



**CONVENTION ON  
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**COMPILATION OF DEFINITIONS AND TERMS RELEVANT TO A BIOSAFETY PROTOCOL**

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**ACCEPTABLE LEVEL OF RISK**

Definitions from Binding International Agreements

[Air quality limit values] means the concentration of [polluting substances] in the [air] during a specified period which is not to be exceeded. (**Council Directive 84/360/EEC of 28 June 1984 on the Combating of Air Pollution from Industrial Plants**)

**ACCIDENT**

Definitions from Binding International Agreements

Accident shall mean any incident involving a significant and unintended release of genetically modified micro-organisms in the course of their contained use which could present an immediate or delayed hazard to human health and the environment. (**Council Directive 90/219/EEC on the Contained Use of Genetically Modified Micro-organisms**)

**ACCIDENTAL RELEASE**

Country Submissions

Accidental release is any incident involving an unintended release of LMOs in the course of their contained

handling, transfer or use which could present a risk to the conservation and sustainable use of biological diversity. **(Australia)**

Accidental release is any incident involving a significant and unintended release of genetically modified organisms in the course of their contained use which could present an immediate or delayed hazard to human health and the environment. **(China)**

Accidental release is any incident involving a significant and unintended release of a living modified organism in the course of its contained use which could adversely affect the conservation and sustainable use of biological diversity. **(New Zealand)**

The definition of accidental is not restricted to the accidental release into the environment from a contained setting; it will also occur in a natural setting. Peru believes it is necessary to put in place mechanisms (antidotes) to remedy release in the natural environment. **(Peru)**

#### Other Definitions

Accidental release is the unintentional discharge of a [microbiological agent] (i.e. micro-organism or virus) or [eukaryotic cell] due to a failure in the containment system. **(Proposed Action under the Guidelines for Research Involving Recombinant DNA Molecules (51 Federal Register 16958) National Institute of Health 55 FR 53258)**

### **ADVANCE INFORMED AGREEMENT/PRIOR INFORMED CONSENT**

#### Definitions from Binding International Agreements

Prior informed consent means the principle that international shipment of a [chemical which 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. **(Council Regulation (EEC) No. 2455/92 of 23 July 1992 concerning the export and import of certain dangerous chemicals)**

#### Country Submissions

Advanced informed agreement means an agreement by the competent authority of the State of import to the transfer of any living modified organisms or products thereof based on the information supplied by the State of export with the understanding that the information is accurate and complete. **(African Region)**

Advanced informed agreement refers to the principle that international exchange of transgenic plants, animals and micro-organisms that could adversely affect plants and animals should not proceed without the informed agreement of, or contrary to the decision of, the competent authority in the recipient country. **(China)**

“Advance informed agreement” is the principle that international shipment of a GMO that could have adverse effects on the environment and human health should not proceed without the agreement, where such agreement exists, or contrary to the decision of the designated national authority in the importing country. **(Cuba)**

“Advance informed agreement procedure” is the procedure to obtain and spread officially decisions of the importing countries on whether they want to receive future imports of living modified organisms that have been prohibited or rigorously limited. **(Cuba)**

“Prior informed consent” means the principle that any international sending of an LMO can have adverse impacts to environment and human health and should not be done without the agreement, when corresponding, or against, the national authority of the importing country. **(Cuba)**

The advanced informed agreement procedure should stipulate that a person intending to transfer beyond the national boundary living modified organisms (LMOs) falling into the scope of the protocol should provide the competent authorities of the recipient State with information on the transboundary transfer of the LMOs in question and receive agreement in advance. **(Japan)**

Advanced informed agreement is the advance agreement, with such conditions as appropriate, by the affected country, through the competent authority, regarding any intended transfer, handling and use of LMOs, based on relevant information supplied by the exporting country and/or person undertaking that activity in advance of the intended activities, as requested by the affected country. **(Malaysia)**

Advance informed agreement refers to the principle that international exchange of transgenic organisms that could affect other biota should not proceed without the informed agreement of, or contrary to the decision of, the competent authority of the recipient country. **(New Zealand)**

#### Other Definitions

Prior informed consent is the principle that 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 in the importing country. **(UNEP London Guidelines for the Exchange of Information on Chemicals in International Trade and UNEP/FAO Draft PIC, Convention for Certain Hazardous Chemicals and Pesticides in International Trade)**

Prior informed consent procedure (PIC procedure) means the procedure for formally obtaining and disseminating the decisions of importing countries as to whether they wish to receive future shipments of [chemicals which have been banned or severely restricted]. A specific procedure was established for selecting [chemicals] for initial implementation of the PIC procedures. These include [chemicals which have been previously banned or severely restricted] as well as certain [pesticide formulations which are acutely toxic]. **(London Guidelines for the Exchange of Information on Chemicals in International Trade)**

Advanced informed agreement refers to the principle that international exchange of [transgenic plants and micro-organisms] that could adversely affect [plants] should not proceed without the informed agreement of, or contrary to the decision of, the competent authority in the recipient country. **(FAO Draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources)**

Prior informed consent is the principle that international shipment of a [pesticide 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 in the participating

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importing country. **(FAO International Code of Conduct on the Distribution and the Use of Pesticides)**

## **ADVERSE EFFECTS**

### Definitions from Binding International Agreements

Adverse effects are changes in the physical environment or biota, including changes in climate, which have significant deleterious effects on human health or on the composition, resilience and productivity of natural and managed ecosystems, or on materials useful to mankind. **(1985 Vienna Convention on the Protection of the Ozone Layer)**

“Effects” means any direct or indirect, immediate or delayed adverse consequences caused by an [industrial] accident on, inter alia, (i) human beings, flora and fauna; (ii) soil, water, air and landscape; (iii) the interaction between the factors in (i) and (ii); (iv) material assets and cultural heritage, including historical monuments. **(1992 Convention on the Transboundary Effects of Industrial Accidents)**

Adverse effects [of climate change] means changes in the physical environment or biota resulting from [climate change] which have significant deleterious effects on the composition, resilience or productivity of natural and managed ecosystems or on the operation of socio-economic systems or on human health and welfare. **(UN Framework Convention on Climate Change)**

### Country Submissions

Adverse effects are consequences of activities involving LMOs which are deleterious to the conservation and sustainable use of biological diversity. These effects may be direct or indirect, immediate or delayed. **(Australia)**

Adverse effects means any direct or indirect, immediate or delayed adverse consequences caused by LMOs accident on, inter alia, human health, biodiversity. **(China)**

Adverse effects are potential or probable changes in the physical environment or biota, including changes in climate, which have significant deleterious effects on human health or on the composition, resilience and productivity of natural and managed ecosystems, or in materials useful to humans.

