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ECONOMIC COMMISSION FOR EUROPE

Meeting of the Parties to the
Convention on Access to Information,
Public Participation in Decision-making and
Access to Justice in Environmental Matters

(Second meeting, Almaty, Kazakhstan, 25-27 May 2005)

Item 5 of the provisional agenda

DRAFT DECISION II/1

GENETICALLY MODIFIED ORGANISMS

The Meeting of the Parties,

Recognizing the importance of further developing the application of the Convention to decisions on whether to permit the deliberate release of genetically modified organisms (GMOs) through applying inter alia more precise provisions than those set out in article 6, paragraph 11, of the Convention,

Recalling its decision I/4,

Acknowledging the varying practical needs of the Convention's Parties and Signatories, in particular those with economies in transition, in relation to the development and implementation of national biosafety frameworks, including their needs for stronger provisions on public participation,

Recognizing the need to cooperate with other international organizations and forums, in particular the Cartagena Protocol on Biosafety, with a view to maximizing synergy and avoiding duplication of effort, inter alia through encouraging the exchange of information and further collaboration between the secretariat of the Convention and that of the Cartagena Protocol,

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Calling upon all Parties and Signatories to the Convention to ratify or to accede as appropriate to the Cartagena Protocol, as this provides an opportunity to develop a national biosafety framework, including risk assessment and decision-making procedures involving public participation, and to facilitate participation in capacity-building programmes, particularly in the context of the relevant United Nations Environment Programme/Global Environment Facility project,

Believing that, notwithstanding developments in other forums, the Aarhus Convention provides an appropriate international framework for further developing access to information, public participation and access to justice with respect to GMOs,

Supporting the continued use of the Guidelines on Access to Information, Public Participation and Access to Justice with respect to Genetically Modified Organisms (MP.PP/2003/3), which it adopted as a non-binding, voluntary instrument,

Noting the activities and reports of the Working Group on Genetically Modified Organisms,

- [1. Adopts the amendment to the Convention set out in the annex to this decision;
2. Encourages Parties to ratify, accept or approve the amendment at the earliest opportunity and to apply it to the maximum extent possible pending its entry into force;
3. Also encourages Parties to renew their efforts to implement the Guidelines; and
4. Resolves to review progress in the ratification, acceptance and approval of the amendment and the implementation of the Guidelines at its third meeting.]

Annex I

Article 6

Delete paragraph 11.

Annex I

Paragraph 20

After paragraphs 1-19 insert and 21 bis
Insert a new paragraph reading

21 bis The following activities involving genetically modified organisms (GMOs):

- (a) The deliberate release of a GMO 4/ for any purpose other than its placing on the market, 5/ except if:
 - (i) Such a release in the same location and under comparable conditions has already been approved using a public participation procedure conforming to the requirements of article 6, paragraphs 2 to 10; or
 - (ii) Sufficient experience has been gained with the release of this GMO;
- (b) The placing of a GMO on the market, 6/ except if:
 - (i) It was originally authorized using a public participation procedure conforming to the requirements of article 6, paragraphs 2 to 10, and the authorization needs to be renewed; or
 - (ii) It is intended for research or for culture collections;
- (c) The contained use of a genetically modified micro-organism (GMM), 7/ if:
 - (i) It is foreseen in large-scale industrial installations;
 - (ii) It involves a GMM belonging to risk category 3 or 4;
 - (iii) Contingency plans are deemed necessary for the use of the GMM in a facility;
or
 - (iv) The GMM has not already been used in the same facility and under comparable conditions and been approved using a public participation procedure conforming to the requirements of article 6, paragraphs 2 to 10;
- (d) The contained use of a GMO other than a GMM, 8/ if:
 - (i) Contingency plans are deemed necessary for the use of the GMO in a facility;
or
 - (ii) The GMO has not already been used in the same location and under comparable conditions and been approved using a public participation procedure conforming to the requirements of article 6, paragraphs 2 to 10.

Add the following footnotes

4/ For the purposes of this Convention, ‘genetically modified organism’ or ‘GMO’ means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

5/ For the purposes of this Convention, ‘deliberate release of a GMO’ means any intentional introduction into the environment of a GMO, or a combination of GMOs, for which no specific containment measures are used to limit its contact with and to provide a high level of safety for the general population and the environment.

6/ For the purposes of this Convention, ‘placing on the market’ means making available to third parties, whether in return for payment or free of charge.

7/ For the purposes of this Convention, ‘contained use of a GMM’ means any activity in which a micro-organism is genetically modified or in which such a genetically modified micro-organism is cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit its contact with the general population and the environment.

8/ For the purposes of this Convention, ‘contained use of a GMO other than a GMM’ means any activity in which an organism that is not a micro-organism is genetically modified or in which such a genetically modified organism is cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit its contact with the general population and the environment.

