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

Working Group on Genetically Modified Organisms
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DRAFT GUIDELINES ON GENETICALLY MODIFIED ORGANISMS

Preamble*

Recalling the preamble to the Aarhus Convention, the guidelines aim at addressing the need for increased transparency and greater public participation in decision-making on the deliberate release of genetically modified organisms (GMOs),

Recognizing that intentional or unintentional releases of GMOs from certain types of contained use may have a significant effect on the environment in the meaning of article 6, paragraph 1 (b), of the Aarhus Convention, the guidelines aim at facilitating and improving the practical application of the Convention to public participation in decision-making on the contained use of GMOs,

*The Preamble has not been formally edited.

Recalling further article 6, paragraph 11, of the Aarhus Convention, the guidelines aim at facilitating and improving the practical application of the Convention to public participation in decision-making on the deliberate release of GMOs into the environment,

Noting articles 13 and 14 of the Convention on Biological Diversity and article 23 of the Cartagena Protocol on Biosafety, the guidelines aim at promoting and facilitating public awareness, education and participation in decision-making on activities involving living modified organisms (LMOs),

Taking into account regional and international regulations, for instance of the European Union, on public information and public participation in the areas of contained use and deliberate release of GMOs, the guidelines aim at informing and consulting the public in decision-making on contained use of GMOs and deliberate release of GMOs into the environment,

Notwithstanding article 6, paragraph 11, of the Aarhus Convention, the guidelines aim at developing a common approach to public participation in decision-making on the deliberate release of GMOs into the environment as well as on certain types of contained use of GMOs, thereby providing guidance for further developing legal frameworks at national level,

Recalling the preamble to the Aarhus Convention, the guidelines address the provision of adequate information through labelling of (seed, food, feed and non-food) products consisting of GMOs, containing GMOs or containing ingredients derived from GMOs to consumers to enable them to make informed choices,

Desiring to build confidence in decision-making on the use of GMOs among the public, the guidelines aim at stimulating open, transparent and efficient decision-making on activities with GMOs, thereby fostering good practices for public participation in decision-making that may go beyond the legal requirements of the Convention,

Aiming at a harmonized approach to public information and participation in the decision-making on GMO activities,

the following guidelines on public participation in GMO matters are proposed.

I. PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES WITH GMOs

Definitions

1. For the purpose of the guidelines the following activities with GMOs are further defined as follows:

(a) ‘Deliberate release of GMOs into the environment’ or ‘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;

(b) Two types of deliberate releases of GMOs into the environment can be distinguished: type-I deliberate releases of GMOs for which insufficient experience in certain ecosystems has been obtained, and type-II deliberate releases of GMOs for which sufficient experience in certain ecosystems has been obtained;

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

(d) 'Contained use of GMOs' or 'contained use' is defined as any activity in which organisms are genetically modified or in which such GMOs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment. Four different risk categories of genetically modified micro-organisms (GMMs) - from 1, the lowest risk category, to 4, the highest risk category - are commonly distinguished for determining the specific containment measures for the contained use of GMMs;

(e) 'First-time contained use of GMOs' is defined as the first time use of a GMO in a specific contained facility, where the GMO belongs to a group which has not previously been notified to the public authorities;

(f) 'Subsequent contained use of GMOs' is defined as contained use in a specific facility of GMOs belonging to a group which has previously been notified to the public authorities;

(g) Two types of contained-use operations with GMMs can be distinguished: small-scale operations and large-scale operations. Typically large-scale operations are more than 100 litres of risk-category-1 GMMs and more than 10 litres of risk-category-2 to 4 GMMs.

General considerations

2. 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, inter alia, of:

(a) The notification or application on which a decision will be taken for the following specific activities with GMOs:

- Type-I deliberate release into the environment of GMOs;
- Placing on the market of GMOs;
- Determination of a GMO which fulfils criteria for type-II deliberate releases into the environment and therefore simplified procedures could be allowed;
- The first-time contained use of GMOs; and

- Large-scale contained-use operations with GMMs belonging to risk category 2, 3 or 4;

(b) The nature of possible decisions or the draft decision;

(c) The public authority making the decision;

(d) The envisaged procedure, including, as and when this information can be provided:

(i) The commencement of the procedure;
(ii) The opportunities for the public to participate;
(iii) The time and venue of any envisaged public hearing;
(iv) An indication of the public authority or any other official body where the relevant information has been deposited for examination by the public and from which it can be obtained;
(v) An indication of the relevant public authority or any other official body to which comments or questions can be submitted and of the time schedule for the transmittal of comments or questions;
(vi) An indication of what environmental information on the proposed activity with the GMOs is available.

