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SUBMISSION FROM THE GOVERNMENT OF VIETNAM

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VIEWS OF THE VIETNAM GOVERNMENT ON CERTAIN ELEMENTS OF THE BIOSAFETY PROTOCOL TO BE DEVELOPED UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY

TITLE

Protocol for the Safe Transfer and Use of Modified Gene Organisms (MGOs) [instead of Living Modified Organisms (LMO)]

OBJECTIVES

The objective of this Protocol is to ensure the safe transfer, handling and use of modified gene organisms (MGOs) resulting from modern biotechnology that may have adverse effect on the environment, in particular, the conservation and sustainable use of biological diversity, socio-economic imperatives, and the risks to agriculture and human health.

GENERAL OBLIGATIONS

1. The Parties to the present Protocol undertake to implement the provisions of the Protocol and the Annexes hereto which shall constitute an integral part of the present Protocol.

2. Parties shall ensure that the development, handling, transport, use, transfer and release of any modified gene organisms or products thereof are undertaken in a manner that prevents or reduces to acceptable levels of risks to human and animal health, biological diversity, the environment and socio-economic welfare of societies.

3. Parties shall prohibit the export of modified gene organisms or products thereof unless they obtain an advance informed agreement in writing from the State of import for the specific import.

4. Parties shall prohibit the export of any modified gene organisms or products thereof to the Parties which have prohibited the import of such organisms or products. Parties exercising their right to prohibit the import of modified gene organisms or products thereof shall inform the Secretariat and the Biosafety Clearing-House of their decision.

5. No Party shall export or import modified gene organisms or products thereof to or from non-Parties.

6. Parties shall cooperate among themselves in order to achieve an environmentally sound system of management of the potential risks of modified gene organisms and products thereof.

7. Each Party shall take the appropriate measures to:

(a) Ensure safety in biotechnology, especially in the transboundary transfer and release of modified gene organisms resulting from modern biotechnology;

(b) Ensure that persons involved in the development, handling, transfer, use or release of modified gene organisms and products thereof take such steps as are necessary to avoid unacceptable risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies;

(c) Require that information about a proposed transboundary transfer of any modified gene organisms or products thereof be provided to the States concerned according to the appropriate procedures of notification set out in Article 7 of this Protocol;

(d) Prohibit the export of any modified gene organisms or products thereof to a State or group of States belonging to a regional economic integration organization that includes Parties which have prohibited imports by their legislation, or if it has reason to believe that the organisms or products in question will not be managed in an environmentally sound manner, according to criteria to be decided on by the Parties at their first meeting;

(e) Cooperate with other Parties and may involve interested organizations as appropriate, directly and through the Secretariat and the Biosafety Clearing-House, with respect to the necessary measures for Safety in biotechnology, including the dissemination of information on modified gene organisms or products thereof, in order to ensure the environmentally sound management of such organisms and products and to achieve the prevention of illegal traffic and unintended releases;

8. Furthermore, each Party shall:

(a) Prohibit all persons under its national jurisdiction from developing, transferring, using or releasing modified gene organisms or products thereof unless

such persons are authorized to perform such types of activities or deal with such types of products;

(b) Require that modified gene organisms or products thereof that are to be the subject of transfer or a transboundary transfer be packaged, labeled, and transported in conformity with the rules and requirements to be set out by the Secretariat and the competent authorities of the States concerned;

(c) Require that modified gene organisms and products thereof be accompanied by a transfer document from the point at which a transfer and transboundary transfer commences to the point of use or release.

9. The Parties agree that failure to provide all the necessary information available about the modified gene organisms or products thereof and any illegal traffic are criminal.

10. Each Party shall take appropriate legal, administrative and other measures to implement and enforce the provisions of this Protocol, including measures to prevent and punish conduct in contravention of the Protocol.

11. The obligation under this Protocol of States in which the modified gene organisms or products thereof have been developed and in which they have originated is to require that those organisms or products are managed in an environmentally sound manner and may not under any circumstances be transferred to the States of import.

12. Nothing in this Protocol shall prevent a Party or group of Parties from imposing additional requirements that are consistent with the objective and provisions of this Protocol and are in accordance with the rules of international law, in order to better protect human and animal health, biological diversity, the environment and the socio-economic welfare of societies.

USE OF TERMS

Modified Gene Organism (MGO)

Any organism in which the genetic material including both DNA and RNA has been altered in a way that does not occur naturally by mating and/or natural recombination.

