UNEP

CBD

CONVENTION ON
BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/BSWG/6/Inf. 2

ORIGINAL: ENGLISH

OPEN-ENDED AD HOC WORKING
GROUP ON BIOSAFETY
Sixth meeting
Cartagena, Colombia, 14-19 February 1999

GOVERNMENT SUBMISSION ON THE PREAMBLE AND ANNEXES RECEIVED PRIOR TO BSWG5

PREAMBLE

ECUADOR

We accept option 2, adding "and products thereof" when reference is made to LMOs.

EUROPEAN COMMUNITY

The EC and its Member States propose the inclusion of the following recital:

Recognizing the need to take into account the precautionary principle in the context of the Protocol;”

MEXICO

Add in option 2, second paragraph, the following text in brackets:

Recalling Article 19, paragraphs 3 and 4 [, Article 15, paragraph 7] and Articles 8(g) [, 14, 16] and 17 of the Convention, and recognizing the linkages between them,

Add in option 2, after paragraph 6:

Reaffirming Principles 12, 13, 15 and 26 of the Rio Declaration on Environment and Development,

Add in option 2, after paragraph 8:

Aware that the constant development of biotechnology will enable LMOs to be improved in response to the concern of the general public with respect to their possible adverse effects.

NEW ZEALAND

We favour a modified option 1, including some elements of option 2, as follows.

Modified Option 1

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as “the Convention”,

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Recalling also decision II/5 of the Conference of the Parties to the Convention to develop a Protocol onbiosafety, specificallyfocussing on transboundary movement of any living modified organism (LMO) resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement (AIA),

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the social and economic values ofbiodiversity and the importance of safeguardingbiodiversity through management of the introduction and release ofLMOs,

Noting that where there is a risk of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid orminimize such a risk,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated withLMOs,

Have agreed as follows:

PANAMA

We are of the opinion that, in the Preamble, paragraph 2 on page 4 of the English version of the Protocol document contains a contradiction, and we recommend that it be removed.

Also, paragraph 5 on page 4, is similar to paragraph 7 propose that paragraph 5 be removed.

PERU

Option 1

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8(g) and 17 of the Convention,

Recalling also decision II/5 of the Conference of the Parties to the Convention to develop a protocol onbiosafety, specifically focusing on transboundary movement of any living modified organism (LMO) resulting from modern biotechnology that may have adverse effect on the conservation on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms (LMOs),

Have agreed as follows:

Option 2

2. [The objective of this Protocol is to ensure that transboundary movements of LMOs take place in conditions that are safe for the conservation and sustainable use of biological diversity and human health; to mitigate the harmful effects of unintentional transboundary movement; as well as to strengthen the capacities of developing countries and countries with economies in transition, inter alia, through adequate financing; to control transboundary movement; and for the environmentally sound management of the organisms subject to this Protocol.]

THAILAND

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as “the Convention”,

Recalling Article 19, paragraphs 3 and 4, and Articles 8(g) and 17 of the Convention, and recognizing the linkages between them,

Recalling also decision II/5 of the Conference of the Parties to the Convention to develop a protocol onbiosafety, specifically focusing on transboundary movement of any living modified organism (LMO) resulting from modern biotechnology that may have adverse effect on the conservation and

sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement,

Reaffirming decision III/20 of the Conference of the Parties to the Convention and, in particular its support for a two-track approach through which the promotion of the application of the UNEP International Technical Guidelines for Safety in Biotechnology can contribute to and complement the implementation of this Protocol,

Noting the potential contribution of the United Nations Recommendations on the Transport of Dangerous Goods to the implementation of the Protocol,

Recalling the support of the international community for Agenda 21 adopted by the 1992 United Nations Conference on Environment and Development and, in particular Chapter 16, which provides for the "Environmentally Sound Management of Biotechnology", and which further seeks to ensure safety in biotechnology development, application, exchange and transfer through international agreement,

Recognizing that, while properly addressing the risks from living modified organisms (LMOs) resulting from modern biotechnology the Protocol should avoid causing unnecessary delays, including through the creation of unwarranted administrative requirements for the transboundary transfer of LMOs for contained use,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on human or animal health, biological diversity, the environment, and social and economic welfare,

Aware also of the benefit that biotechnology can bring for health agriculture and the environment and mindful that unnecessary negative impacts on biotechnology research and development and on access to and transfer of technology should be avoided.