3. The public authorities can inform the public about the proposed activity with GMOs through a notice in the official government gazette and/or in appropriate national, regional and/or local newspapers, and/or through a notice on its (official) Internet site and/or at the town hall of the municipality in the proximity of the facilities or site(s) where the proposed activity with GMOs will take place.

4. Public authorities may consider not applying these guidelines to public participation in the case of a notification of subsequent contained use of GMOs not being GMMs belonging to risk categories 2, 3 or 4.

5. Public authorities may consider applying the procedures as described above also to other cases than those laid down in paragraph 2 (a) above.

Access to public information

6. The public authorities should give the public access to all information relevant to the decision-making on specific activities with GMOs that is available at the time of the public participation procedure for examination, as soon as it becomes available, without prejudice to the right of public authorities to refuse to disclose certain confidential information in accordance with article 4, paragraph 4, of the Aarhus Convention. The relevant information should include at least:

(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 type-I deliberate releases into the environment of certain GMOs in the case of a proposal for type-II deliberate releases of those GMOs into the environment and simplified procedures;

(e) The location(s) of the site(s) where the proposed type-I or type-II deliberate release of the GMOs into the environment will take place; the intended uses of the GMOs; a description of the potential effects on the environment and human health; an environmental risk assessment; a description of the measures, if any, to limit potential adverse effects on the environment and human health; a description of the plan for monitoring the effects on the environment and human health; a description of the measures, if any, to treat waste arising from the deliberate release of the GMOs; a description of the emergency response plan;

(f) The location of the facilities where the first-time contained use of GMOs, or large-scale contained-use operations with GMMs belonging to risk category 2, 3 or 4 will take place, and a description of the specific containment measures; a description of the expected waste of GMMs belonging to risk category 2, 3 or 4 and methods to treat this waste; a description of the emergency response plan;

(g) A non-technical summary of the above;

(h) The main reports and advice issued by expert committees or advisory bodies to the public authorities.

7. The public authorities should give the public access to the relevant information for examination by publicly disclosing this information at governmental or public libraries at national, regional and/or local level in the proximity of the contained-use facilities or the site(s) where the deliberate release of GMOs into the environment will take place, and/or by posting the relevant information on their (official) Internet site.

8. The public authorities should endeavour to supply information free of charge in response to requests from the public for copies of the relevant information. However, a reasonable charge for supplying the information requested may be made. In such cases the public authorities shall 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.

Public participation and decision-making

9. The public participation procedures should include reasonable time frames for the different phases, allowing sufficient time for informing the public and for the public to prepare and participate effectively during the decision-making on specific activities with GMOs.

10. The public participation procedures should provide for early participation, when all options are open and public participation can be effective.

11. Potential notifiers or applicants should be encouraged by the public authorities to identify the public concerned, to enter into discussions and to provide information before notifying or applying for a consent or permit for certain specific activities with GMOs.

12. Public participation procedures 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 that the public considers relevant to the proposed activity with GMOs.

13. The public authorities should ensure that in the decision due account is taken of the outcome of the public participation.

14. When the public authorities have taken a decision on a proposed specific activity with GMOs, the public should be promptly informed of the decision through a notice in the official government gazette and/or in appropriate national, regional and/or local newspapers, in the proximity of the contained-use facilities or the site(s) where the deliberate release of GMOs into the environment will take place, and/or through a notice on their (official) Internet site.

15. The public authorities shall make the text of the decision, along with the reasons indicating how due account has been taken of the outcome of the public participation and considerations on which the decision is based, publicly accessible at governmental or public libraries at national, regional and/or local level, in the proximity of the contained-use facilities or the site(s) where the deliberate release of GMOs into the environment will take place, and/or post the relevant information on their (official) Internet site.

16. When the public authorities reconsider or update the operating conditions for a specific activity with GMOs, the above provisions are applied mutatis mutandis, including when reconsidering limitations and/or containment measures attached to a consent or permit after new information on the effects on the environment and human health has become available, and when considering renewing a consent or permit after it has expired.

17. Public authorities may consider exploring other mechanisms for involving the public in decision-making on activities with GMOs and measures to improve public knowledge and awareness of these activities. Such mechanisms and measures could include consensus conferences, round-table discussion, stakeholder dialogues and citizens' juries on issues elating to, for example, the risk assessment and risk management (of new types) of GMOs.

II. COLLECTION AND DISSEMINATION OF INFORMATION ON ACTIVITIES WITH GMOs

18. The public authorities should:

(a) Possess and update information on activities with GMOs;

(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 human health or the environment of

activities with GMOs, disseminate immediately and without delay to members of the public who may be affected, all information that they hold which could enable the public to take measures or mitigate harm arising from the threat.