“Effects” includes any effect on biodiversity that is direct or indirect, positive or adverse, immediate or delayed, potential or probable, temporary or permanent, adverse consequences, on inter alia (i) human beings, flora and fauna; (ii) soil, water, air and landscape; (iii) the interaction between the factors in (i) and (ii); (iv) material assets and cultural heritage, including historical monuments. **(New Zealand)**

Adverse effects should not necessarily be restricted to industrial accidents but should include other causes. Impacts on the physical environment, including the composition, resilience and productivity of natural or managed ecosystems, biota and human health, caused by experimentation in a natural setting, the release or transboundary movement of living organisms modified by biotechnology. **(Peru)**

## **AFFECTED PARTY**

### Definitions from Binding International Agreements

Affected Party means the Contracting Party or Parties to this Convention likely to be affected by the transboundary impact of a proposed activity. (**Convention on Environmental Impact Assessment in a Transboundary Context**)

Affected State means the State under whose jurisdiction or control the transboundary harm arises. (**ILC Draft Articles on Liability for Injurious Consequences of Acts Not Prohibited by International Law**)

### Country Submissions

The “Affected Party” means any Party or Parties affected or likely to be affected by the transboundary transfer or release of living modified organisms or products thereof. (**African Group**)

## **AREA OF RELEASE**

### Country Submissions

Area of release is defined area in the environment where the release of an organism or combination of organisms occurs. (**Cuba**)

## **BIOLOGICAL EMERGENCY**

### Country Submissions

Biological emergency is a situation caused by events that may result in harm with adverse impacts, either immediate or delayed, on the environment in general, and the public and workers in particular, due to the escape or release of organisms. (**Cuba**)

## **BIOSAFETY**

### Country Submissions

Biosafety is the safe handling, transfer and use of LMOs which may have adverse effects on the conservation and sustainable use of biological diversity. (**Australia**)

Biosafety is the result of creation of novel types of organisms which do not occur naturally but originated from well studied organisms (i.e. organisms modified using recombinant DNA techniques). (**Belarus**)

Biosafety is the safety aspects related to the application of biotechnologies and to the release into the environment of transgenic plants and “other organisms” particularly micro-organisms that could negatively affect plant genetic resources, plant, animal or human health, or the environment. **(China)**

Biosafety is the scientific-organizational and technical-engineering measures to protect the worker in the establishment, community and the environment from the risks involved in working with biological agents and the release of organisms into the environment and, in the event of contamination, adverse effects, leakage or losses, to minimize any possible effects and rapidly eliminate the consequences. **(Cuba)**

Biosafety is the safe transfer, handling and use of any LMO resulting from biotechnology that may have adverse effect on the environment, in particular the conservation and sustainable use of biological diversity. **(Malaysia)**

Biosafety is the safety aspects related to the application of biotechnologies and to the release into the environment of transgenic organisms that could negatively affect the recipient environment’s genetic resources, people or the environment itself. **(New Zealand)**

#### Other Definitions

Biosafety is safety aspects related to the application of biotechnologies and to the release into the environment of [transgenic plants and other organisms particularly micro-organisms] that could negatively affect plant genetic resources, plant, animal or human health, or the environment. **(FAO Draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources)**

### **BIOTECHNOLOGY**

#### Definitions from Binding International Agreements

Biotechnology means any technological application that uses biological systems, living organisms, or derivations thereof, to make or modify products or processes for specific use. **(Convention on Biological Diversity)**

#### Country Submissions

“Modern” biotechnology means the use of modern biological techniques of genetic modification, and new cell and tissue culture methods for specific purposes. **(African Group)**

“Modern” biotechnology is the use of techniques such as recombinant DNA technology, molecular biology, cell or tissue culture, and cell fusion to modify the genetic material of organisms in ways that do not occur naturally by mutation, mating or natural recombination. **(Australia)**

“Modern biotechnology” means genetic engineering, etc. **(Belarus)**

Biotechnology is the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms. Canada views biotechnology as a developmental tool and that the traits and characteristics of individual organisms (or their “newness”) are more important to safety assessments than how they were incorporated. **(Canada)**

“Modern” biotechnology is a set of non-conventional enabling techniques for bringing about specific man-made changes in the genetic material of organisms. **(Malaysia)**

#### Other Definitions

A set of technologies, including, but not necessarily confined to, tissue culture and recombinant DNA techniques, used to exploit and modify living organisms so as to produce new tools, goods and products. A footnote to this definition provides: This definition is narrower than the one in the Convention on Biological Diversity. In effect it is restricted to the “new” biotechnologies. **(FAO Draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources)**

The integration of natural sciences and engineering science in order to achieve the application of organisms, cells, parts thereof and molecular analogues for products and services. **(European Federation of Biotechnology, BIOTECH, Europe 6, 96)**

Modern Biotechnology consists of activities which involve the use of genetic engineering techniques and others which do not. In some activities, living organisms are used in a contained system; in others, organisms are deliberately released, or used, in the environment. **(UK Royal Commission on Environmental Pollution: The Release of Genetically Modified Organisms to the Environment, 13 Report, July 1989)**

### **CAPACITY BUILDING**

#### Country Submissions

Capacity building means any facilitating scheme for the effective implementation of this protocol, in particular the strengthening and/or development of trained human resources and institutional capacities in terms of techniques and skills necessary to carry out the assessment and management of risks associated with living modified organisms or products thereof, and to implement the procedure of advance informed agreement. **(African Region)**

Capacity building is the strengthening and/or development of human resources and institutional capacities. It involves the transfer of know-how, the development of appropriate facilities, training in sciences related to safety in biotechnology and in the use of risk assessment and management techniques. **(Cuba)**

#### Other definitions

Capacity building is the strengthening and/or development of human resources and institutional capacities. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

### **CASE-BY-CASE**

Each proposal is reviewed individually. This does not imply that every case requires review by national or other authority since various classes of proposals may be excluded. The case-by-case approach involves assessing organisms or category of organisms. It involves first considering key issues, for example the potential to

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transfer genetic material. If such potential exists the approach proceeds to assess the risk of adverse effect consequent to gene transfer and then, if appropriate, proceeds to risk management. **(Report of Panel of Experts on Biosafety, Cairo 1995)**

### **CENTRES OF GENETIC DIVERSITY**

#### Country Submissions

Centers of genetic diversity is a region where a particular taxonomic group of organisms exhibits greater genetic diversity than it does elsewhere. **(Australia)**

Centers of genetic diversity is the place or region where the source of diversity is located. **(Malaysia)**

### **CENTRES OF ORIGIN**

#### Country Submissions

Centers of origin is the area in which a given taxonomic group of organisms originated and from which it has subsequently spread. **(Australia)**

Centers of origin is the country which possesses those genetic resources in in-situ conditions. **(Malaysia)**

### **CENTRES OF ORIGIN AND DIVERSITY**

Centers of origin and diversity are places in the world where [crops] have the greatest genetic diversity in the form of traditional crop and varieties and/or wild relatives. Centers of diversity are typically, but not always, the same location as the centers of origin or [oldest cultivation of the crop]. **(UNIDO BINAS Website: Biotechnology Library: Perils amidst the promise: glossary)**

Centre of origin of diversity is the place or region where the source of diversity is located. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

### **COMPENSATION**

Compensation shall mean payment of damages by a Party who has caused injury to another and must therefore make the other whole. **(CBD)**

### **COMPETENT AUTHORITY**

#### Definitions from Binding International Agreements

Competent authority means any governmental authority designated by a Party to be responsible, within such geographical areas as a Party may think fit, for receiving the notification of a transboundary movement of [hazardous wastes or other wastes], and any information related to it, and for responding to such a notification.



