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DRAFT GUIDELINES ON ACCESS TO INFORMATION, PUBLIC PARTICIPATION AND ACCESS TO JUSTICE WITH RESPECT TO GENETICALLY MODIFIED ORGANISMS

The various terms used in these Guidelines, such as GMO, are defined in annex I.

Preamble

<u>Mindful</u> of the need for transparency and public participation in decision-making on genetically modified organisms (GMOs),

<u>Recognizing</u> that the deliberate release of GMOs into the environment and the accidental release of GMOs from certain types of contained use may have significant adverse effects on the environment, and pose risks to human health,

<u>Taking into account</u> the regional and international instruments with a bearing on public information and public participation in the area of GMOs, such as the Convention on Biological Diversity, the Cartagena Protocol on Biosafety and its Biosafety Clearing House, and European Union legislation, MP.PP/2002/6 Page 2

<u>Recognizing</u> the need for consumers to have adequate information on products consisting of or containing GMOs to enable them to make informed environmental choices,

Desiring to build public confidence in decision-making on the use of GMOs,

<u>The Parties</u> to the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention) hereby adopt the following Guidelines:

I. OBJECTIVE AND INTRODUCTION

1. The objective of these Guidelines is to:

(a) Facilitate and give guidance to the practical application of the provisions of the Aarhus Convention relevant to GMOs;

(b) Provide guidance to Parties on the operation and where appropriate on the further development of national legal frameworks and on practices with respect to matters within the scope of these Guidelines;

(c) Encourage the development of a common approach to access to information, public participation and access to justice with respect to GMOs, including on GMO-related matters which are not explicitly referred to in the Convention;

(d) Assist other States seeking to develop or expand access to information, public participation and access to justice with respect to GMOs;

(e) Stimulate open, transparent, efficient and accountable decision-making on activities with GMOs, thereby fostering good practices for public participation in decision-making that may go beyond the scope of the Convention; and

(f) Promote and facilitate public awareness, education and participation in decision-making on activities involving GMOs.

2. The Guidelines provide a non-legally binding and voluntary framework and should be used as examples of good practices. Not all of the Guidelines will be applicable to all situations. The Guidelines should be applied in a flexible manner, taking into account the existing framework in the respective country, its particular situation as regards the uses of GMOs and the specific activity with GMOs. They should also be without prejudice to any other further differentiated guidance at the national level.

II. PUBLIC PARTICIPATION IN DECISION-MAKING ON SPECIFIC ACTIVITIES WITH GMOs

Scope

3. It is recommended that, in principle, public participation should be provided for in decisionmaking procedures in all three areas of GMO applications, and adapted to the specific requirements of these decision-making procedures and uses:

- (a) Deliberate release;
- (b) Placing on the market;
- (c) Contained use.

This does not mean that public participation processes should be applied to all decision-making procedures in these areas. The following two paragraphs aim to give guidance on which decision-making procedures should generally be subject to public participation.

4. It is recommended that public participation as described in paragraphs 6 to 21 should be provided for as appropriate in the following GMO-related decision-making procedures:

(a) First-time deliberate release into the environment of GMOs in any new location;

(b) First-time placing on the market of GMOs not exclusively intended for research or for culture collections;

(c) Procedures for determining whether sufficient experience has been obtained with respect to deliberate releases of certain GMOs in certain ecosystems and simplified procedures could therefore be followed;

(d) Taking into account annex I, paragraph 21, to the Aarhus Convention, the contained use of GMOs in a specific installation where in the event of an accident there would be a risk of serious damage to the environment and/or human health and therefore suitable contingency/emergency plans are foreseen.

5. States may also consider applying the processes described in paragraphs 6 to 21 below to cases other than those referred to in paragraph 4 above. It is recommended that the following general criteria should be considered when deciding if a specific case should be subject to public participation or not:

- (a) The type of GMO (host organism, genetic modification);
- (b) The intended use;

(c) The characteristics of the potentially affected environment;

(d) The level of experience obtained with the GMO and intended use in question with respect to risks to the environment and/or human health;

(e) Any proposal for simplified procedures in the decision-making procedure on the basis of experience;

- (f) For genetically modified micro-organisms, the risk category (if any);
- (g) First-time or subsequent application;
- (h) The scale of use, if applicable;
- (i) Any planned containment or other risk management measure, if applicable;

(j) The significance of any adverse affects on the environment and/or human health that could result from the unintended release of the GMO or from a lack of appropriate risk management measures.