(The term "Living Modified Organism" is not exact one what we mean because of the followings :

- *Any organism is living, so "living" is not necessary;*
- *"modified organism" is not specific enough and one can mix with several other meanings)*

Novel traits

Novel traits are characteristics in an organism that have been created or introduced through a specific genetic change using modern biotechnology or techniques specified in the definition of MGOs or by mating with initial MGOs and that make the MGO different from the unmodified organism.

Organism

An organism is the active, infective, or dormant stage or life form of any biological acellular, unicellular or multi-cellular entity capable of replication reproducing itself or of transferring genetic material. This definition covers plants, animals, fungi, mycoplasma, mycoplasma-like organisms, micro-organisms, viruses and viroids, including cell and tissue cultures, germinal cells, seeds, pollen and spores, other than human or human embryo.

Product

Product means anything made by or from, or derived from MGOs or a combination of MGOs, gene or dead , which is placed on the market.

CAPACITY-BUILDING

1. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and biosafety including where necessary, through the appropriate international and national institutions. They shall take due account of the needs of developing countries with respect to capacity-building in order to promote the development and transfer of safe biotechnology and knowledge.

2. The Secretariat, in collaboration with the Biosafety Clearing-house, shall develop and implement regional and global capacity building programmes based on the identified needs of the concerned Parties. The Secretariat and the Biosafety Clearing-house shall, in particular, assist developing countries in their efforts to identify and plan their capacity-building requirements and secure funds for the implementation of their capacity-building programmes.

3. The Parties agree that, according to the specific needs of different regions and subregions, regional or subregional activities/centers for training and capacity-

building regarding the safe management of modified gene organisms shall be established. with financial assistance provided through the financial mechanisms under the Convention on Biological Diversity (CBD).

4. The Parties shall promote technical and scientific cooperation capacity-building, including the promotion of cooperation in the training of personnel and the exchange of experts, informational exchange and institutional capacity building in order to strengthen the ability of importing States to perform risk assessments and to develop and implement decision-making and risk-management procedures.

5. Capacity-building programmes should maximize the use of existing multilateral, regional and bilateral mechanisms where possible, including those addressed under the Convention. Technical assistance from the private sector should also be facilitated and encouraged.

6. Such capacity-building shall aim to ensure:

(a) That Parties develop and strengthen their capacities to implement this Protocol;

(b) That national legislation, frameworks and guidelines related to biosafety are developed;

(c) That States involved in the transfer, handling and use of MGOs and or products thereof are aware of any associated risks and have the means to assess and manage the risks;

(d) That States are able to achieve safety through proper risk assessment and management when certain MGOs and or products thereof are transferred into and/or to be used in their territories and act adequately in cases of accidental release of MGOs;

(e) The development of procedures for risk assessment and risk management of MGOs.

7. Any Party to this Protocol or any of its signatories will be able to make scientific-technical cooperation requests to the Secretariat for the purpose of applying the Protocol or participating in it, in particular:

(a) Preparing or evaluating risk-assessment reports or impact statements;

(b) Developing or evaluating risk-management schemes and appropriate monitoring programmes, procedures and standards;

(c) Preparing emergency plans and other safety measures;

(d) Transmitting requests for assistance and relevant information in the event of accidents;

(e) Providing information that may be relevant to the settlement of disputes.

8. The developed country Parties shall establish effective measures for strengthening and/or development of human resources and institutional capacities in biotechnology and biosafety in developing country Parties, encompassing technical, financial and institutional provisions.

9. The developed country Parties shall establish such measures to enhance the capacity of developing country Parties to acquire and/or develop relevant biotechnology, and its proper and safe management, and the building up of their local, technological and institutional competence, thereby contributing to the distribution of benefits from the potentials of biotechnology. through training in science related to safety in biotechnology and in the use of risk assessment and risk management techniques and the transfer of relevant knowledge, in biotechnology and biosafety on fair and most favourable terms including on concessional and preferential terms.

SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties shall ensure that the socio-economic impacts specific and unique to the use of modified gene organisms that may manifest adverse consequences are appropriately considered during the assessment and management of risks taking into account the fact that socio-economic considerations will vary considerable from Party to Party.

2. Parties shall encourage research on socio-economic considerations relating to the use, handling and transfer of modified gene organisms and the exchange of the results of such research.

LIABILITY AND COMPENSATION

The exporter shall be liable for and shall fully compensate any damage deriving from the transboundary movement of MGOs, in accordance with the provisions of the present Protocol.