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VIEWS OF THE GOVERNMENT OF MALAYSIA ON THE CONTENTS OF THE FUTURE PROTOCOL

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CONTENTS OF THE FUTURE PROTOCOL ON BIOSAFETY

THE GOVERNMENT OF MALAYSIA

CONTENTS OF THE FUTURE PROTOCOL ON BIOSAFETY - THE GOVERNMENT OF MALAYSIA

Pursuant to the decision of the Open-Ended Ad Hoc Working Group on Biosafety, for Governments to submit their views to the Secretariat on the contents of the future protocol on biosafety, Malaysia hereby submits her views.

Title

Protocol on Biosafety

Preamble

The Preamble should contain the following elements:

a) The reference to Article 19(3) of the Convention on Biological Diversity.

b) The precautionary principle as stipulated under Principle 15 of the Rio Declaration and the Convention on Biological Diversity (CBD), as follows : Where there are threats of serious or irreversible damage/significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.

c) The principle of Advance Informed Agreement (AIA) as stipulated under Art. 19(3) of the CBD. AIA means the advance agreement, with such conditions as appropriate, by the affected country through the competent authority, of any transfer, handling and use of living modified organisms (LMOs), based on relevant information supplied by the exporting country and/or person undertaking the relevant activities as requested by the affected country.

d) Reference to Art 8(g) which speaks about the establishment or maintenance of the means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity , taking also into account the risks to human health.

e) Recalling the following elements of the Preamble of the CBD :

* that special provision is required to meet the needs of developing countries, including the provision of new and additional financial resources and appropriate access to relevant technologies.

* reaffirmation that States have sovereign rights over their own biological resources.

* awareness of the general lack of information and knowledge regarding safety in biotechnology and of the urgent need to develop scientific, technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures.

Objective

The objective of this protocol is to ensure the safe transfer, handling and use of living modified organisms (LMOs), specifically focusing on transboundary movement, which shall include all activities relating to transboundary movement, of any LMO resulting from modern biotechnology that may have adverse effects on the environment, in particular, the conservation and sustainable use of biological diversity, taking into account the risks to agriculture, human health and socio-economic welfare.

Use of Terms

"advance informed agreement"	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.
"biosafety"	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.
"centres of genetic diversity"	the place or region where the source of diversity is located.
"centres of origin"	the country which possesses those genetic resources in in-situ conditions.
"competent authority"	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.
"contained use"	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.

"deliberate release"	any use of organisms that is not a contained use.
"living modified organisms"	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. Organisms is further defined as acellular, unicellular or multicellular entity in any form (other than human or human embryo).
"modern biotechnology"	a set of non-conventional enabling techniques for bringing about specific man-made changes in the genetic material of organisms.
"risk"	the combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences will occur.
"risk assessment"	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 impacts, including in particular to human health, agriculture and welfare.
"risk management"	the measures to ensure that the transfer, handling and use of an LMO is safe, including measures to mitigate any damage likely to occur.
"transboundary movement"	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 modificaton, and products derived therefrom, within the national boundaries of a State, by persons (legal or natural). Transboundary movement also entails the behaviour of the LMOs, in particular in the receiving country, ie. in R&D, in handling, transfer, use and disposal of the LMOs.
"transfer"	includes the intentional transboundary movement of LMOs and the unintended movement of LMOs across national boundaries.
"unintended release"	any release which is not deliberate.

Identification/classification of LMOs : Separate categories/classifications of LMOs can in principle be defined based on the potential risk factors of the LMOs, and taking into account the needs of individual countries. The protocol should additionally apply to LMOs which have already been deregulated in any country.

Designation of a National Competent Authority

The establishment of the National Competent Authority :

Each party to the protocol shall establish and designate a National Competent Authority (NCA). It shall be the **authoritative** body regarding any intended transfer/movement/release/activity of an LMO which affects its country. It should be a mandatory requirement for parties who intend to transfer/move/release/undertake any activity regarding LMOs to approach this NCA and seek its permission regarding thereto. This Article should clearly define the responsibilities of the

National Competent Authority. In formulating such responsibilities, regard must be given to:

a) recognition of its supreme decision-making power;

b) preservation of its independence;

c) preservation of its flexibility to take into consideration any matter of national interest it deems fit in making its decisions;

d) the condition that all intended transfers/movement/release/activity shall also be subject to the national laws of the affected country.

