



**CONVENTION ON  
BIOLOGICAL DIVERSITY**

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COMPILATION OF GOVERNMENT SUBMISSIONS OF DRAFT TEXT ON ITEMS OTHER  
THAN ARTICLES 1, 1 BIS, AND 23-27

Title

AUSTRALIA

[ORIGINAL: ENGLISH]

"Protocol on the Safe Transboundary Movement of Living Modified  
Organisms".

Preamble

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

The Parties to the Protocol,

Recalling Article 19, paragraph 3, of the Convention on Biological  
Diversity,

Recalling also Article 19, paragraph 4, and Articles 8(g) and 17,

Recalling decision II/5 of the Conference of the Parties to the Convention  
on Biological Diversity to develop a protocol on biosafety, specifically  
focusing on transboundary movement of any living modified organism resulting

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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,

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

Recognizing that while properly addressing biosafety concerns, the Protocol should avoid causing unnecessary delays to the benefits that biotechnology can bring for health, agriculture and the environment as well as should avoid unnecessary negative impacts on biotechnology research and development and on access to and transfer of technology,

## Article 2

### USE OF TERMS

COLOMBIA

[ORIGINAL: ENGLISH/SPANISH]

#### Accidental release

Advance Informed Agreement (AIA): AIA means the principle that the transboundary movement of living modified organisms should not take place without the authorization, or contrary to the decision, of the Designated National Authority of the recipient Party.

Capacity-building: Capacity-building means the creation and/or enhancement, where appropriate, of institutional or human resources, in accordance with the needs and priorities identified by each Party, for the management and effective exchange of information related to the implementation of the Protocol, the risk assessment and management and the development and/or adaptation of national legislation for the application of the Protocol.

#### Commercial conditions

#### Confined conditions

#### Contained conditions

Contingency: Any sudden occurrence or any series of occurrences having the same origin, which causes damage or creates a grave and imminent threat of causing damage after the entry into force of this Protocol.

Damage: Damage means:

- (a) Loss of life or personal injury;
- (b) Loss of or damage to property other than to the installation itself

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or property held under the control of the operator, at the site of the dangerous activity (confined or liberated environments);

(c) Loss or damage by impairment of the environment in so far as this is not considered to be damage within the meaning of subparagraphs (a) or (b) above, provided that compensation for impairment of the environment, other than for loss of profit from such impairment, shall be limited to the costs of measures of reinstatement actually undertaken or to be undertaken;

(d) The costs of preventive measures and any loss or damage caused by preventive measures.

Deliberate release

Donor organism

Host organism

Illegal traffic: Any transboundary movement of living modified organisms that occurs outside the provisions of this Protocol shall be deemed to be illegal traffic.

Living modified organism

Party of origin

Party of transit

Receiving Party

Recipient organism

Semi-confined conditions

Transboundary movement: Any movement of living modified organisms from the territory of one State bound for the territory of another State or a State through which the movement is intended to take place, provided that the movement involves at least two States. The term includes commercial transactions (export and import) and donations, as well as not-for-profit transfers for research or development purposes.

Unintended release

Unintended transboundary movement: Accidental or unintended release of living modified organisms, the natural movement of living modified organisms deliberately released that may result in an unintended transboundary movement.

Vector or insert

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Alternative to the existing definition of "export and import"

Export and import mean, in their respective connotations, the movement of a living modified organism from the territory of one Party to the territory of another Party, but does not include transit movement through a third State.

Alternative to the existing definition of "Party of export"

Exporting Party means a Party from the territory of which an export of a living modified organism occurs under this Protocol.

New definition

Field growth means intentional growth or propagation of living modified organisms conducted in the environment for non-experimental purposes.

Alternative to the existing definition of "field trial"

Field test means an experiment involving the growth or propagation of living modified organisms which is conducted in the environment under controlled conditions so that the living modified organisms will not persist in the environment.

Alternative to the existing definition of "focal point"

Focal point means a national authority designated by a Party and authorized to act on that Party's behalf with respect to the functions required by this Protocol.

Alternative to the existing definition of "Party of import"

Importing Party means a Party into the territory of which an import of a living modified organism occurs under this Protocol.