Public notice and access to information relevant to public participation

6. Providing adequate public notice of a specific planned activity with GMOs within the scope of this chapter of the Guidelines should be the first step in the public participation process. The nature and contents of the public notice will vary, depending inter alia on the type of the planned activity (e.g. contained use, deliberate release, placing on the market). The following paragraphs provide examples of good practice and should be applied in a flexible manner.

7. It is recommended that the public concerned should be informed, either by public notice or individually as appropriate, early in the decision-making procedure, and in an adequate, timely and effective manner of the aspects described in annex II.

8. The public authorities should find effective means to inform the public concerned about the proposed activity with GMOs, for example through notices:

- (a) In the official government gazette;
- (b) In appropriate national, regional or local newspapers;

(c) At the town hall of the municipality in the proximity of the facility or site where the proposed activity (contained use or deliberate release) with GMOs is intended to take place;

- (d) On their Internet site; and/or
- (e) On any existing national or regional clearing-house mechanisms.

9. In addition to notifying the public concerned according to paragraphs 6 to 8 above, it is recommended that the public authorities should provide opportunities for members of the public concerned to seek and obtain information relevant to the decision-making procedure so that they can participate in an informed manner.

10. Without prejudice to their right to refuse to disclose certain confidential information in accordance with article 4, paragraphs 3 and 4, of the Aarhus Convention, the information which should be publicly accessible includes, where appropriate, the elements described in annex III. In this context, annexes II, III and IV to Directive 2001/18/EC and annexes I, II and III to the Cartagena Protocol on Biosafety may also be useful sources of information. It is recommended that the public authorities should give the public access to the information that they possess and that is available at the time of the public participation.

11. The public authorities may give the public access to the relevant information for examination by publicly disclosing this information:

(a) At national, regional and, where applicable, local governmental or public premises, such as libraries, in the proximity of the facility or the site where the contained use or the deliberate release of GMOs into the environment will take place; and/or

(b) On their Internet site.

12. It is recommended that the public authorities should provide public access to information for examination free of charge and endeavour to supply copies of information free of charge in response to requests from the public. However, a reasonable charge for supplying the information requested may be made. In such cases the public authorities should make available a schedule of charges which may be levied, indicating the circumstances in which they may be levied or waived and when the supply of information is conditional on the advance payment of such a charge.

Processes for public participation and decision-making

13. The public participation processes should provide for early participation, when all options are open and effective public participation can take place. The following paragraphs provide examples of good practice for processes for public participation and should be applied in a flexible manner.

14. The public participation processes should include reasonable time frames for the different phases, which should take into account any legally binding time frames and allow sufficient time for informing the public and for the public to prepare and participate effectively during the decision-making on certain specific activities with GMOs.

15. The public authorities should encourage potential notifiers or applicants to identify the public concerned, to enter into discussions and to provide information regarding the objectives of their application before notifying or applying for a consent or permit for certain specific activities with GMOs.

16. Public participation processes should allow the public to submit, in writing or, as appropriate, at a public hearing or inquiry (with the notifier or applicant), any comments, information, analyses or opinions in relation to the proposed activity with GMOs.

17. The public authorities should ensure that in the decision due account is taken of the outcome of the public participation. This should, where appropriate and feasible, include an analysis of the comments and a description of the reasons for taking or not taking them into account in the (draft) decision.

18. When the public authorities have taken a decision on a proposed specific activity with GMOs, the public should be promptly informed of the decision, e.g. through a notice:

(a) In the official government gazette;

(b) In national, regional and, where applicable, local newspapers, in the proximity of the facility or the site where the contained use or the deliberate release of GMOs into the environment will take place;

- (c) On the public authority's Internet site (e.g. in cases of placing on the market); and/or
- (d) On any existing national, regional or international clearing-house mechanisms.

19. It is recommended that the public authorities should make publicly accessible the text of the decision and the reasons and considerations on which the decision is based, together with, where appropriate, a description indicating how due account has been taken of the outcome of the public participation. This can be done by making the information available, for example:

(a) At national, regional and, where appropriate, local governmental or public premises, such as libraries, in the proximity of the facility or the site where the contained use or the deliberate release of GMOs into the environment will take place;

(b) On their Internet site.

20. The public authorities should consider, when deciding on whether to renew a consent or permit after it has expired, if paragraphs 13 to 19 above should be applied mutatis mutandis and where appropriate. In a similar way this could be done when the public authorities reconsider or update the operating conditions for a specific activity with GMOs on the basis of new information on the potential significant effects on the environment and/or human health.

