

**CONVENTION ON
BIOLOGICAL DIVERSITY**Distr.
GENERALUNEP/CBD/BSWG/2/5
18 March 1997

ORIGINAL: ENGLISH

OPEN-ENDED AD HOC WORKING
GROUP ON BIOSAFETY
Second meeting
Montreal, 12-16 May 1997

GLOSSARY OF TERMS RELEVANT TO A BIOSAFETY PROTOCOL

Results from a preliminary survey by the Secretariat*

A. DEFINITIONS FROM BINDING INTERNATIONAL AGREEMENTS

Adverse effects

"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 for 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)

Competent authority

* The Secretariat is continuing to conduct this survey in order to identify more terms relevant to a biosafety protocol and a revised glossary will be provided once it becomes available.

"One governmental authority designated by a Party to be responsible, within such geographical areas as the 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." (1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal)

Focal point

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. (1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal)

Prior Informed Consent

"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/FAO draft PIC Convention for Certain Hazardous Chemicals and Pesticides in International Trade)

Transboundary movement

"Means any movement of hazardous wastes or other wastes from an area under the national jurisdiction of one 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"] 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, provided at least two States are involved in the movement." (1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, and 1991 Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Waste Within Africa)

B. OTHER DEFINITIONS

Advanced informed agreement (see also "Prior Informed Consent")

"Advanced informed agreement refers to the principle that international

exchange of transgenic plants and microorganisms 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)

Accident (Accidental)

"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

"The unintentional discharge of a microbiological agent (i.e., microorganism 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)

Biosafety

"Safety aspects related to the application of biotechnologies and to the release into the environment of transgenic plants and other organisms particularly microorganisms 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)

Centres of origin and diversity

"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 locations as the centers of origin or oldest cultivation of the crop." (UNIDO BINAS Website: Biotechnology Library: Perils amidst the promise: glossary)

Competent authority

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"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)

Contained use

"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)

"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)

Deliberate release

"Any use of an organism that is not a contained use." (UNEP International Technical Guidelines for Safety in Biotechnology)

"Introduction into the environment for scientific or commercial purposes of transgenic plants and microorganisms." (FAO draft International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources)

"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)

Familiarity

"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

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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)

"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 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)

Living modified organisms (LMOs)

"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)

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

Move (moving, movement) (see "transfer")

"To ship, offer for shipment, offer for entry, import, receive for transportation, carry or otherwise transport or move, or allow to be

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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)

Prior Informed Consent

"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)

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

Risk assessment

"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)

"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

"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)

"Refers to the ways that appropriate methods are applied in order to minimise 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)

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

Safe or safety

"The conditions determined with reasonable certainty to have acceptable or negligible risk to human health or to managed or natural ecosystems." (Proposed United States Department of Agriculture 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

"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 17th Street NW, Suite 413, Washington, DC 20006)

Unintended release

"Any release of GMOs which is not a deliberate release." (UNEP Expert Panel IV Report)