**(Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal)**

Competent authority means the national authority or authorities designated by a Party as responsible for performing the tasks covered by this Convention and/or the authority or authorities entrusted by a Party with decision-making powers regarding a proposed activity. **(Convention on Environmental Impact Assessment in a Transboundary Context)**

Government Submissions

Competent authority means an authority designated or established by a Party to be responsible, for receiving application and notification of a transboundary transfer or release of a living modified organism or organisms and for providing advance informed agreement in the case of receiving or importing living modified organisms or products thereof resulting from modern biotechnology. **(African Region)**

The “designated” national authority is a government authority designated by a Party to serve as the focal point and be responsible for communication between Parties and with any centralized data base or clearing house mechanism designated by the protocol in relation to any matter which is the subject of the protocol. **(Australia)**

Competent authority is a government agency or agencies responsible for regulating biotechnology, biosafety, intellectual property rights and other relevant aspects. **(China)**

The “national” authority means the government authority designated by a State party to propose to its Government national policy on safety in biotechnology, to manage, control and inspect the activity, and to establish procedures, draw up measures and make the necessary recommendations. **(Cuba)**

The competent authority designated by parties to be the national competent authority in respect of overseeing the implementation of this protocol, as provided under Article [ ] of this protocol. **(Malaysia)**

Competent authority is a government agency or agencies responsible for regulating biotechnology, biosafety, intellectual property rights and other relevant aspects. **(New Zealand)**

Competent authority is an entity or public state body designated by each Party and authorized to administer the protocol on biosafety, to notify and provide information. Do not include the management of toxic wastes, only the management of biosafety or the products of biotechnology. **(Peru)**

Other Definitions

A competent authority is a government agency or agencies responsible for regulating biotechnology, biosafety, intellectual property rights and other relevant aspects. **(FAO Draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources)**

Competent authorities means any authority responsible in the Member States for the application or administration of this regulation or of any other authority designated by the Member State. **(Council Directive Euratom/1493/93 of 8 June 1993 on Shipments of Radioactive Substances Between Member States)**

Competent authority means an authority designated or otherwise recognized by a government for specific purposes in connection with [radiation protection and/or nuclear safety]. **(IAEA Code of Practice on the**

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## **International Transboundary Movement of Radioactive Waste)**

### **CONFINED FIELD TESTING**

Confined field testing involves the release of a [Plant with Novel Traits] (PNT) under terms and conditions of confinement including reproductive isolation, site-monitoring and post-harvest land use restriction. Within these conditions, trials designed to determine outcrossing rates in outcrossing species, “weediness” characteristics of the [PNT], persistence in the environment, impact on other species and other studies may be permitted.

**(Canadian Regulatory Directive Dir.94.08, Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits)**

### **CONTAINED USE**

#### Definitions from Internationally Binding Agreements

Contained use shall mean any operation in which micro-organisms are genetically modified or in which such genetically modified micro-organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers, or a combination of physical barriers together with chemical and/or biological barriers, are used to limit their contact with the general population and the environment. **(Council Directive 90/219/EEC on the Contained Use of Genetically Modified Micro-organisms)**

#### Country Submissions

“Contained use” or “containment” means any use of living modified organisms where the contact between the organisms and the environment is prevented by physical barriers or a combination of physical, chemical and/or biological barriers. **(African Region)**

Contained use is any operation involving LMOs which are controlled by physical barriers or a combination of physical and biological barriers designed to prevent release of the LMOs into the open environment. **(Australia)**

Contained use is any operation involving organisms which are controlled by physical barriers or a combination of physical and/or biological barriers which limit their contact with, or their impacts on, the potentially receiving environment, which includes humans. **(China)**

Contained use is any activity in which LMOs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the environment. **(European Union)**

Contained use is any operation involving organisms which are controlled by physical barriers or a combination of physical and/or chemical and/or biological barriers which limit their contact with, or their impacts on, the potentially receiving environment, which includes humans. **(Malaysia)**

Contained use means an operation which restricts an organism to a secure location or facility to prevent escape by providing appropriate barriers. **(New Zealand)**

Contained use is any operation in which genetically modified organisms are produced, grown, stored, destroyed

or used in some other way in a closed system in which physical barriers are employed, either alone or together with chemical and/or biological barriers, to limit contact between the organisms on the one hand and humans and the environment on the other. **(Norway)**

Contained use is any operation involving organisms which are controlled by physical barriers or a combination of physical and/or chemical and/or biological barriers which limit their contact with, or their impacts on, the potentially receiving environment, which includes humans. [In accordance with the UNEP Technical Guidelines]. **(Peru)**

A use of organisms is said to be contained when their contact with the population or the environment is restricted or prevented by physical barriers or by a combination of physical and chemical or biological barriers. **(Switzerland)**

#### Other Definitions

Contained use is any operation involving organisms which are controlled by physical barriers or a combination of physical and/or biological barriers which limit their contact with, or their impacts on, the potentially receiving environment, which includes humans. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

Contained use shall mean any operation in which genetically modified organisms are produced, grown, stored, destroyed or used in some other way in a closed system which physical barriers are employed, either alone or together with chemical and/or biological barriers, to limit contact between the organism on the one hand and humans and the environment on the other. **(The Norwegian Gene Technology Act 1993)**

#### CONTAINED WORK

Contained work is genetic manipulation work which is carried out in such a way that the spread of genetically manipulated organisms outside the laboratory is prevented. Physical containment is accomplished by the use of special procedures and facilities. Biological containment is accomplished by the use of particular strains of the organism which have a reduced ability to survive or reproduce in the open environment. **(Australian Guidelines for Planned Release of GMOs)**

#### CONTAINMENT

Containment means the prevention of the spread of organisms outside the facilities which may be achieved by physical containment (the use of good work practices, equipment and installation design) and/or biological containment (the use of organisms which have reduced ability to survive or reproduce in the environment). **(UNEP International Technical Guidelines for Safety in Biotechnology)**

Containment and/or inactivation controls means any combination of engineering, mechanical, procedural, or biological controls designed and operated to restrict environmental release of [viable micro-organisms] from a structure. **(U.S. Federal Register, Volume 62, Part 725)**

#### CONTAINMENT LEVEL

Containment level is the degree of physical containment which depends on the design of the facility, the equipment installed and the procedures used. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

### **CONTROLLED RELEASE**

Controlled release is the deliberate release of organisms where risk management measures are applied. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

### **CONVENTION**

#### Country Submissions

Convention means the Convention on Biological Diversity adopted on June 5, 1992. **(African Group)**

### **DISPOSAL**

#### Definitions from Binding International Agreements

Disposal is any operation specified in Annex IV to this Convention. Annex IV: Operations which do not lead to the possibility of resource recovery, recycling, reclamation, direct reuse or alternative uses. **(Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal)**