21. In order to improve public knowledge, public participation and awareness of activities involving GMOs, the public authorities are encouraged to explore other mechanisms and measures. Such mechanisms and measures could include consensus conferences, round-table discussions, stakeholder dialogues and citizens' juries on issues relating to, for example, the risk assessment and risk management of GMOs.

III. ACCESS TO ENVIRONMENTAL INFORMATION ON GMOs, COLLECTION AND DISSEMINATION OF INFORMATION ON ACTIVITIES WITH GMOs

Scope

22. This chapter of the Guidelines is based on articles 4 and 5 of the Convention. It deals with the broader and more general access to information for the public in the context of activities with GMOs. The Guidelines cover information on:

- (a) Deliberate releases of GMOs;
- (b) Placing on the market of GMOs as or in products;
- (c) Contained uses of GMOs.

Recognizing that countries may wish to require provision of information on products produced from GMOs, the question of including information on products produced from GMOs, which do not necessarily contain the GMO as such, should be revisited at the second meeting of the Parties in the light of developments in other forums.

23. As GMOs are explicitly mentioned in the definition of environmental information in article 2, paragraph 3 (a), of the Convention, articles 4 and 5 of the Convention may generally apply. Consequently, the following paragraphs build on that and aim to assist in the application of these provisions of the Convention to some types of GMO activities.

Collection and dissemination of information on GMOs by the public authorities

24. In addition to the information requirements for notification of the public in the context of public participation in decision-making, the public authorities may collect and disseminate further information on GMO activities which can be made accessible to the public. It is recommended that the public authorities should:

(a) Maintain and update information on activities with GMOs, e.g. via registers and databases;

(b) Establish mandatory systems so that they receive an adequate flow of information about proposed and existing activities with GMOs;

(c) In the event of any imminent threat to the environment and/or human health of activities with GMOs, disseminate immediately and without delay to members of the public who may be affected, all information that they hold and that could enable the public to take measures or mitigate harm arising from the threat.

25. It is recommended that the public authorities should have transparent ways of making information on activities with GMOs available to the public and effectively accessible, inter alia, by the ways described in annex IV.

26. It is recommended that the publicly accessible lists, registers or files established and maintained by the public authorities as described in paragraph 25 above and annex IV should contain, inter alia, the information on activities with GMOs listed in annex V.

27. The UNECE secretariat is requested to establish and maintain on the Convention's web site an up-to-date list of web sites which are considered to be examples of good practice in this area.

28. It is recommended that the Parties should, at regular intervals not exceeding in principle three years, publish and disseminate reports on the experience gained with activities with GMOs, including any results of monitoring their effects on the environment and/or human health, and also including possible implications for the risk assessment and risk management of further activities with GMOs.

29. It is recommended that the Parties should develop mechanisms to ensure that sufficient information on products consisting of GMOs or containing GMOs is made available to the public in a manner which enables consumers to make informed environmental choices about such products. It is recommended that activities and progress in other forums, such as the Cartagena Protocol and the Codex Alimentarius, should be taken into account.

30. One such mechanism is the labelling of products consisting of or containing GMOs or the provision of relevant accompanying documentation in particular for bulk quantities at any stage of the production and distribution chain.

31. The notifiers or applicants for activities with GMOs having a significant impact on the environment are encouraged to inform the public regularly of the environmental impact of such activities.

IV. ACCESS TO JUSTICE

32. If a Party decides to implement the provisions of these Guidelines through a legally binding framework, it is recommended that it should also, within the framework of its legislation, provide for access to justice in accordance with article 9 of the Convention, including, where appropriate, with respect to GMO activities that fall within the scope of these Guidelines but may not be subject to the provisions of article 9 of the Convention.

V. IMPLEMENTATION OF THE GUIDELINES

33. The public authorities of different countries should, to the extent possible and where appropriate, cooperate and assist each other in capacity-building for the practical implementation of these Guidelines.

34. The Parties should monitor and keep under review the implementation of these Guidelines and should report for the first time on their usefulness and the progress made in implementing them to the Meeting of the Parties not later than two years after their adoption.

35. The need for and the possible substance of proposals for further refinements and amendments of the Guidelines, as may be necessary, as well as proposals for complementing the Guidelines with more detailed guidance (such as detailed handbooks) should be further assessed and, if need be, acted upon after the first meeting of the Parties.

Annex I

USE OF TERMS

1. Unless otherwise stated, the terms 'public authority', 'environmental information', 'public' and 'public concerned' shall have the meanings given to them in article 2 of the Convention.