Concerned that significant gaps in scientific knowledge remain, specifically with regard to the interaction between the environment and living modified organisms (LMOs) resulting from modern biotechnology,

Noting that, in accordance with the precautionary principle, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize risk where such a risk is posed by living modified organisms (LMOs) resulting from biotechnology,

Recognizing also that, although considerable knowledge has accumulated, significant gaps in knowledge have been identified, specifically in the field of interaction between living modified organisms (LMOs) resulting from modern biotechnology and the environment, taking into account the relatively short period of experience with releases of such organisms, the relatively small

number of species and traits used, and the lack of experience in the range of environments, specifically those in centres of origin and genetic diversity,

Determined to avoid and minimize the risks associated with the transfer, handling and use of living modified organisms (LMOs) through appropriate risk assessment and management techniques,

Recognizing the need to establish a minimum condition of safety and a procedure for the assessment and management of the potential risks arising from the development, use, release and transfer of living modified organisms (LMOs) and products thereof,

Recognizing that the socio-economic impacts of the introduction of LMOs and products thereof should be considered in risk assessment and management, taking particularly into account the needs and concerns of developing countries,

Affirming the need to provide adequate compensation for in the event of any damage caused by or arising from the handling, transfer and use of living modified organisms (LMOs),

Conscious of the need to promote and encourage public awareness of the safe use, handling and transfer of living modified organisms (LMOs) through the development and implementation of educational and public awareness programmes, and through public participation in risk assessment and management procedures,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms (LMOs),

Acknowledging the need for appropriate policies and measures to develop and strengthen human resources and institutional capacities in the safe handling, transfer and use of living modified organisms (LMOs), taking due account of the needs of developing countries,

Noting that the provisions of the Protocol should contribute to the field of biosafety, based on scientific risk assessment.

Have agreed as follows:

Annexes

I. INFORMATION REQUIRED IN NOTIFICATIONS FOR ADVANCE INFORMED AGREEMENT

NEW ZEALAND

We favour the following modification:

(a) Name and address of applicant

(b) Name and address of receiving company/institution/individual

(c) Common name and taxonomic status of the organism

(d) Centre of origin/genetic diversity relevant to the organism that has been modified

(e) Description of nucleic acid fragment(s)/trait introduced or modified and resulting characteristics of the LMO

(f) Intended use of the LMO

(g) Quantity of LMOs to be transferred or volume and physical state of culture

(h) A risk assessment report in accordance with the risk assessment guidelines outlined in Annex II of the Protocol

(i) Suggested methods to ensure safe handling, storage, transport and use, including packaging, documentation, disposal and contingency methods where appropriate

(j) Intended date of first movement

(k) Declaration that the information is factually correct

NORWAY

Add in Annex I on Information required for AIA as a new element m) «the status of the LMO in question within the exporting state and if known, also in the importing state (whether it is prohibited in the state of export/import or whether there are other restrictions)

PERU

(a) Designation [and classification of biosafety levels] of LMO(s)[or products thereof].

(b) Name and address of the exporter.

(c) Name and address of the importer.

(d) Common name, taxonomic status, [source and characteristics] of recipient organism [and donor organism].

(e) Centre of origin/genetic diversity [if known] relevant to the organism that has been modified.

(f) Description of DNA/RNA fragment(s)/traits introduced or modified and resulting characteristics of the LMO [or products thereof].

(g) Intended use of the LMO [or products thereof][if known].

(h) Quantity of LMOs [or products thereof] to be transferred or volume and physical state of culture.

(i) A [known and available] risk assessmentreport [carried out on the LMO [or products thereof] in question] in accordance with the risk assessment parameters as stated in Annex II of the Protocol.

(j) Suggested methods to ensure safe handling, storage, transport and use, including packaging, [labelling,] documentation, disposal and contingency procedures.

(k) Intended date[s] of [first] [transfer] [movement].

(l) Declaration that the information is [factually] correct.

SLOVENIA

(a) Designation and classification of Biosafety level ofLMOs and products thereof.

(b) and (c) no comments

(d) Common name, taxonomic status, source and characteristics of recipient organism and donor organism.

(e) no comment

(f) Description of DNA/RNA fragment(s) /traits introduced or modified and resulting characteristics of theLMOs and products thereof.

(g) Intended use of the LMOs and products thereof.

(h) Quantity of LMOs and products thereof.

