restrictions or standards imposed, such as notification, packaging, labelling and handling requirements may create conflict between a State's obligations under a biosafety protocol and its obligations under the General Agreement on Tariffs and Trade (GATT)/WTO system and the specific agreements developed within its framework, such as the Agreement on Technical Barriers to Trade and the Agreement on Sanitary and Phytosanitary Measures.

2. Methods of ensuring WTO compatibility

(a) General principles

114. The WTO system imposes several obligations on its members. In particular, article III of GATT provides that members must not discriminate between imports from different sources or between similar domestic and imported products. Any trade measures taken that are compatible with these principles would not breach any WTO obligation.

115. Article XX, paragraphs (b) and (g), of GATT represent the "environmental exceptions" which could include, in principle, scientifically grounded biosafety regulations. Article XX, paragraph (b), allows a contracting party to take measures that are necessary to protect "human, animal or plant life or health". Under paragraph (g) of article XX, a party may take trade measures that are related to "the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption."

116. Chapters 2 and 30 of Agenda 21 identified the following principles which should apply if trade measures are found necessary for the enforcement of environmental policies:

(a) The principle of non-discrimination;

(b) The principle that the trade measures chosen should be the least trade-restrictive necessary to achieve the objectives;

(c) An obligation to ensure transparency in the use of trade measures related to the environment and to provide adequate notification of national regulations.

(b) Specific methods

117. The proposed biosafety regulations should also be consistent with the Agreement on the Application of Sanitary and Phytosanitary Measures. article 2, paragraph 2, of that Agreement states that members should ensure that any such measure is based on "scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of article 5", which states that:

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information ... Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

118. Article 3, paragraph 2, of the Agreement states that:

> "Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994."

119. Those standards developed by OIE, the Codex Alimentarius Commission and IPPC are mentioned specifically in the Agreement and can therefore be deemed to be WTO-consistent. Furthermore, article 3, paragraph 3, of the Agreement allows members to "introduce or maintain sanitary or phytosanitary measures which result in a higher level of ... protection than ... measures based on relevant international standards, guidelines or recommendations, if there is a scientific justification" (emphasis added).

120. If the provisions of any biosafety protocol are based on internationally agreed scientific standards and are designed in conformity with the Sanitary and Phytosanitary Agreement, issues of WTO compatibility should not arise.

C. Liability and compensation

121. Article 14, paragraph 2, of the Convention on Biological Diversity requires the Conference of the Parties to the Convention to examine the issue of liability and redress for damage to biological diversity. Further, paragraph 18 (b) of annex I to the report of the Open-ended Ad Hoc Group of Experts (UNEP/CBD/COP.2/7) and decision II/5 of the Conference of the Parties to the Convention on Biological Diversity both make reference for the need to examine the need for a liability and compensation regime.

122. The agreements analysed in part one above generally avoid tackling issues of liability and compensation, leaving responsibility to domestic law-makers. A clear indication of this approach is found in the FAO Biotechnology Code, which states that liability for eventual environmental damage should be specified by the national competent authority. There does, however, exist a number of international agreements - and others are being developed - which deal with liability and compensation for damage to persons, property and the environment arising from potentially hazardous activities. The most developed regimes address oil pollution damage and damage caused by nuclear incidents. These regimes seem to indicate that there are essentially three functions of liability in international law, namely:

(a) A corrective function, which refers to liability as a method of enforcing the law ex post facto. It provides an injured international person with an instrument to secure his legally protected interests and covers the punitive function of liability to the extent that such a function exists in international law;

(b) A preventive function, which appears as an ex ante facto incentive that urges an actor to do its utmost to avert the imposition of liability;

(c) A reparative function, which shifts the injurious consequences of conduct in whole or in part from the victim to the author of the conduct through a compensatory arrangement.

123. The existing international instruments on State and civil liability contain a number of substantive and procedural elements that may need to be addressed within any liability regime under a biosafety protocol. The principal common elements contained in these instruments are:

(a) Definition of the activities or substances covered (scope);

(b) Question of whether to designate environmental damage as a distinct category of damage (separate from personal injury and property damage);

(c) Definition of environmental damage;

(d) Establishment of standard of care (absolute, strict or fault);

(e) Establishment of the measure of damages;

(f) Identification of the person or persons against whom the claim should be brought;

(g) Determination of who may bring a claim;

(h) Designation of the forum or forums before which claims may be brought;

(i) Determination of the remedies which are available;

(j) Provision for the availability of certain defences;

(k) Requirement to maintain adequate insurance or other financial security;

(l) Identification of a court or tribunal to receive claims; and

(m) Provision for recognition and enforcement of judgements.