Annex II

ALTERNATIVE A

Article 6, paragraph 1

Insert a new subparagraph (a) bis reading

(a) Shall apply the provisions on public participation to decisions on whether to permit proposed activities relating to genetically modified organisms in accordance with the modalities established in annex I bis.

Article 6, paragraph 11

Delete this paragraph.

ALTERNATIVE B

Article 6, paragraph 11

[Delete this paragraph.]

Insert a new article 6 bis as follows:

Each Party shall apply the provisions on public participation to decisions on whether to permit [the deliberate release and placing on the market of] [proposed activities relating to] genetically modified organisms in accordance with the modalities established in annex I bis. Any Party may, however, determine that its domestic regulatory framework shall instead apply if this affords public rights of participation in such decisions [broadly] equivalent to those laid down in annex I bis.

FOR ALTERNATIVES A AND B:

Annex

Insert a new annex I bis reading

Genetically modified organisms

1. For the purposes of this annex, [the deliberate release of] [proposed activities relating to] genetically modified organisms (GMOs) in the environment shall include:

(a) The deliberate release of a GMO for any purpose other than its placing on the market, except if:

- (i) Such a release under comparable bio-geographical conditions has already been approved using a public participation procedure conforming to the requirements of paragraph 3 below; or
- (ii) Sufficient experience has been gained with the release of this GMO;

(b) The placing of a GMO on the market, except if:

- (i) It was originally authorized using a public participation procedure conforming to the requirements of paragraph 4 below, and the authorization needs to be renewed in accordance with a Party's regulatory framework; or
- (ii) It is intended for research or for culture collections.

[2. For the purposes of this annex, the contained use of GMOs shall include:

(a) The contained use of a genetically modified micro-organism (GMM), if:

- (i) It is foreseen in large-scale industrial installations;
- (ii) It involves a GMM belonging to the two highest risk categories;
- (iii) Emergency plans are deemed necessary for the use of the GMM in a facility; and
- (iv) The GMM has not already been used [in the same facility and] under comparable conditions and been approved using a public participation procedure conforming to the requirements of paragraph 5 below;]

[(b) The contained use of a GMO other than a GMM, if:

- (i) Emergency plans are deemed necessary for the use of the GMO in a facility; and
- (ii) The GMO has not already been used [in the same location and] under comparable conditions and been approved using a public participation procedure conforming to the requirements of paragraph 5 below].

3. Decisions to permit deliberate releases of GMOs for purposes other than placing on the market will be subject to article 6, paragraphs 2 to 10, except for:

- (a) Paragraphs 2 (e), 6 (e) and 10, which shall be applied only to the extent feasible and appropriate; and
- (b) Paragraph 6 (a) and (c), which shall be construed in a manner applicable to GMOs.

The obligation to take due account of the outcome of public participation shall not be construed as implying an obligation to provide individual responses to submissions from the public.

4. Decisions to permit GMOs for placing on the market will be subject to article 6, paragraphs 2 to 10, except for:

- (a) Paragraphs 2 (d) (iii) and (e), 6 (e) and 10, which shall be applied only to the extent feasible and appropriate; and
- (b) Paragraph 6 (a) and (c), which shall be construed in a manner applicable to GMOs.

The relevant information in article 6, paragraph 6, shall contain a description of the geographical area(s) of the proposed activity, including the specific conditions of use and handling. The obligation to take due account of the outcome of public participation shall not be construed as implying an obligation to provide individual responses to submissions from the public.

[5. Decisions to permit GMMs and GMOs for contained use will be subject to article 6, paragraphs 2 to 10, except paragraphs 2 (e) and 6 (e).]

6. For the purposes of this annex and article 4, paragraphs 3 and 4, the following information shall not be considered as confidential by Parties:

- (a) General description of the GMO or GMOs, the name and address of the notifier, the purpose of the release, the location of the release and the intended uses;
- (b) Methods and plans for monitoring the GMO or GMOs and for emergency response;
- (c) The environmental risk assessment.

7. For the purposes of this Convention, 'genetically modified organism' or 'GMO' means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination and covers genetically modified micro-organisms'. Within the terms of this definition, genetic modification is considered to result, inter alia, from the use of the following techniques:

- (a) Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

- (b) Techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; or

- (c) Cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

It is not considered to result from in vitro fertilization, natural processes such as conjugation, transduction and transformation, or polyploidy induction, on condition that these techniques do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than mutagenesis or cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

8. For the purposes of this Convention, 'deliberate release of a GMO' means any intentional introduction into the environment of a GMO, or a combination of GMOs, for which no specific containment measures are used to limit its contact with and to provide a high level of safety for the general population and the environment.

9. For the purposes of this Convention, 'placing on the market' means making available to third parties, whether in return for payment or free of charge. The following operations shall not be regarded as placing on the market:

(a) Making available GMMs for contained use;

(b) Making available GMOs with the exception of such micro-organisms referred to in subparagraph (a) above to be used exclusively for activities where appropriate stringent physical containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment.