(I) A known and available risk assessment report carried out on the LMOs and products thereof in accordance with the risk assessment parameters as stated in Annex II of the Protocol.

(j) Suggested methods to ensure safe handling, storage, transport and use, including packaging and labelling, documentation, disposal and contingency procedures.

(k) Intended date of first transfer movement.

(l) Declaration that the information is correct.

THAILAND

(a) Designation [and classification ofbiosafety levels] of LMO(s)[or products thereof].

(b) Name and address of the exporter.

(c) Name and address of the importer.

(d) Common name, taxonomic status, [source and characteristics] of recipient organism [and donor organism].

(e) Centre of origin/genetic diversity relevant to the organism that has been modified.

(f) Description of DNA/RNA fragment(s)/traits introduced or modified and resulting characteristics of the LMO [or products thereof].

(g) Intended use of the LMO [or products thereof].

(h) Quantity of LMOs [or products thereof]to be transferred or volume and physical state of culture.

(i) A [known and available] risk assessment report [carried out on the LMO [or products thereof] in question] in accordance with the risk assessment parameters as stated in Annex II of the Protocol.

(j) Suggested methods to ensure safe handling, storage, transport and use, including packaging, [labelling,] documentation, disposal and contingency procedures.

(k) Intended date[s] of [first] [movement].

(l) Declaration that the information is [factually] correct.

II. RISK ASSESSMENT

AUSTRALIA

Australia wishes to see the following alternative option included:

1. The objectives of risk assessment in relation to the transboundary movement of living modified organisms under the Protocol are:

(a) identification of any hazardous characteristics associated with the novel trait(s) introduced into the LMO that may have adverse effects on the conservation and sustainable use of biological diversity;

(b) an evaluation of the likelihood of these hazards being realized, taking into account the level and kind of exposure of the receiving environment to the LMO;

(c) an evaluation of the consequences for biological diversity should these hazards be realized;

(d) an evaluation of the overall risk posed by the LMO based on the assessed likelihood and consequences for biological diversity of the identified hazards; and

(e) an evaluation of whether or not the risks are acceptable or manageable, including identification of strategies to manage these risks and minimise the possibility of adverse consequences.

2. Risk assessment should be carried out in a scientifically sound and transparent manner, taking into account relevant scientific evidence, expert technical and technological advice, experience and techniques developed by relevant international organizations.

3. Risk assessment shall, inter alia, take into account:

(a) characteristics of the recipient organism;

(b) characteristics of the donor organism;

(c) characteristics of the vector;

(d) characteristics of the living modified organism;

(e) information concerning the intended use of the LMO;

(f) characteristics of the potential receiving environment related to biological diversity.

NEW ZEALAND

Modified Option 1

1. The objective of risk assessment is to consider, as appropriate the following points:

(a) Identification of any characteristics of the LMO linked to genetic modification that may have adverse effects in the receiving environment

(b) Estimation of the risk of each adverse effect by determining the likelihood and extent of the consequences of the adverse effect being realised.

(c) Application of management strategies, when appropriate, for risks from the release of the LMO. The management strategies should be commensurate with the results of the risk assessment.

2. Any new risks associated with the LMO or its use should be considered in the context of the risks posed by other organisms not subject to this risk assessment or risks that my be posed if the LMO is not deliberately released.

3. Full regard should be paid to the experience gained and to the relevant literature and consultation with available experts and public authorities.

4. The information required for a scientifically sound risk assessment will vary case by case, but should include, as appropriate:

(a) Characteristics of the LMO itself (including the organisms from which the novel trait is derived, the donor, the vector, and the inserted nucleic acid)

(b) Intended use (in containment or for deliberate release)

(c) Characteristics of the receiving environment

NORWAY

Contained use of LMO

The containment of LMOs must be based on the principle that a precautionary approach as regards safety to human health and the environment shall be followed in order to ensure that the expected benefits can develop safely.

When facilities are to be used for the first time for activities involving the contained use ofLMOs, the users shall be required to submit to the competent authority an application for approval. The facility shall be suitable and equipped for the intended purpose, and shall be classified according to the risk, the type ofacitivity and the LMOs to be used.

The LMOs intended for contained use and the type ofacitiviy planned, shall be reigstered or approved by the competent authority according to the risk involved. The use shall carry out a prior risk assessment of the contained use as regards risks to human health and the environment.

All activities with LMOs that take place within the approved facility shall be registered by the responsible person (s) in a protocol. The protocol shall be available for the competent authorities when required.