Disposal means the processing or destruction of [waste oils] as well as their storage and tipping above or under ground. **(Council Directive of 22 December 1986 amending Directive 75/439/EEC on the Disposal of Waste Oils OJ L42/87/p.43)**

#### Other Definitions

Disposal means the emplacement of [waste] in a repository, or at a given location, without the intention of retrieval. **(IAEA Code of Practice on the International Transboundary Movement of Radioactive Waste)**

### **DONOR**

Donor is the organism from which genetic material is derived for insertion into or combination with another organism. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

Donor organism is the organism from which genetic material is obtained for transfer to the recipient organism. **(U.S. Federal Register, 7 CFR, Volume 52 No. 115, Part 340)**

### **EXAMINATION BODY**

Country Submissions

Examination body is the institutional structure created in accordance with national law of the Parties, so as to evaluate the risks associated to a release proposal of a living modified organism to the environment. **(Cuba)**

**EXPORT AND IMPORT**

Export and import mean, in their respective connotations, the movement of a [chemical] from one State to another State, but exclude mere transit operations. **(London Guidelines for the Exchange of Information on Chemicals in International Trade)**

**EXPORTER**

Country Submissions

Exporter means any user under the jurisdiction of the state of export who arranges for living modified organisms or products thereof to be exported. **(African Group)**

**FAMILIARITY**

Country Submissions

Familiarity is the knowledge and experience with an LMO, an intended activity involving the LMO, and the potential receiving environment, which would enable a risk/safety assessment of that activity. **(Australia)**

Familiarity is the knowledge and experience with an organism, the intended application and the potential receiving environment. **(China)**

With respect to living modified organisms, familiarity means knowledge and experience with an organism or with its close relatives, the extent of the modification made, and its intended application and its potential effects on the receiving environment. **(New Zealand)**

Familiarity is the knowledge and experience with an organism, the intended application and the potential receiving environment. [In accordance with the UNEP Technical Guidelines]. **(Peru)**

Other Definitions

Familiarity is having enough information to be able to judge the safety or risks of an LMO. It can be used to indicate ways of handling risks. It is not synonymous with safety. Relatively low degree of familiarity may be compensated for by appropriate management practices. Familiarity can be increased as a result of trial or experiment. This increased familiarity can then form a basis for future risk assessment. **(Panel of Experts on Biosafety, Cairo, 1995)**

Familiarity is the knowledge and experience with an organism, the intended application and the potential receiving environment. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

Familiarity comes from the knowledge and experience available for conducting a risk/safety analysis prior to

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scale-up of any new [plant line or crop cultivar] in a particular environment. Familiarity takes into account of but need not be restricted to knowledge and experience with: the crop plant, including its flowering/reproductive characteristics, ecological requirements, and past breeding experiences; the agricultural and surrounding environment of the trial site; specific trait(s) transferred to plant line(s); results from previous basic research including greenhouse/glasshouse and small-scale field research with the new plant line or with other plant lines having the same trait; the scale-up of lines of the crop plant developed by more traditional techniques of plant breeding; the scale-up of other plant lines developed by the same technique; the presence of related (and sexually compatible) plants in the surrounding natural environment; and knowledge of the potential for gene transfer between the crop plant and the relative; and interactions between/among the crop plant, environment and trait. **(Safety Considerations for Biotechnology Scale-up of Crop Plants: OECD 1993)**

## **FIELD TRIAL**

### Country Submissions

Field trial is the introduction of an LMO into the environment with provisions for limiting the potential for uncontrolled dissemination or persistence of the LMO or its genetic material in the environment. **(Australia)**

## **FOCAL POINT**

### Definitions from Binding International Agreements

A focal point designated by the Parties responsible for receiving and submitting information of accidents occurring due to transboundary movements of [waste] and other information to the Conference of Parties. **(Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal)**

### Country Submissions

A focal point designated by the Parties responsible for receiving and submitting information of accidents occurring due to transboundary movements of LMOs and other information to the Conference of the Parties. **(China)**

A focal point designated by the countries responsible for receiving and transmitting information. [May or may not be included within the competent national authority]. **(Peru)**

## **GENERAL RELEASE**

### Country Submissions

General release is the introduction of an LMO into the environment with no provisions for limiting the potential for uncontrolled dissemination or persistence of the LMO or its genetic material in the environment. **(Australia)**

Release means the introduction of a living modified organism, or a combination, into the environment. **(Cuba)**

## **GENETIC MODIFICATION**

Definitions from Binding International Agreements

Genetic modification occurs at least through the use of the following techniques: (i) recombinant DNA techniques using vector systems; (ii) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; (iii) cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally. **(Council Directive 90/220/EEC of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms)**

Other Definitions

Genetic modification shall mean modern biotechnology used to alter genetic material of living cells or organisms in order to make them capable of producing new substances or performing new functions. **(UNEP International guidelines for safety in Biotechnology)**

**GENETICALLY MODIFIED ORGANISMS**

Definitions from Binding International Agreements

Genetically modified micro-organism shall mean a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. **(Council Directive 90/220/EEC of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms)**

Genetically modified organism means any organism in which the genetic material has been altered in a way which does not occur naturally by mating and/or natural recombination. **(Council of Europe Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment)**

Country Submissions

“Genetically engineered organisms(GMOs)” means that organisms are produced through using different techniques of directed modification of genetic structure and/or genetic activity of some particular genes - genetic engineering. **(Belarus)**

Genetically modified organism is any organism in which the genetic material has been modified, using modern biotechnology, in a way that does not occur naturally, either through mating or natural recombination. **(Cuba)**

Genetically modified organisms means organisms whose genetic material has been modified in a way that does not occur naturally, either by mating or by natural recombination. **(Switzerland)**

Other Definitions

Any living organism whose genome has been modified through genetic engineering technologies. **(FAO Draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources)**

An organism is “genetically modified” if any of the genes or other genetic material in the organism (a) have been modified by means of an artificial technique prescribed in regulations by the Secretary of State; or (b) are inherited or otherwise derived, through any number of replications, from genes or other genetic material (from any source) which were so modified. The techniques which may be prescribed for such purposes include (a) any technique for the modification of any genes or other genetic material by recombination, insertion or deletion of, or of any component parts of, that material from its previously occurring state, and (b) any other technique for modifying genes or other genetic material which in the opinion of the Secretary of State would produce organisms which should be treated as having been genetically modified, but not include techniques which involve no more than, or no more than the assistance of, naturally occurring processes of reproduction (including selective breeding techniques or *in vitro* fertilization). **(UK Environmental Protection Act 1990 sec. 106)**

Genetically modified organisms are microorganisms, plants and animals in which the genetic material has been altered by means of gene or cell technology. **(The Norwegian Gene Technology Act 1993)**

### **HANDLING OF LMOs**

#### Country Submissions

Handling of LMOs is any research and development activity carried out with living organisms with a view to achieving a genetic modification. **(Cuba)**

### **HAZARD**

Hazard shall mean the potential of an organism to cause harm to human health and/or the environment. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

### **HOST**

Host shall mean an organism in which the genetic material is altered by modification of a part of its own genetic material and/or insertion of foreign genetic material. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