The responsibilities of the National Competent Authority shall include the following:

* to serve as the focal point for handling enquiries and proposals regarding any intended transfer/ transboundary movement/release which affects its country or any activity undertaken within its national boundaries, of LMOs.
* to receive all relevant information, including the risk assessment report of the relevant party, regarding the intended transfer/release/movement/activity, supplied by the exporting country /person prior to such transfer/ release/movement/activity.
* to establish and impose such conditions it deems fit regarding the transfer etc. in order to protect its environment and human health.
* to be given prior notice regarding any proposed/intended transfer etc. which may affect its country or which will be transferred etc. into its country.
* to give make decisions on the transfer etc. of the LMO.
* to undertake its own risk assessment and give its own risk management decisions.
* to establish and impose such procedures it deems fit .
* to state whether particular measures will be needed to protect its interests, in particular its biodiversity.
* to be informed immediately in the event of an adverse effect of the transfer etc. of the LMOs which could affect it.

Composition of NCA :

Consideration must be given to the composition of the NCA which must be commensurate with the functions of the NCA as stipulated above. Experts from the relevant fields pertaining to biosafety should be in the NCA.

Exchange of Information

There should be an obligation for the international exchange of information. Cooperation with existing international agencies, organizations, mechanisms and regional networks for the dissemination of biosafety-related information could be implemented through a national focal point. Exchange of information could include information regarding national biosafety mechanisms, approvals already given regarding any transfer etc. of LMOs, subject to national legislation. The national focal point could also facilitate the exchange of mutually acceptable data and assessments.

GENERAL OBLIGATIONS

Procedures for Information, Notification and Advance Informed Agreeement

Express procedures must be established with respect to notification, provision of information and advanced informed agreement. These procedures will represent the cumulative set of procedures applicable **before/up to** the moment the affected state gives its consent on the release/transfer/movement/activity.

Notification :

This 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 etc. represents a threat to the affected country. This notification must be supplemented with relevant information as defined below. The potentially affected country must also be given notice of the intended use of the LMO and where applicable, the possible LMOs produced as a result of any activity undertaken within the affected country. The affected country must be given the right to state whether the intended/proposed transfer etc. is agreed or whether any other information is required from the transferor etc.

Information :

The principle of advance informed agreement entails the provision of comprehensive, relevant, adequate and timely information that will enable the receiving/affected country to reach an informed decision on the proposed/intended transfer etc. and to enable the affected country to undertake its own risk assessment and risk management decisions. The information should be supplied in advance of the transfer etc. so as to be consistent with the principle of advance informed agreement. Such information could include the following :

* name and address of agency/body/person intending/proposing to transfer etc.;
* name and address of intended user;
* origin, name and taxonomic status of recepient organisms;
* description of traits introduced or modified and characteristics of the organism;
* summary of the assessment of risks to human health and the environment of the affected country and the risk management measures applicable in respect of the affected country;
* a copy of the risk assessment and risk management report undertaken by the country/person in respect of the affected country;
* intended dates of transfer/movement/release/activity;
* number of organisms to be transferred or volume of culture and physical form;
* any relevant requirements to ensure safe handling, storage, subsequent transport and use;
* methods for safe disposal and suitable procedures in case of accidents;
* intended purpose of the transfer, etc., and intended use of the organism, including possible products derived therefrom;

* intended location of the release or activity;
* information on previous releases and the impacts on the environment and human health on such releases;
* information on experimentation, field trials, situation at the home of origin of the LMOs;
* information on the relevant biosafety standard of the country/person intending/proposing to transfer etc.;
* information on the use of the LMO that has been prohibited in another country;
* the applicable laws, procedures and guidelines of the country intending the transfer etc. of the LMO;
* any other information deemed relevant by the affected country.