Information required for approval of contained use ofLMOs:

(a) name of company or institution, location and address of the facility

(b) responsible person (s)

(c) the date of when the facility received the approval for contained use

(d) information to, and training of, employees and other personnel handling the LMOs

(e) summary of the risk assessment

(f) the intended use and application of the LMO

(g) planned containment measures (physical and biological)

(h) plans for preventing accidents and unexpected events

(i) contingency plans if accidental release

(j) plans for waste treatment

(k) possible interactions between theLMOs and the environment associated with an unintended release into the environment

PERU

Option 1

RISK ASSESSMENT FACTORS

1. The objective of risk assessment is to consider, as appropriate, the following points:

(a) Identification of any [hazardous] characteristics of the LMO [or products thereof] linked to the genetic modification [that may have adverse effects on the conservation and sustainable use of biological diversity [or] [taking also into account risks to] human health];

(b) The extent of the consequences of the [hazard][adverse effect] resulting from the genetic modification being realized;

(c) The likelihood of the [hazard][adverse effect] being realized;

(d) Estimation of the risk posed by each identified [hazard][adverse effect];

(e) Application of management strategies, when appropriate, for risks from the release of the LMO [or products thereof]. The management strategies should be commensurate with the results of the risk assessment;

(f) Determination of the overall risk of adverse effects.

2. Any new risks associated with the LMO [or products thereof] or its use should be considered in the context of the risks posed by using other organisms not subject to this risk assessment or risks that may be posed if the LMO [or products thereof] is not released.

3. Full regard should be paid to the experience gained and to the relevant literature and consultation with available experts and public authorities.

4. [The level of risk can be minimized either by applying risk management strategies or by deciding not to proceed with the intended use of the LMO [or products thereof].]

5. The information required for a scientifically sound risk assessment could include the following, depending on the LMO [or products thereof], the application, the receiving environment and the interaction between the environment and the LMO [or products thereof], as appropriate. The application of this list may vary from LMO [or products thereof] to LMO [or products thereof]. Risk assessment may require more specific information about individual topics, which may be obtained during the assessment process, while other topics may not be relevant in some instances. Discussion of the scientific rationale for including particular data in particular instances is often appropriate in deciding how to conduct the assessment.

INFORMATION RELATING TO THE LMO [OR PRODUCTS THEREOF]

A. Characteristics of the recipient organism

6. The relevant biological, physiological and genetic and environmental characteristics of the recipient/parental/host organism include, as appropriate:

(a) The name and identity of the organism;

(b) Pathogenicity and toxicity;

(c) The natural habitat and the geographic origin of the organism, its distribution and its role in that habitat;

(d) Mechanisms by which the organism survives, multiplies and disseminates in the environment;

(e) Means for transfer of genetic material to other organisms.

B. Characteristics of the organisms from which the DNA/RNA fragments [nucleic acid] are obtained (the donor)

7. The relevant characteristics include, in particular, pathogenicity and toxicity.

C. Characteristics of the vector

(a) Identity, origin, natural habitat, integrative properties and the relevant safety characteristics of the vector.

(b) The frequency at which the vector can be mobilized or can transfer itself to other organisms.

(c) Factors which would influence the ability of the vector to become established in other hosts.

D. Characteristic of the inserted DNA/RNA fragments [nucleic acid] (the insert)

(a) Functions as specified by the insert, including any residual vector.

(b) Information on the expression of the insert and the activity of the gene products.

E. Characteristics of the LMO [or products thereof]

8. The LMO [or products thereof] should be compared with the organism from which it is derived, examining, where relevant, the following points:

(a) Pathogenicity and toxicity to other organisms;

(b) Survival, persistence, competitive abilities and dissemination in the environment or other relevant interactions;

(c) Capacity to transfer genetic material and the way in which this might occur;

(d) Functions which might affect its ecological range;

(e) Characterization of the products of the inserted genes and, where appropriate, the stability of the modification.

INFORMATION RELATING TO THE INTENDED USE

9. The amount of information required will vary with the characteristics of the LMO [or products thereof] and use, frequency and the scale of the intended use. Also consider possible new or changed use or practice, compared to traditional use or practice with similar non-modified organisms (for example, new or changed farming, forestry and aquaculture practice, etc. as a consequence of the living modified organism).