### **ILLEGAL TRAFFIC**

#### Country Submissions

Illegal traffic means any transboundary movement or transfer of living modified organisms or products thereof as specified in Article 8. [Article 8 refers to any transboundary transfer of living modified organisms or products thereof without notification to, or advance informed agreement of, all States concerned; pursuant to the provisions of this protocol; or with advance informed agreement obtained from States concerned through falsification, misrepresentation or fraud; or with advance informed agreement which does not conform in a material way with the documents submitted or which results in the deliberate release of living modified organisms in contravention of this protocol and of general principles of international law, shall be deemed to be illegal traffic]. **(African Region)**

### **IMPACT**



### Definitions from Binding International Agreements

Impact means any effect caused by a proposed activity on the environment including human health and safety, flora, fauna, soil, air, water, climate, landscape and historical monuments or other physical structures or the interaction among these factors; it also includes effects on cultural heritage of socio-economic conditions resulting from alterations to those factors. **(Convention on Environmental Impact Assessment in a Transboundary Context)**

## **IMPORTER**

### Country Submissions

Importer means any user under the jurisdiction of the state of import who arranges for living modified organisms or products thereof to be imported. **(African Group)**

## **INFORMATION EXCHANGE**

For the protection of human health and the environment, States should facilitate (i) the exchange of scientific information (including toxicological and safety data) and technical, economic and legal information concerning the management of [chemicals], particularly through designated national government authorities and through intergovernmental organizations as appropriate; (ii) the provision upon request of technical advice and assistance concerning the management of [chemicals] to other States, on a bilateral or multilateral basis taking into account the special needs of developing countries. **(UNEP London Guidelines for the Exchange of information on Chemicals in International Trade)**

## **INTENDED/DELIBERATE RELEASE**

### Definitions from Binding International Agreements

Deliberate release is any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment. **(Council Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms)**

### Country Submissions

Deliberate release means any intentional introduction into the environment of living modified organisms or products thereof. **(African Region)**

Intended/deliberate release is the intentional introduction of an LMO into the open environment, including for scientific or commercial purposes. This may take the form of a field trial or a general release. **(Australia)**

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Deliberate release is the introduction into the environment for scientific or commercial purposes of transgenic plants, animals and micro-organisms. **(China)**

“Intended transboundary movement” is the deliberate transfer of LMOs across national borders. “Deliberate release” is any intentional introduction into the environment of a LMO or a combination of LMOs without specific containment measures to limit their contact with the environment. **(European Union)**

Deliberate release is any use of organisms that is not a contained use. **(Malaysia)**

Intended/deliberate release means to allow the organism to move freely within the jurisdiction of the Party free of restrictions imposed during its contained use. **(New Zealand)**

Deliberate release means any production and use of living modified organisms that is not considered to be contained use. **(Norway)**

With regard to deliberate release, the definition in the FAO draft Code of Conduct on Plant Biotechnology is more in line with the sense of the Convention. **(Peru)**

#### Other Definitions

Deliberate release is any use of an organism that is not a contained use. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

Deliberate release is the introduction into the environment for scientific or commercial purposes of [transgenic plants and micro-organisms]. **(FAO Draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources)**

An organism under a person’s control is “released” if he deliberately causes or permits it to cease to be under his control or the control of any other person and to enter the environment; and such an organism “escapes” if, otherwise than by being released, it ceases to be under his control, or that of any other person and enters the environment. **(UK Environmental protection Act)**

#### **LIABILITY**

Liability shall mean the quality or state of being legally obligated or responsible. **(CBD)**

#### **LIVING MODIFIED ORGANISMS**

##### Country Submissions

“Living modified organism” means any living organism or part thereof which is capable of regenerating itself on its own or in the body or cell of another organism and whose genetic material has been modified by modern biotechnology in a way which does not occur naturally by mating or recombination, or any living organism or part thereof which had been a fossil but has been resuscitated through modern biotechnology. **(African Group)**

Living modified organisms are organisms or parts of organisms which are capable of propagation, in which the genetic material has been altered by techniques of modern biotechnology (that is, in a way that does not occur naturally by mutation, mating or natural recombination). **(Australia)**

Canada proposes the following definition for living modified organisms (not including humans in this context): living organisms that have been deliberately modified to exhibit one or more traits, that do not exist in/are novel to the species in the receiving country, not excluding when the LMO is a modified form of an organism that is a new species (exotic) to the receiving country. "Deliberately modified" means altered by any means. **(Canada)**

Living modified organisms are all organisms produced through the use of recombinant DNA technology, with a wider range of modifying technologies relevant when considering living modified prokaryotes and yeast.

**(China)**

Living modified organism means a genetically modified organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. **(Cuba)**

Living modified organism resulting from modern biotechnology is an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. . **(European Union)**

LMOs resulting from applying certain techniques of alteration of genetic material would be covered by the protocol, while organisms resulting from certain other techniques should not per se be considered to be LMOs. **(European Union)**

Living modified organisms are organisms or components thereof having reproductive capability, produced by genetic modification and where the resultant genetic makeup is unlikely to occur in nature. **(India)**

Living modified organisms are organisms produced through genetic modification and whose genetic make-up is unlikely to occur in nature, including any genetic material intended for use to produce LMOS, and products derived therefrom. These include subcellular particles such as plasmids, DNA fragments and vectors. **(Malaysia)**

Living modified organism means all organisms produced through the use of recombinant DNA or in vitro technology whose genetic combination does not occur naturally by mating or by naturally occurring recombination processes. **(New Zealand)**

Living modified organism resulting from modern biotechnology means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. **(Norway)**

Living modified organisms are genetically modified organisms, in line with the proposal of Expert Panel IV. **(Peru)**

#### Other Definitions

Living modified organisms are all organisms produced through the use of recombinant DNA technology, with a wider range of modifying technologies relevant when considering living modified prokaryotes and yeast. **(Report of the Panel of Experts on Biosafety, Cairo 1995)**

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Living modified organisms are genetically modified organisms (GMOs) whose genetic material does not occur naturally by mating or natural recombination. **(Report of UNEP Expert Panel IV)**

## **MANIPULATION**

### Country Submissions

Manipulation means all activities of research and development done with living organism to achieve a genetic modification. **(Cuba)**

## **NOTIFICATION**

### Definitions from Internationally Binding Agreements

Notification shall mean the presentation of documents containing the requisite information to the competent authorities of a Member State. **(Council Directive 90/219/EEC of 23 April 1990 on the Contained Use of Genetically Modified Micro-organisms)**

### Country Submissions

Notification entails the express written notification by the country/person to the affected country prior to any proposed/intended transfer/movement/release/activity into/within the affected country which may affect/have an impact on the potentially affected country. It may also entail notification to third parties, as appropriate. Notification will be necessary whether or not the intended/proposed transfer represents a threat to the affected country. **(Malaysia)**

## **NOVEL TRAITS**

### Country Submissions

Novel traits are characteristics in an organism that have been created or introduced through a specific genetic change and that make the organism different from the unmodified organism. **(Canada)**