New option for the existing definitions of "living modified organism (LMO)"

Any organism which is capable of reproduction and whose genetic material has been modified by modern biotechnology in a way which does not occur naturally by mating or recombination, including viruses and viroids.

Alternative to the existing definition of "unintended release"

Unintentional release means a release of a living modified organism which is not a deliberate release.

Alternative to the existing definition of "unintended transboundary movement"

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Unintentional transboundary release is an unintentional release that occurs after a living modified organism has left the area under the national jurisdiction of the exporting Party and before it has entered the area under the national jurisdiction of the importing Party.

New options

Each definition not covered under new legal texts above is unnecessary, and should contain a notation indicating a new option saying:

"This definition is not necessary."

Article 3

ADVANCE INFORMED AGREEMENT

COLOMBIA

[ORIGINAL: SPANISH]

1. Obligations of the receiving Party:

(a) The Designated National Authority of the receiving Party shall, within xxx days following the notification, inform the Designated National Authority of the Party of origin of its decision pursuant to Article 6;

(b) Each receiving Party shall communicate its response to the Secretariat no later than xxx days after its notification to the Designated National Authority of the country of origin.

2. Obligations of the Party of origin. Each Party of origin shall:

(a) Provide all the information required under Article 4;

(b) Apply adequate legislative and/or administrative provisions for communicating the responses of the receiving Party to the natural and legal persons concerned in its territory;

(c) Respect the conditions laid down in the response of the receiving Party no later than xxx days after the receipt of such communication;

(d) Take adequate legislative or administrative measures to ensure that the transboundary movement of living modified organisms complies with the stipulations in:

(i) The response of the receiving Party;

(ii) The provisions of Article 18;

/...

(e) Provide advice and assistance, at the request of the Designated National Authority of the receiving Party, for obtaining information on decisions of other Designated National Authorities concerning the living modified organism involved in the transboundary movement.

Article 4

NOTIFICATION PROCEDURE FOR AIA

COLOMBIA

[ORIGINAL: SPANISH]

1. The AIA procedure shall be triggered by the notification of a request for transboundary movement of each living modified organism by the Designated National Authority of the Party of origin addressed to the Designated National Authority of the receiving Party and, where applicable, to the Designated National Authority of the Party of transit.

2. The request for transboundary movement shall contain the information specified in Annex I to the present Protocol.

Article 5

RESPONSE TO AIA NOTIFICATION

COLOMBIA

[ORIGINAL: SPANISH]

Possible responses

1. The response of the Designated National Authority of the receiving Party with respect to the request for a transboundary movement shall take one of the following forms:

- (a) A firm decision to:
  - (i) Permit the transboundary movement;
  - (ii) Deny permission for the transboundary movement, in which case the Party of origin shall only be able, through its Designated National Authority, to request the receiving Party to undertake the risk assessment with a view to reviewing its decision. In such a case, the receiving Party shall be able to require the Party of origin to cover some or all of the costs of the assessment;
- (b) An interim response which:
  - (i) States the need to conduct a risk assessment;

/...

(ii) Requests additional information.

2. In the event that the Designated National Authority of the receiving Party decides to conduct the risk assessment, the time-limits laid down in Article 3 shall cease to run.

3. Once the risk assessment has been conducted, the Designated National Authority of the receiving Party may:

- (a) Permit the transboundary movement;
- (b) Permit the transboundary movement subject to specified conditions;
- (c) Deny permission for the transboundary movement, in which case there shall be no recourse.

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

E. Information to notifier

New legal text

Any Party may notify the Secretariat at any time that the advance informed agreement provisions shall not apply with respect to imports to such Party.

F. Time frames

Option 3c should be amended to read as follows:

An importing Party shall communicate to the notifier its decision with respect to importation of a living modified organism that is subject to the AIA as soon as possible, but not later than 180 days after transmission of the notification of an intention to export the living modified organism to the importing Party.

Extension of time frame

Option 4c should be amended to read as follows:

When calculating the period of time for the importing Party to communicate its decision to the notifier, the number of days for which the importing Party is waiting for additional information which it has requested from the notifier, shall not be taken into account.