10. For the purposes of this Convention, "contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves genetically modified organisms, that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.

Annex III

Article 6

Insert a new article 6 bis reading

The Parties shall, in accordance with their laws and regulations, inform and consult the public in the decision-making process regarding the deliberate release and placing on the market of genetically modified organisms except for the purpose of contained use and shall make the results of such decisions available to the public, while respecting confidential information. The national requirements adopted in application of this provision are without prejudice to other specific requirements to be developed in accordance with article 23 of the Cartagena Protocol on Biosafety.

Annex IV

Article 6

Insert a new article 6 bis reading

Subject to annex 1bis, each Party shall provide for early and effective information and public participation prior to making decisions on whether to permit the deliberate release into the environment and placing on the market of genetically modified organisms.

Annex 1bis

1. Subject to the following paragraphs of this annex, each Party shall lay down, in its regulatory framework, arrangements for effective information and public participation procedures for decisions subject to the provisions of article 6 bis, which shall include a reasonable time frame, in order to give the public an adequate opportunity to express an opinion on such proposed decisions.

2. In its regulatory framework a Party may provide for exceptions to the public participation procedure laid down in this annex:

(a) In the case of the deliberate release of a genetically modified organism (GMO) into the environment for any purpose other than its placing on the market, if:

- (i) Such a release [in the same location] and under comparable [bio-geographical] conditions has already been approved within the regulatory framework of the Party concerned; and
- (ii) Sufficient experience has previously been gained with the release of the GMO in question in comparable ecosystems;

(b) In the case of the placing of a GMO on the market, if:

- (i) It was originally authorized within the regulatory framework of the Party concerned; or
- (ii) It is intended for research or for culture collections.

3. Relevant information shall be made available to the public in an adequate, timely and effective manner, subject to paragraphs 3, 4 and 6 of article 4 [free of charge]. [Each Party may allow its public authorities to make a charge for supplying information, but such charge shall not exceed a reasonable amount.] Parties shall in no case consider the information referred to in subparagraphs (a), (b) and (c) as confidential:

(a) A general description of the genetically modified organism or organisms concerned, the name and address of the applicant for the authorization of the deliberate release, the intended uses and, if appropriate, the location of the release;

(b) [A summary of] the methods and plans for monitoring the genetically modified organism or organisms concerned and for emergency response;

(c) [A summary of] the environmental risk assessment.

In addition, each Party shall ensure transparency on decision-making and [may, where appropriate,] provide the following procedural information to the public:

- (i) The nature of possible decisions;
- (ii) The public authority responsible for making the decision;
- (iii) Public participation arrangements laid down pursuant to paragraph 1;
- (iv) An indication of the public authority from which relevant information can be obtained;
- (v) An indication of the public authority to which comments can be submitted and of the time schedule for the transmittal of comments.

4. The procedures laid down pursuant to paragraph 1 shall allow the public to submit any comments, information, analyses or opinions that it considers relevant to the proposed deliberate release, including placing on the market, in any appropriate manner.

5. Each Party shall endeavour to ensure that, when decisions are taken on whether to permit the deliberate release of GMOs into the environment, due account is taken of the outcome of the public participation procedure organized pursuant to paragraph 1.

6. When a decision subject to the provisions of this annex has been taken by a public authority, each Party shall take all necessary measures to ensure that the text of the decision is made publicly available along with the reasons and considerations upon which it is based.

7. For the purposes of this Convention, 'genetically modified organism' or 'GMO' means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. Within the terms of this definition, genetic modification is considered to result, inter alia, from the use of the following techniques:

(a) Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(b) Techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; or

(c) Cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

It is not considered to result from in vitro fertilization, natural processes such as conjugation, transduction and transformation, or polyploidy induction, on condition that these techniques do

not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than mutagenesis or cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

8. For the purposes of this Convention, ‘deliberate release of a GMO’ means any intentional introduction into the environment of a GMO, or a combination of GMOs, for which no specific containment measures are used to limit its contact with and to provide a high level of safety for the general population and the environment.

9. For the purposes of this Convention, ‘placing on the market’ means making available to third parties, whether in return for payment or free of charge. The following operations shall not be regarded as placing on the market:

- (a) Making available genetically modified micro-organisms (GMMs) for contained use;
- (b) Making available GMOs with the exception of such micro-organisms referred to in subparagraph (a) above to be used exclusively for activities where appropriate stringent physical containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment.

[10. For the purposes of this Convention, ‘contained use of a GMM’ means any activity in which a micro-organism is genetically modified or in which such a genetically modified micro-organism is cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit its contact with the general population and the environment.

11. For the purposes of this Convention, ‘contained use of a GMO other than a GMM’ means any activity in which an organism that is not a micro-organism is genetically modified or in which such a genetically modified organism is cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit its contact with the general population and the environment.]

Editor’s note: The phrases “contained use of a GMM” (para. 10) and “contained use of a GMO other than GMM” (para. 11) are not used as such in this option.