Advance Informed Agreement :

Any intended/proposed transfer/release/movement/activity by a country/agency/person to the affected country must first require the agreement of the affected country. Such agreement must be based on the information stated above and can be given with conditions attached. AIA must be effected through the national competent authority. The autonomy of the affected country must at all times be preserved. AIA also means that the consent given by the affected country must be express.

Mechanisms for Risk Assessment

The persons/bodies to which this obligation applies eg. the country/person intending/proposing to transfer etc. the LMOs to another/within the affected country should be defined. The **timing** for the submission of the report eg. prior to the proposed transfer etc. and **who** the report should be submitted to, ie. the National Competent Authority should also be expressly stated..

The objective of a risk assessment is to enable evaluation of possible harm or likelihood of it occurring to the affected country and its environment, taking into account socio-economic impacts, including in particular, to its human health, agriculture and welfare, during the transfer,

handling and use of the LMO. It should cover expected probabilities of events occurring and the magnitude of their effects. Risk assessment should not only be based on scientific data but should also take into account the characteristics of the organism concerned and its potential to have adverse effects on the receiving environment of the affected state and on the conservation and sustainable use of its biological diversity, and its socio-economic impacts, in particular to human health, agriculture and welfare. Evaluation of risk should be conducted, where applicable, at each step of development from the research laboratory to small-scale and large-scale release for production and testing, including commercial use. A multi-disciplinary approach is necessary.

The risk assessment should be based upon the following key parameters :

a) Focus on the organisms;
b) Application or intended use of the LMO;
c) The receiving environment.

The key parameters of the risk assessment should be specified in sufficient detail in the protocol and may be reflected in an Annex which shall be an integral part of the protocol.

Risk assessment shall be based on knowledge about the organism, the genetic modification, knowledge about ecological interactions, and particularly on the receiving environment and its possible socio-economic impacts. Risk assessment shall be applied for safety in biotechnology including a step-wise and case-by-case approach. Special considerations should be applied to risk assessment in connection with biotechnology in centres of origin and genetic diversity.

The affected country may lack the technical capacity to evaluate the quality of the data provided, analyse them, and draw scientifically valid conclusions. In this respect, measures to assist these countries financially and technically must be incorporated in the protocol. At the same time, the affected country must be allowed to take its own risk assessment decisions on the matter.

Mechanisms for Risk Management

Risk management strategies and measures must be formulated and incorporated in the risk assessment report. The type of risk management to be considered will depend on the LMOs and the activity in question. Management strategies/measures should be commensurate with the results of the risk assessment.

Risk management should be implemented during handling, transfer and use of LMOs. Although the obligation to implement the risk management measures appears largely to be on the affected country, there are also activities where the affected country may not be the only party responsible for undertaking risk management measures (eg. research undertaken by multinationals within the affected country. Here, risk management measures must be implemented by the multinational in question).

Emergency Measures

Emergency measures and procedures related to accidental releases and movements of LMOs should be established. An integral part of these procedures is the requirement to provide information expeditiously to the relevant affected countries regarding, inter alia, the LMO that has been released and the emergency measures that need to be taken in regard therewith. At national level, emergency contingency plans should be developed to rectify and/or mitigate the effects of the accident.

Handling, Transport and Transit Requirements for LMOs

One of the elements of transfer and handling of LMOs is the physical transboundary movement of that LMO, and products derived therefrom, from one country to another. In such cases, transportation and transit aspects are crucial and accordingly should be given adequate consideration in the protocol so that safety is ensured and risks minimized. The relevant affected countries should require that countries or parties involved in the handling and transfer conform with generally accepted and recognized international rules and standards in the field of packaging

and transport and that due account is taken of relevant internationally recognized practices.

Capacity-building

Express measures for strengthening and/or development of human resources and institutional capacities in biotechnology and biosafety should be established. This includes the transfer of relevant know-how from developed countries to developing countries, development of the necessary legal framework to facilitate such transfer, the development of appropriate facilities, training in science related to safety in biotechnology and in the use of risk assessment and risk management techniques. Capacity-building encompasses technical, financial and institutional capacity-building dimensions. The capacity of developing countries to acquire and/or develop relevant biotechnology, and its proper management, and the building up of their local, technological and institutional competence, thereby contributing to the distribution of benefits from the potentials of biotechnology, requires the technical and financial assistance and support of the developed countries .