Article 6

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DECISION PROCEDURE FOR AIA

COLOMBIA

[ORIGINAL: SPANISH]

Review of the request

1. The Designated National Authority of the receiving Party shall review the content of the request and, if found in order, shall within XXX days following notification, so communicate in writing to the Designated National Authority of the Party of origin.

2. In the event that the request is found not to be in order, the Designated National Authority of the receiving Party may request, within the period specified above, the missing information, in which event the deadlines specified herein shall be suspended until the requested information is provided.

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

H. Decision by the importing State

Yes, yes with conditions, or no

Option 1 should be supplemented as follows:

The State of import shall respond to the notifier in writing by:

(a) Consenting to the intended movement with or without conditions; or

(b) Denying permission for the movement; or

(c) Requesting additional relevant technical information.

Basis of decision

New legal text

Should the importing Party impose conditions on the import, deny permission for the import, or request additional information, it shall state its reasons for doing so in the response.

I. Consequences of failure to respond

Option 3 should be amended as follows:

If the importing Party fails to communicate its final decision to the notifier within 180 days of the transmission of the notification of intention to export, the transboundary movement is no longer governed by

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the terms of this Protocol and the exporting Party shall have no further obligations under this Protocol with respect to such transboundary movement.

J. Responsibility of Contracting Parties

New option

No provision for responsibilities of Contracting Parties is necessary.

Article 7

REVIEW OF DECISION UNDER AIA

Article 8

NOTIFICATION OF TRANSIT

COLOMBIA

[ORIGINAL: SPANISH]

The Party of transit shall be able with due substantiation to object to or place conditions on the passage of the living modified organism through its territory.

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

No provision on notification of transit is necessary.

Article 9

SIMPLIFIED PROCEDURE

AUSTRALIA

[ORIGINAL: ENGLISH]

Importing Parties may introduce simplified procedures for Advance Informed Agreement for imports of living modified organisms, provided that any relevant international standards are applied and that adequate measures are observed to ensure the safe transboundary movement of living modified organisms resulting from modern biotechnology, in accordance with the objectives of this Protocol.

Article 10

/...

SUBSEQUENT IMPORTS

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

No provision on subsequent imports is necessary.

Article 11

BILATERAL AND REGIONAL AGREEMENTS

COLOMBIA

[ORIGINAL: SPANISH]

1. Parties may enter into bilateral or regional agreements regarding procedures and information exchange relating to transboundary movements of living modified organisms, provided that such agreements do not run counter to the provisions of the present Protocol.
2. Parties shall notify the Secretariat of any bilateral or regional agreement referred to in the previous paragraph.

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

Option 3 should be amended to read as follows:

Parties to this Protocol may enter into bilateral or multilateral agreements or arrangements between or among them regarding requirements relating to the import and/or export of living modified organisms between or among them, in lieu of the Advance Informed Agreement requirements. In addition, any Party may notify the Secretariat at any time that the Advance Informed Agreement provisions shall not apply with respect to imports by such Party.

Article 12

RISK ASSESSMENT

COLOMBIA

[ORIGINAL: SPANISH]

1. Each country shall define internally its institutional mechanism to undertake risk assessments and to issue a technical opinion on requests for transboundary movement in accordance with its relevant domestic law.
2. For the purposes of conducting the risk assessment, the receiving country shall, inter alia:

/...

- (a) Take into account the information provided by the country of origin;
- (b) Consider the actual and/or potential effects on human health, the environment and agricultural production, including the population balance of the related species;
- (c) Ensure that the risk-assessment and management processes for micro-organisms of all kinds are conducted in contained conditions.

Article 13

RISK MANAGEMENT

COLOMBIA

[ORIGINAL: SPANISH]

Risk-management strategies shall:

- (a) Correspond to the results of the assessment referred to in Article 12;
- (b) Be established for both confined and contained uses and semi- and commercial releases;
- (c) Contain a description of the type and class of containment and confinement of the organism under consideration;
- (d) Include an outline of the procedures and methods for minimizing risk in the management and use of the organism under consideration.