[10. For contained uses, this can include:

(a) Number or volume of LMO [or products thereof] to be used;

(b) Scale of the operation;

(c) Proposed containment measures, including the verification of their functioning;

(d) Training and supervision of personnel carrying out the work;

(e) Plans for waste management;

(f) Plans for safety of the health of personnel;

(g) Plans for handling accidents and unexpected events;

(h) Relevant information from previous uses.]

11. For deliberate releases, this can include:

(a) Purpose and scale of the release;

(b) Geographical description and location of the release;

(c) When relevant, proximity to residences and human activities;

(d) Method and frequency of release;

(e) As appropriate, training and supervision of personnel carrying out the work;

(f) Likelihood of unintended transboundary movement;

(g) Time and duration of the release;

(h) Expected environmental conditions during the release;

(i) As appropriate, proposed risk-management measures, including verification of their functioning;

(j) As appropriate, subsequent treatment of the site and plans for waste management;

(k) Plans for handling accidents and unexpected events;

(l) Relevant information from any previous releases.

CHARACTERISTICS OF THE POTENTIAL RECEIVING ENVIRONMENT

12. The potential for an organism to cause harm is related to the environment into which it may be released and its interaction with other organisms. Relevant information can include:

(a) The geographical location of the site, the identity and any special features of the receiving environments that expose them to damage;

(b) Where relevant, the proximity of the site to humans and to significant biota;

(c) Any flora, fauna and ecosystems that could be affected by the release, including keystone, rare, endangered or endemic species, potential competitive species and non-target organisms;

(d) The potential of any organism in the potential receiving environment to receive genes from the released LMO [or products thereof].

13. Note should be taken of any likely changes to interaction between the LMO [or products thereof] and non-target organisms, or between any target organisms of the LMO [or products thereof] and other organisms in the ecosystems.

SLOVENIA

Option 1

THAILAND

RISK-ASSESSMENT PARAMETERS

1. Prior to the use and release of living modified organisms an assessment as regards the risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies shall be performed. This assessment shall take the following parameters into consideration, including any other parameter deemed to be relevant.

A. General principles

2. The guiding principle of risk assessment is the precautionary approach. Where the transboundary movement, or use or handling of LMOs [or products thereof] may cause, or has the potential to cause harm to biodiversity, human or animal health, the lack of full scientific certainty or consensus regarding the level of risk should not be interpreted as the lack of risk, or as acceptable risk.

3. The risk assessment should, inter alia, take into account all relevant scientific evidence and experience, including previous risk assessments. This enables the risk assessment to evolve in the light of new evidence and knowledge; an LMO [or products thereof] previously considered acceptable may no longer be acceptable, and vice versa.

4. The risk assessment should, inter alia, take into account:

(a) All relevant scientific evidence and experience;

(b) The general characteristics of both the living modified organism and the parent organism(s), the vector(s) used, the genetic modification(s) and the novel trait(s), including marker trait(s) and other sequences even when not expressed;

(c) The native environments or host range of the recipient organism and donor organism(s);

(d) The intended use(s) of the living modified organism and the nature of the receiving and surrounding environments;

(e) Potential impact of the LMO [or products thereof] on the environment(s), including long-term ecological impacts, particularly on centers of origin and areas with high genetic diversity oftaxa related to the living modified organism;

(f) Effects of the LMO [or products thereof] on human health and animals;

(g) Socio-economic impacts;

(h) Conformity with ethical norms of receiving party/State;

(i) Details of risk assessments completed elsewhere.

5. The information required for risk assessment should include the following:

B. Specific information requirements

6. Characteristics of donor and recipient organisms or parental organisms:

(a) Scientific name and taxonomy;

(b) Strain, cultivar or other name;

(c) Species it is related to and degree of relatedness;

(d) The degree of relatedness between the donor and recipient organisms, or between the parental organisms;

(e) All sites from where the donor and recipient organisms or parental organisms were collected, if known;

(f) Information on the type of reproduction (sexual/asexual) and the length of reproductive cycle or generation time, as appropriate, as well as the formation of resting and survival stages;

(g) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;

(h) Phenotypic and genetic markers of interest;

(i) Description of identification and detection techniques for the organisms, and the sensitivities of these techniques;

(j) Geographic distribution and natural habitats of the organisms including information on natural predators, prey, parasites, competitors, symbionts and hosts;

(k) Climatic characteristics of original habitats;

(l) Ability of the organisms to survive and colonize the environment to which release is intended or otherwise;