2. For the purpose of these Guidelines, the following use of terms for activities with GMOs, which is based on existing international and regional documents, such as the Cartagena Protocol on Biosafety and the European Community Directives on the deliberate release (2001/18/EC) and contained use (90/219/EEC as amended by 98/81/EC) of GMOs, applies:

(a) 'Genetically modified organism' (GMO) means any organism with the exception of human beings that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

- (b) 'Modern biotechnology' means the application of:
 - (i) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or
 - (ii) Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(c) 'Micro-organism' means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture;

(d) 'Deliberate release' is defined as any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment;

(e) 'Placing of GMOs on the market' is defined as making GMOs available to third parties, whether in return for payment or free of charge;

(f) 'Contained use' means any activity, 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;

(j) 'Accident' shall mean any incident involving a significant and unintended release of GMOs in the course of their contained use which could present an immediate or delayed hazard to the environment and/or human health.

MP.PP/2002/6 Page 10 Annex I

3. Where reference is made to human health, this refers to aspects of human health which are linked to the use of a GMO and its intended or unintended release into the environment.

4. The terms "State", "country" and "national" shall be construed as applying also to regional economic integration organizations constituted by sovereign States members of the Economic Commission for Europe to which their members have transferred competence over matters governed by the Aarhus Convention unless otherwise indicated.

Annex II

RECOMMENDED CONTENTS OF THE PUBLIC NOTICE DESCRIBED IN PARAGRAPH 7

It is recommended that the following information should be actively notified to the public concerned in the context of the decision-making procedures referred to in chapter II:

(a) The proposed activity and the application on which a decision will be taken;

(b) The type of decision which is being taken (e.g. a decision on whether to grant a permit for the import of a GMO, a deliberate release, etc.);

- (c) The public authority responsible for making the decision;
- (d) The envisaged process, including, as and when this information can be provided:
- (i) The commencement of the process;
- (ii) The opportunities for the public to participate (these can vary depending on the case: e.g. examination of the dossier and/or draft decision, possibility for written comments, participation in any public hearing);
- (iii) The time and venue of any planned public hearing;
- (iv) The public authority or any other official body from which relevant information can be obtained and where the relevant information has been deposited for examination by the public;
- (v) The public authority or any other official body to which comments or questions can be submitted and the time schedule for the transmittal of comments or questions; and
- (vi) An indication of what environmental information relevant to the proposed activity with the GMOs is available, e.g. a notification dossier; and
- (e) Any other information that the public authority considers appropriate.

Annex III

INFORMATION RECOMMENDED TO BE AVAILABLE WITHIN A PUBLIC PARTICIPATION PROCESS

In addition to the information items listed in annex II, the following information should be available to the public in the context of the decision-making procedures referred to in chapter II:

- (a) A general description of the GMOs;
- (b) The name and address of the notifier or applicant;
- (c) The purpose of the proposed activity with the GMOs;
- (d) Experience obtained with deliberate releases into the environment of certain GMOs;

(e) In the case of a proposal for simplified procedures for deliberate releases of certain GMOs into the environment, experience obtained with deliberate releases into the environment of those GMOs;

(f) The location of the site where the proposed deliberate release of the GMOs into the environment will take place (depending on the legal and administrative practice in a country this can vary between the description of the exact plot, the land register or the local community); the intended uses of the GMOs; an environmental risk assessment including a description of the potential effects on the environment and/or human health; a description of the measures, if any, to limit potentially adverse effects on the environment and/or human health; a description of the measures, if any, to treat waste arising from the deliberate release of the GMOs; a description of any emergency response plan;

(g) The location of the facility where the contained use of GMOs under the scope of this chapter of the Guidelines will take place, and a description of the specific containment measures; a description of the expected waste of the GMOs and its treatment; a description of any emergency response plan and the possibility for its implementation;

(h) A non-technical summary of the above; and

(i) The main reports and advice issued by expert committees or advisory bodies to the public authorities, in accordance with national legislation.

Annex IV

POSSIBLE WAYS FOR THE PUBLIC AUTHORITIES TO MAKE INFORMATION ON GMOS AVAILABLE TO THE PUBLIC

(a) Providing sufficient information to the public about the type and scope of information on activities with GMOs that they hold, the basic terms and conditions under which such information is made available and accessible, and the process by which it can be obtained. This can be done through Internet sites or regular publications;

(b) Establishing and maintaining practical arrangements, such as: (i) publicly accessible lists, registers or files; (ii) requiring officials to support the public in seeking access to information; and (iii) the identification of points of contact;

(c) Providing access to the information on activities with GMOs contained in publicly accessible lists, registers or files free of charge; and

(d) The lists, registers or files with publicly accessible information on activities with GMOs may be available at national, regional and/or local governmental or public premises, as appropriate, and progressively on their Internet sites.