Article 14

MINIMUM NATIONAL STANDARDS

Article 15

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS

COLOMBIA

[ORIGINAL: SPANISH]

1. Parties shall immediately notify affected Parties, potentially affected Parties, non-Parties and the clearing-house mechanism in case of known unintentional transboundary movements of living modified organisms or domestic releases of living modified organisms that may result in an unintentional transboundary movement.

/...

2. The Party of origin of the unintentional transboundary movement shall, in consultation with the affected Party, immediately take appropriate actions to mitigate the adverse effects on human health, the environment and agricultural production, including the population balance of related species.

3. When an unintentional transboundary movement occurs, the Party of origin shall take the appropriate actions and measures to prevent future unintentional transboundary movements and to minimize the associated risks.

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

Option 2, paragraph 9, should be amended to read as follows:

[9. In the event of an unintentional release occurring during the international transport of a living modified organism subject to the article on Advance Informed Agreement [where such unintentional release is likely to present risks to the conservation and sustainable use of biodiversity], each Party shall, whenever it comes to its knowledge, endeavour to ensure that the national focal point of each suspected affected Party is immediately informed and provided with all available relevant information [, subject to the domestic legal requirements for the protection of confidential information and intellectual property rights in the Party providing such information]. For purposes of this Article, international transport refers to that portion of movement that occurs after the living modified organism has left the area under the national jurisdiction of the exporting Party and before it has entered the area under national jurisdiction of the importing Party.]

Article 16

EMERGENCY MEASURES

COLOMBIA

[ORIGINAL: SPANISH]

1. Each Party that undertakes a transboundary movement of a living modified organism in accordance with the present Protocol shall provide in the Safety Information Sheet referred to in Article 18 information on contingency measures or plans, as well as measures for the prevention and mitigation of accidents.

2. In the event of an unintentional transboundary movement, an emergency or an accident, the Party undertaking the transboundary movement of a living modified organism shall take the appropriate measures to ensure that the Designated National Authorities of the potentially affected Parties and the non-party countries are immediately notified and provided with sufficient information to assess the effects of the accident on human health, the

/...

environment and agricultural production, including the population balance of related species, and the emergency measures to be taken. The information shall include, inter alia:

- (a) The circumstances of the accident;
- (b) The identity and quantity of the living modified organisms unintentionally or accidentally released;
- (c) The location of the release or accident;
- (d) The most advisable technical recommendations to mitigate or reduce the damage.

3. Each Party shall promote at the national level the development or strengthening of measures and procedures, including contingency methods or plans, as well as methods to prevent and mitigate adverse effects on human health, the environment and agricultural production, including the population balance of related species, resulting from unintentional transboundary movements, emergencies or accidents involving living modified organisms.

#### Article 17

##### HANDLING TRANSPORT, PACKAGING AND LABELLING

COLOMBIA

[ORIGINAL: SPANISH]

1. The Secretariat of the Convention on Biological Diversity shall cooperate with the World Customs Organization with a view to assigning a universal identification code for products subject to this Protocol.
2. Each Party undertaking a transboundary movement of a living modified organism in accordance with Article (AIA) shall ensure that the product is duly wrapped, packaged, crated and labelled, including the corresponding Safety Information Sheet, which shall include the information specified in Annex 5.
3. The Parties shall ensure that the transboundary movement of living modified organisms from their territory are subject to wrapping, packaging, crating and labelling requirements no less than those required by its national legislation.
4. The information on the Safety Information Sheet shall, to the extent possible, be in the language of the receiving Party.

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

/...

Each Party shall promote, as appropriate, measures for the appropriate handling, transport and packaging of living modified organisms subject to the Article on Advance Informed Agreement.

Article 18

COMPETENT AUTHORITY/FOCAL POINT

COLOMBIA

[ORIGINAL: SPANISH]

1. Each Party shall designate a national authority that shall be empowered to act on the behalf of that Party and to discharge the administrative functions required for the implementation of the present Protocol.
2. The Parties shall strive to ensure that the Designated National Authorities have sufficient resources to perform their tasks effectively.
3. Each Party, no later than the date of deposit of its instrument of ratification of the present Protocol for that Party, shall notify the Secretariat of the Convention on Biological Diversity of the name and contact of its Designated National Authority and shall keep this information updated.
4. The Secretariat shall communicate to the Parties without delay the notifications received pursuant to the previous paragraph and any change in the information concerning Designated National Authorities.