(m) Genetic stability of the organisms, and factors affecting the stability;

(n) The presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability;

(o) The potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;

(p) Pathogenicity to humans or animals, if any;

(q) If pathogenic, their virulence, infectivity, toxicity and modes of transmission;

(r) Known allergenicity and/or toxicity of biochemical and metabolic products;

(s) Availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

7. Characteristics of the vector(s):

(a) Nature and source of the vector(s);

(b) Genetic map of the vector(s), position of the gene(s) inserted for the transfer, other coding and non-coding sequences affecting the expression of introduced gene(s), and marker gene(s);

(c) Ability of the vector(s) to mobilize and transfer genes by integration and methods for determining the presence of the vector(s);

(d) Complete nucleotide sequence of the vector(s);

(e) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;

(f) Potential for pathogenicity and virulence;

(g) Natural and host range of vectors;

(h) Natural habitat and geographic distribution of natural and potential hosts;

(i) Potential impacts on human and animal health and the environment;

(j) Measures for counteracting adverse impacts;

(k) Potential to survive and multiply in the environment, or to form genetic recombinants;

(l) Genetic stability of vector(s), such ashypermutability.

8. Characteristics of living modified organism:

(a) The description of the modifications made using gene technology;

(b) The function of the genetic modifications and/or the new insert, including any marker gene(s);

(c) Purpose of the modification and intended use in relation to need or benefit;

(d) Method of modification and, in case oftransgenic organisms, the methods for constructing inserts and to introduce them into the recipient organism;

(e) Whether introduced gene(s) are integrated orextrachromosomal;

(f) Number of insert(s) and its/their structure(s), for example, the copy number whether in tandem or other types of repeats and the position of each insert;

(g) Nucleotide sequence of each insert, including at least one kilobase up and down stream from the insert;

(h) Product(s) of the transferred gene(s), levels of expression and methods for measuring expression;

(i) Stability of the introduced gene(s) in terms of expression and integration;

(j) Biochemical and metabolic differences of living modified organism compared with the unmodified organism;

(k) Probability of vertical or horizontal gene transfer to other species;

(l) Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;

(m) Allergenicities, toxicities, pathogenicities and unintended effects;

(n) Autecology of the living modified organism compared with that of the unmodified organism;

(o) Susceptibility of the living modified organism to diseases and pests compared with the unmodified organism;

(p) Detailed information on past uses including results on all experiments leading to previous releases.

9. Characteristics of resuscitated organism(s) and gene(s) and fossil DNA sequences:

Resuscitated organism

(a) Scientific name and taxonomy;

(b) Identity of nearest species and their characteristics which are of relevance to the intended use;

(c) Site at which it was found;

(d) Method used for resuscitation;

(e) Purpose of introducing the organism and benefits, if any;

(f) Impacts on human and animal health and the environment;

(g) Measures for counteracting adverse impacts;

(h) Length of time the organism has been in use;

(i) Genetic stability;

(j) Likelihood of gene transfer to other organisms;

(k) Fossil and living nearest relative species;

(l) Biological and biochemical differences from related living species;

(m) Information on previous uses since resuscitation.

DNA sequences from fossils or from resuscitated organism

(a) Scientific name and taxonomy of the species whether resuscitated or a fossil;

(b) Site of origin of the fossil;

(c) Site of the gene in the resuscitatedgenome, if known;

(d) Base sequence of the extracted gene;

(e) Method used in extracting the gene;

(f) Function of gene, if known;

(g) Purpose of use and benefits, if any

(h) Environment in which it lived beforefossilization;

(i) Fossil species related to the species from which the gene was taken;

(j) Living species related to the species from which the gene was taken.

10. Safety considerations for human and animal health:

Information on the living modified organism and when it is genetically engineered, information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled, regarding:

(a) Capacity for colonization;

(b) If the living modified organism is pathogenic to humans or animals the following information is required:

(i) Diseases caused and mechanism of pathogenicity, including invasiveness and virulence, and property of virulence;

(ii) Communicability;

(iii) Infective dose;

(iv) Host range and possibilities of alteration;

(v) Ability to survive outside of the human or animal host;

(vi) The existence of vectors or other means of transmission;

(vii) Biological stability;

(viii) Allergenicity;

(ix) Availability of appropriate therapies.