D. Transport

124. One of the more apparent gaps identified in the analysis of existing agreements relates to the standards which apply to the actual transportation of LMOs across national borders. Some of the agreements, such as European Council directive 90/220/EEC expressly exempt transportation issues, while the majority refer only to labelling and handling requirements in passing. Although the United Nations Recommendations on Transport of Dangerous Goods make reference to GMOs, they again leave responsibility for the regulation of their transport to the "competent authorities". The adoption of uniform standards in relation to the transportation of GMOs should be treated as a matter of some importance.

E. Information exchange and the need for a biosafety clearing-house

125. The rapid pace of technological development and the burgeoning amount of scientific data relating to LMOs necessitate the development of an effective system of information exchange. The establishment of a clearing-house to receive, coordinate and disseminate information from national Governments, designated national authorities and existing international organizations is a fundamental requirement of any protocol. Another fundamental requirement is the designation of a specific national authority to coordinate all scientific and regulatory information relating to LMOs originating at the domestic level. This authority should then forward the information to the international clearing-house. At both the domestic and international levels a "one-stop-shop" approach to LMO information retrieval would appear highly beneficial for potential importers, exporters and concerned Governments and organizations. Of the agreements covered in this report, four can be seen to have model information exchange systems.

1. European Union system

126. Under Directive 90/220/EEC, the Commission of the European Communities performs a clearing-house function, receiving and disseminating information to member States. In addition, under its role as chair of the committee

established under article 21 of the Directive, the Commission can assist in the resolution of difficult issues. An indication of the importance of the Commission in the functioning of the system is given in the 1996 Commission report, which notes the "absence of an active role for the Commission on a number of aspects, including the right to propose simplified procedures ... which has led to delays in exploiting existing possibilities for simplification".

2. London Guidelines for the Exchange of Information on Chemicals in International Trade and the FAO International Code of Conduct on the Distribution and Use of Pesticides

127. Under the London Guidelines and the FAO Code of Conduct, the efficient flow of information is coordinated through the UNEP/FAO Joint Programme on the Implementation of the PIC procedure. All designated national authorities should be registered with the Joint Secretariat, and it acts as the repository for all control action notifications. In addition, the Joint Secretariat must forward this information to all designated national authorities. Administratively, the Secretariat is responsible for periodically reviewing the effectiveness of the procedure, liaising with relevant governmental and non-governmental organizations and developing recommendations. It is, however, the role of the Secretariat under the PIC procedure which is most significant. It maintains the database at the heart of the PIC procedure and coordinates the traffic in DGDs and ICRs. It is clear that both the Guidelines and Code of Conduct, and the PIC procedure in particular, rely heavily on an efficient central organization.

3. Office International des Epizooties

128. The provision of information is the primary function of OIE. The notification procedure which operates in the event of a List A disease outbreak is a crucial function of the organization. The distribution of regular reports on animal health, scientific information and research are also essential to the workings of the organization.

4. Codex Alimentarius Commission

129. The most significant feature of the Codex system is the method by which it develops standards. The committees that develop these standards rely heavily on the Commission and secretariat for administrative coordination and access to information. The secretariat also ensures that exporters are regularly informed of any changes in standards adopted by member countries.

F. Conclusion

130. A plethora of international agreements have the potential to impact upon the work of the Ad Hoc Working Group on Biosafety. As the selected agreements illustrate, however, they do not constitute a system that can adequately address issues relating to the transboundary movement of LMOs. Many of these agreements may assist in the development of such a system, and the models that they provide have the potential to be incorporated into any future biosafety protocol. The UNEP International Technical Guidelines for Safety in Biotechnology may prove to be of greatest assistance. They

represent the "state-of-the-art" in these matters as they cover such issues as information exchange, capacity-building and Advanced Informed Agreement.