Article 19

INFORMATION SHARING/BIOSAFETY CLEARING-HOUSE

AUSTRALIA

[ORIGINAL: ENGLISH]

Add to paragraph 7, an additional point:

"information on risk assessments and import decisions relating to living modified organisms, including the time taken for import decisions to be made."

COLOMBIA

[ORIGINAL: SPANISH]

1. The Mechanism for the exchange of information and cooperation under the Protocol shall be that established by the Convention on Biological Diversity in its Article 18, paragraph 3.

/...

2. This mechanism shall include, inter alia, the following information:

(a) Information on measures adopted under the national legislation of countries;

(b) Information on the decisions adopted by countries with regard to the transboundary movement of living modified organisms;

(c) Information on accidental/unintentional movements of living modified organisms, including contingency or mitigation plans used in such event;

(d) Information relating to the appropriate assessment and management of risks;

(e) Information on the implementation of Advance Informed Agreement, including simplified procedures and bilateral, multilateral and regional agreements;

(f) Updated information on the Designated National Authorities for the purposes of the present Protocol.

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

Option 2 should be amended to read as follows:

1. Stet.

2. Stet.

3. Stet.

4. Each Party shall make available publicly information on its decisions regarding the importation, field testing, or commercial use of any living modified organism, including any decisions to deny the importation of an living modified organism that has previously been imported by that Party.

5. Each Party should, whenever it comes to its knowledge, share relevant publicly available information when an unintentional release of an living modified organism is likely to present risks to the conservation and sustainable use of biological diversity.

Article 20

CONFIDENTIAL INFORMATION

AUSTRALIA

/...

[ORIGINAL: ENGLISH]

Parties shall respect the need to protect commercial-in-confidence information relevant to living modified organisms.

COLOMBIA

[ORIGINAL: SPANISH]

1. The request for a transboundary movement shall identify, with due justification, the information requiring confidential treatment.
2. In no case may the following data be considered confidential:
  - (a) The following information concerning the host organism:
    - (i) Pathogenicity, toxicity, allergenicity to humans and, if any, to other species;
    - (ii) Capacity to transfer genetic material and potential pathways;
    - (iii) Methods for detecting the organism in the environment and for detecting the effective insertion of donated nucleic acid;
    - (iv) Potential of the organism to affect ecosystemic relations;
  - (b) A summary of the risk assessment on the effects on the conservation and sustainable use of biological diversity, including the effect on domesticated animals and human health;
  - (c) Any contingency method or plan;
  - (d) Accident prevention or mitigation method.

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

1. A Party shall protect confidential information which it receives under the Protocol, including any confidential information which it requires in the context of the Protocol's Advance Informed Agreement process.
2. A Party receiving such confidential information shall establish appropriate internal procedures for the protection of information, and shall protect the confidentiality of such information in a way no less favourable than its treatment of confidential information in connection with domestic living modified organisms.
3. A Party may not use such information for a commercial purpose.
4. The importing Party shall permit the notifier to identify any information submitted under the procedures of this Protocol or required by the importing

/...



Party as part of the Protocol's Advance Informed Agreement process that should be treated as confidential. Justification must be given in such cases upon request.

5. The importing Party shall consult with the notifier if it believes that information identified by the notifier as confidential does not qualify for such treatment and shall inform the notifier of its decision prior to disclosing the information.

Article 21

CAPACITY-BUILDING

COLOMBIA

[ORIGINAL: SPANISH]

1. The building of national capacity is an indispensable requirement for the effective implementation of the present Protocol.
2. The building of national capacity shall be achieved, inter alia, through:
  - (a) New and additional financial resources;
  - (b) Training and technical assistance;
  - (c) Technology transfer relevant to the scope of this Protocol.