### Other Definitions

Novel traits are genetic changes in species occur continually in nature. Occasionally a new trait may appear that confers a selective advantage resulting in an organism that could become more numerous, have an expanded host and geographical range, and/or utilize new resources and habitats. **(OECD Recombinant DNA Safety Considerations, 1986)**

## **OPEN ENVIRONMENT**

### Country Submissions

An open environment is an environment in which containment of an LMO or its genetic material may not be possible. **(Australia)**

#### Other Definitions

Open environment includes all life forms in the environment. **(Australian Guidelines for Planned Release of GMOs)**

### **ORGANISM**

#### Definitions from Binding International Agreements

An organism is any biological entity capable of replication or of transferring genetic material. **(Council Directive 90/220/EEC of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms and Council of Europe Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment)**

#### Country Submissions

A living organism is any biological entity capable of replication or of transferring genetic material. This definition covers plants, animals, fungi, micro-organisms, viruses and viroids, including cell and tissue cultures, germinal cells, seeds, pollen and spores. **(European Union)**

Organisms are defined as acellular, unicellular or multicellular entity in any form (other than human or human embryo). **(Malaysia)**

Organisms means the biological and cellular and non-cellular entities that are capable of reproducing themselves or of transferring genetic material. Mixtures or objects containing such entities are assimilated to them. **(Switzerland)**

#### Other Definitions

Organism shall mean any entity able to replicate its own genetic material including viruses. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

Organism means any active, infective, or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living related to the foregoing. **(U.S. Federal Register, 7 CFR, Volume 52 No. 115, Part 340)**

### **ORGANISMS WITH NOVEL TRAITS**

Organisms with novel traits are organisms produced by genetic modification and whose resultant genetic make-up is unlikely to occur in nature. These do not include organisms obtained by conventional techniques and traditional breeding methods. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

## **OVERSIGHT**

Oversight is a system for addressing questions of potential risk through guidelines, regulations or other structures. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

## **PARENTS**

Parents are organisms from which an organism with novel trait(s) is derived. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

## **PARTY OF ORIGIN**

### Country Submissions

Party of origin means the Party or Parties to this protocol from whose jurisdiction a transboundary release or transfer of living modified organisms or products thereof has taken place or is envisaged to take place. **(African Group)**

### Other Definitions

State of origin means the State which exercises jurisdiction or control over the activity. **(ILC Draft Articles on Liability for Injurious Consequences of Acts Not Prohibited by international Law)**

## **PARTY/PARTIES**

### Definitions from Internationally Binding Agreements

Party means a State or any regional economic integration organization constituted by sovereign States which has competence in respect of the negotiation, conclusion and application of international agreements in matters covered by this [Convention] for which this [Convention] is in force. **(Convention on the Conservation of Migratory Species of Wild Animals)**

### Country Submissions

Parties means, unless the text otherwise indicates, Parties to this Protocol. **(African Group)**

## **PATHOGEN**

Pathogen is an organism that can cause disease. **(UNEP International Technical Guidelines for safety in Biotechnology)**

## **PERSON**

### Definitions from Internationally Binding Agreements

Person means any individual or partnership or any public or private body, whether corporate or not, including a

State or any of its constituent subdivisions. (**International Convention on Civil Liability for Oil Pollution Damage**)

Person means any individual or partnership or any body governed by public or private law, whether corporate or not, including a State or any of its constituent subdivisions. (**Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment**)

#### Country Submissions

Person means an natural or legal person. (**African Group**)

#### Other Definitions

Person shall mean any individual, partnership, corporation, company, society, association, or other organized group. (**U.S. Federal Register, 7 CFR, Volume 52 No. 115, Part 340**)

### **POTENTIAL RECEIVING ENVIRONMENT**

Potential receiving environment is an ecosystem or habitat, including humans and animals, which is likely to come in contact with released organism. (**UNEP International technical Guidelines for Safety in Biotechnology**)

### **PRECAUTIONARY PRINCIPLE/PRECAUTIONARY APPROACH**

#### Definitions from Binding International Agreements

The precautionary principle, by virtue of which preventive measures are to be taken when there are reasonable grounds for concern that [substances or energy] introduced, directly or indirectly, into the [marine environment] may bring about hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with other legitimate uses of the sea, even when there is no conclusive evidence of a causal relationship between the inputs and the effects. (**1992 Convention for the Protection of the Marine Environment of the North-East Atlantic**)

Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as reason for postponing cost-effective measures to prevent environmental degradation. (**Principle 15, Declaration of the UN Conference on Environment and Development, Rio de Janeiro, 3-14 June 1992**)

### **PRIOR INFORMED CONSENT PROCEDURE**

Prior Informed Consent Procedure (PIC) is the procedure for formally obtaining and disseminating the decisions of importing countries as to whether they wish to receive future shipments of [chemicals which have been banned or severely restricted]. A specific procedure was established for selecting [chemicals] for initial implementation of the PIC procedures. These include [chemicals which have been previously banned or severely restricted] as well as certain [pesticide formulations which are acutely toxic]. (**UNEP London Guidelines for the Exchange of Information on Chemicals in International Trade**)

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of importing countries as to whether they wish to receive future shipments of [pesticides which have been banned or severely restricted]. A specific procedure was established for selecting [pesticides] for initial implementation of the PIC procedures. These include [pesticides which have been previously banned or severely restricted] as well as certain [pesticide formulations which are acutely toxic]. This procedure is described in the Guidelines on the Operation of Prior Informed Consent. **(FAO Code of Conduct on the Distribution and Use of Pesticides)**

## **PRODUCT**

Product means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market. **(Council Directive 90/220/EEC of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms)**

Product means the [pesticide] in the form in which it is packaged and sold; it usually contains an [active ingredient plus adjuvants] and may require dilution prior to use. **(FAO Code of Conduct on the Distribution and Use of Pesticides)**

### Other Definitions

Product is anything made by or from, or derived from an organism, living or dead. **(U.S. Federal register, CFR 7, Volume 52 No. 115, Part 340)**

## **PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT**

Protection seen from the point of view of the protection of man, animals, plants, soil, water, air, and all possible interactions between these factors: ecosystems and biodiversity. This definition includes the protection of both wildlife and domesticated species. **(Recommendation No. R(92)9 of the Committee of Ministers to Member States on the Potential Ecological Impact of the Contained Use and Deliberate Release of Genetically Modified Organisms - adopted by the Committee of Ministers on 18 May 1992, Council of Europe)**

## **RISK**

### Definitions from Binding International Agreements

“Appreciable” “significant” risk means risk which presents either the low probability of causing very considerable [disastrous] harm or the higher than normal probability of causing minor, though [appreciable][significant], transboundary harm. **(ILC Draft Articles on Liability for Injurious Consequences of Acts Not Prohibited by International Law)**

### Country Submissions

Risk is the combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences will occur. **(Malaysia)**

### Other Definitions

Risk means the expected frequency of undesirable effects of exposure to the [pesticide]. **(FAO Code of**