11. Environmental considerations:

Information on the living modified organism and, when it is genetically engineered, information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled, regarding:

(a) Factors affecting the survival, reproduction and spread of the living modified organism in the environment;

(b) Available techniques for detection, identification and monitoring of the living modified organism;

(c) Available techniques for detecting transmission of genes from the living modified organism to other organisms;

(d) Known and predicted habitats of the living modified organism;

(e) Description of the ecosystems which could be affected by accidental release of the living modified organism;

(f) Possible interactions between the living modified organism and other organisms in the ecosystem which might be affected by accidental release;

(g) Known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, being a vector of pathogens, allergenicity, and colonization;

(h) Possible involvement in biogeochemical processes;

(i) Availability of methods for decontamination of the area in case of accidental releases;

(j) Effects on agricultural practices with possible undesirable impacts on the environment.

12. Socio-economic considerations:

(a) Anticipated changes in the existing social and economic patterns resulting from the introduction of the living modified organism or product thereof;

(b) Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture;

(c) Impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of theiragro-climatic zones;

(d) Anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and, in general, means of livelihood of the communities likely to be affected by the introduction of the living modified organisms or products thereof;

(e) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare;

(f) Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the living modified organism [or the product thereof].

III. LIST OF ANNEXES TO THE DRAFT PROTOCOL

EUROPEAN COMMUNITY

i. as regards the Annex referred to in Article 3A option 1 paragraph 2(a) and listed in Annex III, item 3(a), of doc. UNEP/CBD/BSWG/5/Inf.1, the EC and its Member States propose the inclusion of:

" - LMOs which are pharmaceuticals for humans;"

ii. As regards the Annex listed in Annex III, item 29(e), of doc. UNEP/CBD/BSWG/5/Inf.1, the EC and its Member States propose the following:

"Annex 2 (e):Information requirements for unintentional release /transboundary movement (Article 15)

- use of LMO in the originating Party;
- identity, relevant characteristics/traits of the LMO;
- estimated amount of the LMOs unintentionally moved;
- estimated date of the unintentional movement;
- assessment of the methods for monitoring, control and mitigation or emergency measures, as appropriate, including possible contingency measures or methods for the removal or the safe disposal of the LMO from the areas affected;
- assessment of possible adverse effects;
- contact point for further information;"

iii. As regards the Annex referred to in Option 2 paragraph 1 d of Article 17 and listed in Annex III, item 3(f), of doc. UNEP/CBD/BSWG/5/Inf.1, the EC and its Member States propose the following:

Annex 3 (f): Information required for the transfer of LMOs (Article 17)

- statement as to the presence of LMOs in the shipment;
- identity and the relevant characteristics/traits of the LMO;
- relevant requirements to ensure safe handling, storage, transport and use;
- name and address of the exporter and importer or contact point for further information;
- declaration that the movement is in conformity with the requirements of the Protocol;"

As regards the Annex referred to in Option 1 paragraph 1 c of Article 9 and listed in Annex III, item 2(j) [information requirements for simplified procedures], of doc. UNEP/CBD/BSWG/5/Inf.1, the EC and its Member States are of the view that its content should be identical to that of Annex I of doc. UNEP/CBD/BSWG/5/Inf.1 [information required in notifications for AIA].

THAILAND

1. Consolidated text from Contact Group I

Annex I: Information required in notifications for Advance Informed Agreement.

Annex II: Risk assessment.

2. Annexes in government submissions

(a) Risk management;

(b) Function of focal points/competent authorities;

(c) Information to be provided to the Secretariat under information-sharing/clearing house;

(d) (i) Contained use of the living modified organism;

(ii) Requirements/guidelines for the use of LMOs in contained facilities;

(e) Information requirements for unintentional release/transboundary movement;

(f) Information requirements for notifications;

(g) Lists of, and criteria for, LMOs, genes/traits and activities with LMOs to which the Protocol shall not apply;

(h) Relevant information on LMOs (in relation to the European Union submission for Article 4, paragraph 4);

(i) Cases of explicit consent;

(j) Information requirements for simplified procedures

3. Annexes referred to in the consolidated text of the sub-working groups

(a) LMOs not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 3);

(b) Criteria for LMOs to be included in the AIA procedure (Article 3);

(c) Cases of transboundary movement subject to explicit consent (Article 6);

(d) LMOs to be exempted from AIA procedure (Article 9 (cf. Article 3));

(e) Information required in the notification of transboundary movement (Article 9);

(f) Information required for the transfer ofLMOs (Article 17).