Centres of Origin and Genetic Diversity

An abundance of biological diversity resides in the centres or origin and genetic diversity and are normally found in developing countries. In view of the great uncertainty and very little experience of the behaviour of LMOs in the centres of origin and genetic diversity, there should be a separate section to address release of LMOs resulting from modern biotechnology in centres of origin and genetic diversity. Particular risk assessment and risk management measures to address this aspect should be incorporated.

Socio-economic Considerations

Risk assessment on the effects to the receiving environment, including human health, welfare and agriculture must give due consideration to potential socio-economic impacts. The introduction of LMOs in this environment may entail a displacement of a particular agricultural and resource use system and even the culture and livelihood of the local people.

Ethical Considerations

If and when appropriate, consideration should be given to ethical aspects and sensitivities of the culture and religion prevailing in countries.

Participation in Biotechnology Research Activities

Measures should be undertaken to provide for developing countries that provide genetic resources, to participate in biotechnology reasearch undertaken in respect of the genetic resources and for the promotion and advance priority access to the results and equitable sharing of benefits arising from biotechnologies based upon genetic resources provided by those countries.

Liability and Compensation

Responsibility of a State for its actions in the handling, transfer and use of an LMO which results in damage/harm to the affected country must be addressed in the protocol. Where damage/harm to the affected country occurs as a result of a breach by a State of its obligations under the protocol on the basis of its unlawful conduct under the protocol, compensation should be made available to the affected country. The protocol should incorporate the appropriate rules and procedures for liability and compensation in this regard.

Monitoring and Compliance

Appropriate mechanisms for monitoring and compliance must be established. In order to have an effective monitoring mechanism, co-operation and on-going consultation between the person/country/body intending the transfer etc. and the receiving/affected must be established. Particular emphasis on monitoring of risks on specific transfers, movements, releases, activities must also be built into this mechanism. With regard to monitoring of risks in specific transfers, where the affected country so desires, it can request the financial and technical assistance of the country intending to transfer etc. the LMO The person/body intending the transfer etc. should

supply and disseminate relevant information as and when required by the affected country **after** the transfer etc have been effected. The affected country should be informed immediately in the event of any risks that have not been known before regarding the transfer etc. of the LMO. Separate monitoring and compliance procedures for unauthorized movement of LMOs could be considered. Monitoring can be carried by the affected country and is often used to verify assumptions made in a risk assessment and should be used to evaluate whether the risk - management measures used are appropriate and effective.

Technical Information Network

This section entails the establishment of an international clearing house mechanism for biotechnology and biosafety. A regional clearing-house mechanism should also be established. There is a need to address the relationship of this section with the general requirement for international supply and exchange of information through the national focal points. Here, countries are encouraged to co-operate with existing international agencies, organizations, mechanisms and regional networks for the dissemination of biosafety-related information and standards applicable in other countries. General information include those about national biosafety mechanisms, and approvals given for the transfer/release of LMOs in other countries and for the marketing of products containing LMOs.

Public Awareness and Participation

This section stresses the need for openness of the processes under the protocol. Subject to relevant national legislation, countries, including the industry and researchers, have a responsibility to disclose or make available safety information to the public. Acceptance of biotechnology products will be enhanced if the information is disclosed and made available to the public, especially the community where the transfer/release/movement/activity will occur.

Financial Mechanism

The protocol must establish a financial mechanism for the purposes of providing financial

resources to implement the provisions of the protocol by the developing countries, and in particular to implement capacity-building measures for the benefit of developing countries and for meeting contingencies.

Other Clauses

The following clauses should be included in the protocol but should only be discussed at a later stage when the provisions of the protocol are more firmed up:

Settlement of Disputes

Relationship With Other International Agreements

Amendment

Signature

Accession

Right to Vote

Entry into Force

Reservations and Declarations

Withdrawal

Depository

Authentic Texts

Annexes

7.4.1997