## **Conduct on the Distribution and Use of Pesticides)**

Risk is the combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences will occur. **(UNEP International technical Guidelines for Safety in Biotechnology)**

### **RISK ASSESSMENT**

#### Definitions from International Binding Agreements

Risk assessment means an evaluation of (a) the potential for the introduction, establishment or spread of a [pest or disease] and associated biological and economic consequences; or (b) the potential for adverse effects on human or animal life or health arising from the presence of an [additive, contaminant, toxin or disease-causing organism] in a food, beverage, or feedstuff. **(North America Free Trade Agreement)**

Environmental risk assessment means the evaluation of the risk to human health and the environment (which includes plants and animals) connected with the release of GMOs or products containing GMOs. **(Council Directive 90/220/EEC of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms)**

Environmental impact assessment means a national procedure for evaluating the likely impact of a proposed activity on the environment. **(Convention on Environmental Impact Assessment in a Transboundary Context)**

#### Country Submissions

Risk assessment means the identification and evaluation of potential benefits versus harm of living modified organisms and products thereof in accordance with the criteria and procedure set out by this protocol, and based on the characteristics of the organism used, the characteristics of the site and the surrounding environment including socio-economic impacts and conditions of the release. **(African Group)**

Risk assessment is the process of estimating what harm to the conservation and sustainable use of biological diversity might be caused by an LMO, how likely it would be to occur, and the extent of the harm, using scientific data and methodologies. **(Australia)**

Risk assessment is the use of scientific data to identify and characterize the nature and magnitude of hazards, if any, and the likelihood of hazards being realized. **(China)**

Risk assessment means the multi-profile analysis procedure on scientific basis to determine possible damages, occurrence probability and possible scope of the activities related with the use of living modified organisms. **(Cuba)**

Risk assessment inter alia should be based on the characteristics of the organism, the introduced trait, intended use, the receiving environment, knowledge about ecological interactions, possible socio-economic impacts, and the interaction among these. **(India)**

Risk assessment is the measures to estimate what harm might be caused, how likely it would occur and the scale of the estimated damage to the affected country and its environment, taking into account socio-economic

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impacts, including in particular to human health, agriculture and welfare. **(Malaysia)**

Risk assessment is the use of appropriate measures to estimate what adverse effects might be caused, the extent of the adverse effects and how likely they would be to occur. **(New Zealand)**

Risk assessment is the measures to estimate what harm might be caused, how likely it would be to occur and the scale of the estimated damage. [In accordance with the definition in the UNEP Technical Guidelines]. **(Peru)**

#### Other Definitions

Risk assessment is the use of scientific data to identify and characterize the nature and magnitude of hazards, if any, and the likelihood of hazards being realized. **(Report of Panel of Experts on Biosafety)**

Risk assessment is the measures to estimate what harm might be caused, how likely it would be to occur and the scale of the estimated damage. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

### **RISK MANAGEMENT**

#### Country Submissions

Risk management means any appropriate measure for the management of potential risk, including experimental design, post-release monitoring, emergency plans and other measures indicated in this protocol. **(African Group)**

Risk management is the identification and implementation of the most appropriate measures to minimize identified risks. **(Australia)**

Risk management is the implementation of the most appropriate measures to minimize the identified risks and mitigate their effects while achieving the anticipated results. **(China)**

Risk management means the group of measures intended to reach a safe use of living modified organisms. **(Cuba)**

Risk management is the measures to ensure that the transfer, handling and use of an LMO is safe, including measures to mitigate any damage likely to occur. **(Malaysia)**

Risk management refers to the ways that appropriate measures to manage risks and should not be determined by and in proportion to the results of the risk/safety analysis. It does not include broader considerations of a political, socio-economic, value and/or ethical nature. **(New Zealand)**

Risk management is the measures to ensure that the production and handling of an organism are safe. [In accordance with the definition in the UNEP Technical Guidelines. We believe it necessary to include within the definition a warning and prevention system for release into the environment]. **(Peru)**

#### Other Definitions

Risk management is the implementation of the most appropriate measures to minimize the identified risks and mitigate their effects while achieving the anticipated results. **(Report of Panel of Experts on Biosafety)**

Risk management refers to the ways that appropriate methods are applied in order to minimize risks and should not be determined by and in proportion to the results of the risk/safety analysis. It does not include broader considerations of a political, socio-economic, value and/or ethical nature. **(Safety Considerations for Biotechnology Scale-up of Crop Plants, OECD 1993)**

Risk management is the measures to ensure that the production and handling of an organism is safe. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

### **SAFE (SAFETY)**

Safe is the conditions determined with reasonable certainty to have acceptable or negligible risk to human health or to managed or natural ecosystems. **(Proposed USDA Guidelines for Research involving the Planned Introduction into the Environment of Organisms with Deliberate Modified Hereditary traits, US Department of Agriculture, 56 FR 4134, 1 February 1991)**

### **SAFE TRANSFER**

Safe transfer is transfer that completely eliminates any adverse effect on the conservation and sustainable use of biological diversity. **(Draft Biosafety Protocol to the Convention on Biological Diversity, prepared by the Community Nutrition Institute, 910 17<sup>th</sup> Street NW, Suite 413, Washington, DC 20006)**

### **SECRETARIAT**

#### Country Submissions

Secretariat means the Secretariat of the Convention. **(African Group)**

### **STANDARD**

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for [products] or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marketing or labeling requirements as they apply to a [product], process or production method. **(World Trade Organization Agreement on Technical Barriers on Trade)**

### **STATE OF EXPORT**

#### Definitions from Binding International Agreements

State of export means a Party from which a transboundary movement of [hazardous waste or other wastes] is planned to be initiated or is initiated. **(Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal)**

#### Country Submissions

State of export means a Party from which a transboundary transfer of living modified organisms or products thereof is planned to be initiated or is initiated. **(African Group)**

## **STATE OF IMPORT**

### Definitions from Binding International Agreements

State of import means a Party to which a transboundary movement of [hazardous waste or other wastes] is planned or takes place for the purpose of [disposal therein] or for the purpose of [loading prior to disposal] in an area not under the national jurisdiction of any State. . **(Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal)**

### Country Submissions

State of import means a Party to which a transboundary transfer of living modified organisms or products thereof is planned to take place or is made. **(African Group)**

## **STATE OF TRANSIT**

### Definitions from Binding International Agreements

State of transit means any State, other than State of export or import, through which a movement of [hazardous wastes or other wastes] is planned or takes place. **(Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal)**

## **STATES CONCERNED**

### Definitions from Binding International Agreements

States concerned means Parties which are States of export or import, or transit States, whether or not Parties. **(Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal)**

States concerned means the State or States of origin and the affected State or States. **(ILC Draft Articles on Liability for Injurious Consequences of Acts Not Prohibited by International Law)**

### Country Submissions

States concerned means Parties which are states of export or import, or transit states. **(African Group)**

## **SUSTAINABLE USE**

Sustainable use shall mean the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations. **(Convention on Biological Diversity, Rio de Janeiro , June 5 1992, 31 ILM 818)**