Article 22

PUBLIC AWARENESS/PUBLIC PARTICIPATION

COLOMBIA

[ORIGINAL: SPANISH]

Parties shall put in place the necessary mechanisms at the national level to ensure adequate public information on issues related to the implementation of the present Protocol.

Article 28

FINANCIAL MECHANISM AND RESOURCES

COLOMBIA

[ORIGINAL: SPANISH]

1. With regard to the financial resources for the implementation of the

/...

present Protocol, the arrangements provided for in Article 20 of the Convention on Biological Diversity shall be taken into account.

2. The Financial Mechanism shall be that established by Article 21 of the Convention on Biological Diversity.

Article 29

CONFERENCE OF THE PARTIES

UNITED STATES

[ORIGINAL: ENGLISH]

Paragraphs 1-3 should be amended to read as follows:

1. Those members of the Conference of the Parties to the Convention who are also Parties to this Protocol shall serve as the supreme body of this Protocol. Meetings of the Parties to this Protocol should, as needed, generally take place in conjunction with the Conference of Parties to the Convention.

2. In accordance with Article 32, paragraph 2, of the Convention, when such supreme body exercises its functions in relation to this Protocol, decisions shall be taken only by Parties to this Protocol, and any Contracting Party to the Convention that has not ratified, accepted, or approved this Protocol may participate as an observer in such deliberations.

3. Omit this paragraph.

Article 30

SUBSIDIARY BODIES AND MECHANISMS

Article 31

SECRETARIAT

Article 32

JURISDICTIONAL SCOPE

Article 33

RELATIONSHIP WITH THE CONVENTION

/...

Article 34

RELATIONSHIP WITH OTHER INTERNATIONAL CONVENTIONS

Article 35

MONITORING AND COMPLIANCE

Article 36

ASSESSMENT AND REVIEW OF PROCEDURES/ANNEXES

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

No article on assessment and review of procedures/annexes is necessary.

Article 37

SIGNATURE

Article 38

RATIFICATION, ACCEPTANCE OR APPROVAL

Article 39

ACCESSION

Article 40

ENTRY INTO FORCE

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

Paragraph 2 should be amended to read as follows:

2. This Protocol shall enter into force for a Party that ratifies, accepts or approves this Protocol or accedes thereto after entry into force of the Protocol pursuant to paragraph 1 above, on the ninetieth day

/...

after the date on which that Party deposits its instrument of ratification, acceptance, approval or accession.

Article 41

RESERVATION

Article 42

WITHDRAWALS

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

Paragraph 3 should be amended to read as follows:

3. Any Party to the Convention and to this Protocol which withdraws from the Convention shall be considered as also having withdrawn from this Protocol.

Article 43

AUTHENTIC TEXTS

/...

Annexes

COLOMBIA

[ORIGINAL: SPANISH]

Annex I

INFORMATION REQUIRED IN ORDER TO OBTAIN ADVANCE INFORMED AGREEMENT

1. Information concerning the organism

1.1 Characteristics of the parental organism

- (a) Name or identity of the organism (taxonomic classification, phenotypic and genotypic characteristics).
- (b) Pathogenicity, toxicity, allergenicity to humans and, if any, to other species.
- (c) Natural habitat and geographic origin of the organism (its distribution and role within the environment).
- (d) Mechanisms by which the organism survives, multiplies and disseminates (in the environment).
- (e) Means for transfer of genetic material to other organisms.
- (f) Centres of origin of the organism.

1.2 Characteristics of the vector

- (a) Name or identity of the vector (taxonomic classification, general and specific characteristics).
- (b) Pathogenicity, toxicity, allergenicity to humans and, if any, to other species.
- (c) Frequency at which the vector is mobilized or can transfer itself to other organisms.
- (d) Factors that would influence the ability of the vector to become established in other hosts.
- (e) State in which it is in (complete, partial or disarmed plasmid).

1.3 Characteristics of the host organism (without modification)

- (a) Name or identity of the organism (taxonomic classification,

/...

general and specific characteristics).