MP.PP/2002/6 Page 14 Annex V

Annex V

POSSIBLE CONTENTS OF PUBLICLY ACCESSIBLE LISTS, REGISTERS OR FILES ON ACTIVITIES WITH GMOs ESTABLISHED AND MAINTAINED BY THE PUBLIC AUTHORITIES

The contents of this annex are not meant to duplicate existing national obligations or any obligations under other international organizations and instruments, such as the Organisation for Economic Co-operation and Development and the Biosafety Clearing House or other international and regional databases. It is meant as a checklist, which should be applied in a flexible manner according to the specific activity with the GMO. If parts or all of these aspects are dealt with in an existing national or regional register/database/web site, no new mechanism needs to be established. Parts of this paragraph are already listed in annex III (containing the possible information according to paragraph 10) and are not meant as a duplication but have to be seen as complementary to each other. Please observe the different scopes of chapters II and III of these Guidelines and therefore of annexes III and V. It is recommended that the public authorities should take measures within the framework of their legislation for the purpose of disseminating, inter alia, the information items listed in subparagraphs (a) to (d).

(a) Legislation and policy documents on activities with GMOs prepared at various levels (local, national, regional and international). This may include a description and, where applicable, the actual texts of legal and policy frameworks related to GMOs and contact point(s) for further information;

(b) Legislation and policy documents on public information and public participation in decision-making according to (general) administrative laws at various levels (national, regional or international);

(c) International treaties, conventions and agreements relevant to activities with GMOs, such as the Convention on Biological Diversity, the Cartagena Protocol on Biosafety, and European Community Directives 2001/18/EC and 90/219/EEC as amended by 98/81/EC;

(d) Other significant international documents on regulatory approaches and the risk assessment of GMOs by international organizations, such as the Food and Agriculture Organization of the United Nations, the World Health Organization and their Codex Alimentarius Commission, the United Nations Industrial Development Organization and the Organisation for Economic Co-operation and Development;

(e) A non-technical explanation of the types of activities with GMOs regulated by national, regional and international legislati

(f) A list of GMOs which have gained approval for placing on the market within the country including contact points and links to Internet sites for further information on the risk assessments of these GMOs; this may include a list of GMOs which have been approved for food use, feed use or any other use within the country, and the requirements for product information;

(g) (i) Notifications of and/or applications for certain contained uses of GMOs; (ii) a (summary of the) risk assessment; and (iii) any decisions on such applications made by the public authorities;

(h) (i) Notifications of and/or applications for deliberate releases of GMOs into the environment; (ii) a (summary of the) risk assessment; and (iii) decisions made by the public authorities;

(i) Non-technical summaries of applications for deliberate releases of GMOs into the environment and decisions made by the public authorities;

(j) Experience obtained with deliberate releases into the environment of certain GMOs, in particular those for which simplified authorization procedures are proposed;

(k) Information on methods of protection if any risk arises for the environment and/or human health;

(1) New information relevant to the risk assessment that may become available while the notification of or application for a specific activity with GMOs is under consideration by the public authorities;

(m) The advice on a notification or application for a specific activity with GMOs of any expert committee or advisory body to the public authorities;

(n) Decisions to grant or refuse a consent or permit for a proposed specific activity with GMOs;

(o) Any limitations and/or conditions attached to any consent or permit granted, including the reasons of the public authorities for attaching limitations and/or conditions;

(p) Significant new information on a specific activity with GMOs for which a consent or permit has previously been granted subsequently notified to the public authorities and which may have an influence on the risk assessment;

(q) Information on the effects of deliberate releases of GMOs into the environment, including information on the results of the monitoring of their effects on the environment and/or human health, and its implications for any further deliberate releases; information on the monitoring of products containing or consisting of GMOs which have been placed on the market;

(r) Decisions taken by the public authorities to revoke or to vary limitations and conditions attached to a consent or permit granted;

(s) Information on the advance informed agreements on living modified organisms (LMOs) imported into the country as foreseen by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (reference should be made to the Biosafety Clearing House of the Cartagena Protocol);

(t) Information shared by the public authorities of different countries, if a deliberate release of GMOs into the environment will take place in more than one country;

(u) Information on sites of deliberate releases of GMOs and, where appropriate, places where GMOs are grown commercially. This may be information specifying the actual plot, the land register or the local community; and

(v) Contact points to obtain further information from the public authorities.