131. The differing nature of the documents examined also presents something of a paradox, in that those which are mandatory and have global coverage have only an incidental impact on LMOs. Conversely, those which focus specifically on GMOs and biosafety are in the form of voluntary guidelines and standards.

132. Concerns regarding a possible conflict with WTO obligations should not deter the development of an instrument to regulate the transboundary movement of LMOs, as it is clear that multilateral environmental agreements containing trade-related provisions can be developed without impairing the move towards free trade.

Annex

The following materials were consulted in the preparation of this document:

A. International treaties

(a) International Plant Protection Convention

(b) Protocol on Environmental Protection to the Antarctic Treaty

B. OECD publications

(a) Safety Considerations for Biotechnology (1992).

(b) Biotechnology, Agriculture and Food (1992).

(c) Biotechnology for a Clean Environment (1994).

C. European Community materials

1. Directive 90/219/EEC on the contained use of genetically modified organisms

(a) Commission decision 91/448/EEC concerning directive 90/219/EEC

(b) Commission directive 94/51/EC adapting Directive 90/219/EEC

(c) Commission document 95/0340 (CNS) - proposal to amend Directive 20/219/EEC

d) Commission decision 96/134/EC amending decision 91/448/EEC

2. Directive 90/220/EEC on the deliberate release of genetically modified organisms

(a) Council decision 91/596/EEC concerning article 9 of Directive 90/220/EEC

(b) Commission decision 92/146/EEC concerning article 12 of Directive 90/220/EEC

(c) Commission decision 93/584/EEC concerning article 6(5) of Directive 90/220/EEC

(d) Commission decision 93/572/EEC concerning article 13 of Directive 90/220/EEC

(e) Commission directive 94/15/EEC adapting Directive 90/220/EEC

(f) Commission decision 94/211/EEC amending Council decision 91/596/EEC

(g) Commission decision 94/730/EEC concerning article 6 (5) of Directive 90/220/EEC

(h) Commission decision 96/424/EC concerning Directive 90/220/EEC

(i) Commission document COM (96) 630: report on the review of Directive 90/220/EEC

D. OIE documents

All documents sourced from http://www.oie.org/. The site does not provide reference numbers.

E. United Nations documents

General

(a) Recommendations on the Transport of Dangerous Goods, ninth revised edition (1995)

(b) UNIDO Voluntary Code of Conduct for Release of Organisms into the Environment.

UNEP

(a) London Guidelines for the Exchange of Information on Chemicals in International Trade, amended version (1989)

(b) International Technical Guidelines for Safety in Biotechnology (1995)

(c) Proceedings of third meeting of the Conference of the Parties to the Basel Convention

(d) UNEP/CHW.1/WG.1/2/4. Consideration of Draft Articles of a Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes.

(e) UNEP/CBD/BSWG/1/4.

(f) UNEP/CBD/COP/2/7.

FAO and related organizations

(a) International Code of Conduct on the Distribution and Use of Pesticides

(b) Preliminary draft International Code of Conduct on Biotechnology, (CPGR/93/9, annex)

(c) This is Codex Alimentarius, Codex Alimentarius Commission/FAO/WHO 2nd edition, Rome (1995)

(d) Implications of Biotechnology for Food Labelling, Codex Alimentarius Commission/FAO/WHO, Rome (1995), (CL 1995/29-FL)

(e) All material relating to PIC sourced at http://irptc.unep.ch/pic.

F. World Trade Organization/GATT documents

(a) Agreement on Sanitary and Phytosanitary Measures

(b) Singapore Ministerial Declaration, 18 December 1996

(c) Committee on Trade and Environment 1996 Report (WT/CTE/1)

(d) Press releases and other material sourced at http://www.wto.org

G. Other materials

(a) Trade and the Environment, Australian Department of Foreign Affairs and Trade, Canberra (1996)

(b) Environmental Policy and Law, IOS Press, Volume 24, Number 4 (1996)

H. Web sites

(a) UNEP Executive Center Geneva: http://www.unep.ch/

(b) Basel Convention: http://www.unep.ch/sbc/

(c) WTO: http://www.wto.org/

(d) OIE: http://www.oie.org/

(e) IRPTC: http://irptc.unep.ch and http://irptc.unep.ch/pic (for information on PIC)

(f) International Centre For Antarctic Information and Research, ICAIR: http://www.icair.org.nz.