- (b) Pathogenicity, toxicity, allergenicity to humans and, if any, to other species.
- (c) Mechanism for survival, persistence and competitiveness and dissemination in the environment and other relevant interactions.
- (d) Capacity to transfer genetic material and potential pathways.
- (e) Methods for detecting the organism in the environment and for detecting the transfer of donated nucleic acid.
- (f) Potential of the organism to affect ecosystemic relations.
- (g) Characterization of the product or products of the inserted gene or genes and, where appropriate, the stability of the modification.
- (h) Activity/manifestation of the insert.

1.4 Characteristics of the modified organism

- (a) Name or identity of the organism (taxonomic classification, general and specific characteristics).
- (b) Pathogenicity, toxicity, allergenicity to humans and, if any, to other species.
- (c) Mechanism for survival, persistence and competitiveness and spread in the environment and other relevant interactions.
- (d) Capacity to transfer genetic material and potential pathways.
- (e) Methods for detecting the organism in the environment and for detecting the transfer of donated nucleic acid.
- (f) Potential of the organism to affect ecosystemic relations.
- (g) Characterization of the product or products of the inserted gene or genes and, where appropriate, the stability of the modification.
- (h) Activity/manifestation of the insert.

2. Information on the intended use

2.1 Confined conditions

/...

- (a) The number or volume of organisms to be used.
- (b) The scale of operation.
- (c) The proposed confinement measures, including verification and validation of their functioning.
- (d) Information on waste control.
- (e) Relevant information from previous uses.
- (f) Measures to protect personnel.
- (g) Measures for the control of accidents and unforeseen events.
- (h) Description of biosafety techniques and procedures.

2.2 Deliberate releases

- (a) Purpose and scale of the release.
- (b) Geographical description and location of the release.
- (c) Method and frequency of release.
- (d) Waste-control measures.
- (e) Relevant information from any previous uses.
- (f) Proximity to sources of water or residential areas.
- (g) Plans for the control of accidents and unforeseen events/disasters.

3. Relevant information from any previous releases

4. Risk assessments carried out on the living modified organism in question

5. Name and address of the requesting organization, meaning the natural or legal person interested in the transboundary movement

NORWAY

[ORIGINAL ENGLISH]

Addition to Annex II, under "A. General Principles", between subparagraphs (c) and (d) in the consolidated text on "Risk assessment"

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).

Proposal for a new annex

Annex XX

CONTAINED USE OF THE LIVING MODIFIED ORGANISM

The containment of living modified organisms 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 of living modified organisms, 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 of facility and the living modified organisms to be used.

The living modified organisms intended for contained use and the type of activity planned shall be registered or approved by the competent authority according to the risk involved. The user shall carry out a prior risk assessment of the contained use as regards risks to human health and the environment.

All activities with living modified organisms 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 of living modified organisms:

- (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 living modified organisms;
- (e) Summary of the risk assessment;
- (f) The intended use and application of the living modified organism;

/...



- (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; and
- (k) Possible interactions between the living modified organisms and the environment associated with an unintended release into the environment.

UNITED STATES OF AMERICA

[ORIGINAL: ENGLISH]

Annex I

New alternative annex text

INFORMATION REQUIREMENTS FOR NOTIFICATION UNDER AN AIA

The notification shall include the following information:

- (a) The name and address of the importer;
- (b) The taxonomic name and common name of the recipient organism;
- (c) A description of the traits modified or introduced including the taxonomic status of the donor organism and the function of the introduced DNA (if known);
- (d) The characteristics of the living modified organism;
- (e) Known and available assessments that may have been generated by the regulatory process with respect to the living modified organism;
- (f) Any relevant requirements to ensure safe storage, transport, and use; and
- (g) Any applicable methods for safe disposal and procedures for accidents.

Annex II

RISK ASSESSMENT PARAMETERS

New option

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No annex.

Annex III

RISK MANAGEMENT SCHEMES

New option

No annex.

/...

Annex IV

FUNCTION OF FOCAL POINTS/COMPETENT AUTHORITIES

New option

No annex.

Annex V

INFORMATION TO BE PROVIDED TO THE SECRETARIAT  
UNDER INFORMATION-SHARING/CLEARING-HOUSE

New option

No annex.

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