## **TRANSBOUNDARY HARM**

### Definitions from Binding International Agreements

Transboundary harm means the harm which arises as a physical consequence of the activities referred to in article 1 (handling, storage, production, carriage, unloading or other similar operation of one or more [dangerous substances]; use technologies that produce [hazardous radiation]; or introduce into the environment [dangerous genetically altered organisms and dangerous micro-organisms] and which, in the territory or in [places] [areas] under the jurisdiction or control of another State, is [appreciably] [significantly][ detrimental to persons, [objects] [property] or the environment. **(ILC Draft Articles on Liability for Injurious Consequences of Acts Not Prohibited by International Law)**

### Country Submissions

Transboundary harm means serious harm within the jurisdiction of a party as a result of transboundary transfer or release of living modified organisms or products thereof from within the jurisdiction of another party. **(African Group)**

### Other Definitions

Transboundary [air pollution] means [air pollution] whose physical origin is situated wholly or in part within the area under the jurisdiction of one Party and which has adverse effects, other than effects of a global nature, in the area under the jurisdiction of the other Party. **(Agreement Between the Government of the United States of America and the Government of Canada on Air Quality)**

## **TRANSBOUNDARY MOVEMENT**

### Definitions from Binding International Agreements

Transboundary movement means any movement of [hazardous wastes or other wastes] from an area under the national jurisdiction of one State to or through an area under the national jurisdiction of another State or to or through an area not under the natural jurisdiction of any State (meaning any land, marine area or airspace within which a State exercises administrative and regulatory responsibility in accordance with international law in regard to the protection of human health or the environment), provided at least two states are involved in the movement. **(Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, (Basel) 22 March 1989, in force 24 May 1992, 28 ILM 657) and Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Waste Within Africa (Bamako) 29 January 1991, not in force, 30 ILM 775)**

### Country Submissions

Transboundary movement is the transfer of LMOs across national boundaries. **(Australia)**

Transboundary movement means all movement of living modified organisms coming from a State national jurisdiction zone and going to another State national jurisdiction zone or through this zone, or to a zone not

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submitted to any State national jurisdiction, or through this zone, always when this movement affect at least two States. **(Cuba)**

Intended transboundary movement is the deliberate transfer of LMOs across national borders. **(European Union)**

Transboundary movement should imply movement across boundaries of countries, and should include intended as well as unintended movement. **(India)**

Transboundary movement is any intentional and/or unintended physical movement/transport of any LMO or products derived therefrom, across national boundaries, including, without limitation to, organisms that are produced, through genetic modification, and products derived therefrom, within the national boundaries of a State, by persons (legal or natural). Transboundary movement also entails the behavior of the LMOs, in particular in the receiving country, i.e. in R&D, in handling, transfer, use and disposal of the LMOs. **(Malaysia)**

Transboundary movement of a living modified organism from an area under national jurisdiction of one State to or through an area under the national jurisdiction of another State or to or through an area not under the national jurisdiction of any State (meaning any land, marine area, or airspace within which a State exercises administrative and regulatory responsibility in accordance with international law in regard to protection of human health or the environment), provided at least two states are involved in the movement. **(New Zealand)**

Transboundary movement means any movement of organisms and substances or products obtained through biotechnology from the national jurisdiction of one State or through an area under the national jurisdiction of another State or through an area not under the national jurisdiction of any State (any land, marine area or airspace within which the State exercises administrative and regulatory responsibility). It is felt that at least two States should be involved in the movement. **(Peru)**

### **TRANSBOUNDARY RELEASE**

#### Country Submissions

Transboundary release means any unintended release of living modified organisms or products thereof from the jurisdiction of one party to the other or to areas beyond the limits of a national jurisdiction or control. **(African Group)**

### **TRANSBOUNDARY TRANSFER**

#### Country Submissions

Transboundary transfer means any transfer of living modified organisms or products thereof resulting from modern biotechnology from an area under the national jurisdiction or control of one state to or through an area under the national jurisdiction or control of another state or to or through an area not under the national jurisdiction or control of any State. **(African Group)**

### **TRANSFER**

### Country Submissions

Transfer includes the intentional transboundary movement of LMOs and the unintended movement of LMOs across national boundaries. **(Malaysia)**

### Other Definitions

Transfer is to ship, offer for shipment, offer for entry, import, receive for transportation, carry or otherwise transport or move, or allow to be moved into, through, or within the United States. **(US Federal Register, 7 Code of Federal regulations part 340, Restrictions on the Introduction of Regulated Articles, 1993)**

### UNCONFINED RELEASE

Unconfined release shall mean the use of a [Plant with Novel Traits] (PNT) that is not subject to reproductive and physical isolation from the natural or agricultural environment, site inspections, post-harvest land use restrictions and/or restricted use of seed and progeny. **(Canadian Regulatory Directive Dir.94.08, Assessment Criteria for Determining Environmental safety of Plants with Novel Traits)**

### UNINTENDED RELEASE

#### Country Submissions

Unintended release means any release of living modified organisms or products thereof which is not a deliberate release. **(African Group)**

Unintended transboundary movement is the natural or accidental movement of LMOs across national borders. [It will be mentioned under the relevant section(s) that only those unintended transboundary movements which are likely to have significant environmental effects have to be covered]. **(European Union)**

Unintended release is any release which is not deliberate. **(Malaysia)**

#### Other Definitions

Unintended release is any release of GMOs which is not a deliberate release. **(UNEP Expert Panel IV Report)**

### USE

#### Definitions from Binding International Agreements

Use means the deliberate release of a product which has been placed on the market. The persons carrying out this use will be referred to as “users”. **(Council Directive 90/220/EEC of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms)**

#### Other Definitions

“Use pattern” embodies the combination of all factors involved in the use of a [pesticide], including the concentration of active ingredients in the preparation being applied, rate of application, time of treatment, number of treatments, use of adjuvants and methods and sites of application which determine the quantity applied, timing of treatment and interval before harvest, etc. **(FAO Code of Conduct on the Distribution and Use of Pesticides)**

## **USER**

### Definitions from Binding International Agreements

User shall mean any natural or legal person responsible for the contained use of genetically modified micro-organisms. **(Council Directive 90/219/EEC of 23 April 1990 on the Contained Use of Genetically Modified Micro-organisms)**

### Country Submissions

User means any person responsible for the development, production, use, handling, testing, marketing, transfer, release, or distribution of living modified organisms or products thereof. Any member of the general public who purchases and/or uses locally a living modified organism is not a user in the meaning of this protocol. **(African Group)**

### Other Definitions

Users are any persons, institutions or organizations (including companies) responsible for the development, production, testing, marketing and distribution organisms with novel traits. Any member of the general public who purchases and/or uses an organism is not a user in the meaning of these Guidelines, unless specific conditions are attached to its use. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

## **VECTOR**

Vector is an organism or object used to transfer genetic material from a donor organism to a recipient organism. **(UNEP International Technical Guidelines for Safety in Biotechnology)**

Vector or vector agent shall mean organisms or objects used to transfer genetic material from the donor organism to the recipient organism. **(U.S. Federal Register, CFR 7, Volume 52 No. 115, Part 340)**

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