19. The public authorities should have transparent ways of making information on activities with GMOs available to the public and effectively accessible, inter alia, by:

(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;

(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; and

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

20. Publicly accessible lists, registers or files established and maintained by public authorities should contain, inter alia, the following information on activities with GMOs:

(a) A description of the national and, if appropriate, supranational legal framework(s) related to GMOs and products derived therefrom, including labelling requirements and contact point(s) for further information;

(b) A non-technical explanation of the types of activities with GMOs regulated by national and supranational legislation;

(c) A list of GMOs which have gained approval for placing on the market within the country, a list of GMOs and/or ingredients derived therefrom which have been approved for food use, feed use or any other use within the country, and the requirements for labelling, including contact points and links to Internet sites for further information on the risk assessments of these GMOs;

(d) Information on: (i) notifications of and/or applications for first-time contained use of GMOs; (ii) notifications of and/or applications for small-scale and large-scale contained-use operations with GMMs of risk categories 2, 3 and 4; (iii) a summary of the risk assessment; and (iv) decisions made by the public authorities;

(e) Information on: (i) notifications of and/or applications for type-I and type-II deliberate releases of GMOs into the environment; (ii) a summary of the risk assessment; and (iii) decisions made by the public authorities;

(f) Information on experience obtained with type-I deliberate releases into the environment of certain GMOs in the case of (a proposal for) type-II deliberate releases of those GMOs into the environment and simplified procedures;

(g) 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;

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

(i) Information on decisions to grant or refuse a consent or permit for a proposed specific activity with GMOs;

(j) Information on 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;

(k) New information on a specific activity with GMOs for which a consent or permit has previously been granted subsequently notified to the public authorities;

(l) Information on the results of type-I and type-II deliberate releases of GMOs into the environment, including information on the results of the monitoring of their effects on the environment and human health and its implications for any further type-I and type-II deliberate releases;

(m) Information on decisions taken by the public authorities to revoke or to vary limitations and conditions attached to a consent or permit granted;

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

(o) 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 of Biological Diversity;

(p) 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;

(q) Information on sites of deliberate releases of GMOs and places and plots where GMOs are grown commercially;

(r) Contact points to obtain further information from the public authorities, if full information is not provided.

21. It is recommended that the public authorities should make the lists, registers or files with publicly accessible information on activities with GMOs available at governmental or public libraries at national, regional and/or local level, as appropriate, and progressively on their (official) Internet sites.

22. The following Internet sites are identified as examples of good practice regarding one or more of the above aspects:

- Netherlands Environment Ministry: http://www.minvrom.nl
- United Kingdom Department for Environment, Food and Rural Affairs: http://www.defra.gov.uk/
- Austrian Federal Environment Agency: http://www.ubavie.gv.at/umweltregister/genbio/intro.htm
- Austrian biosafety server: http://www.gentechnik.gv.at
- Belgian biosafety server: http://www.biosafety.be
- Norwegian Directorate for Nature Management: http://www.dirnat.no/
- Norwegian Biotechnology Advisory Board: http://www.bion.no/

23. The public authorities should, at regular intervals not exceeding three or four years, publish and disseminate national reports on the results of monitoring the effects on the environment of activities with GMOs, including implications for the risk assessment and risk management of further activities with GMOs.

24. The public authorities should take measures within the framework of their legislation for the purpose of disseminating, inter alia:

(a) Legislation and policy documents on activities with GMOs prepared at various levels of national and supranational government;

(b) Legislation and policy documents on public information and public participation in decision-making according to (general) administrative laws at various levels of national and supranational government(s);

(c) International treaties, conventions and agreements relevant to activities with GMOs, such as the Convention for Biological Diversity, the Cartagena Protocol on Biosafety, and European Union directives 98/81/EC and 2001/18/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.

25. The public authorities should encourage notifiers or applicants for specific activities with GMOs to inform the public regularly of the environmental impact of such activities.

26. It is recommended that the public authorities should:

(a) Publish the facts and analyses of facts which it considers relevant and important in framing major regulatory policy proposals for activities with GMOs;

(b) Publish, or otherwise make accessible, available explanatory material in matters relating to the scope of these guidelines; and

(c) Provide in an appropriate form information on the performance of public functions or the provision of public services relating to activities with GMOs by government at all levels.

27. It is recommended that the public authorities should develop mechanisms to ensure that sufficient information on (seed, food, feed and non-food) products consisting of GMOs, containing GMOs or containing ingredients derived from GMOs is made available to the public in a manner which enables consumers to make informed choices about such products.

28. One such mechanism is the labelling of seed, food, feed and non-food products consisting of GMOs, containing GMOs or containing ingredients derived from GMOs, at any stage of the production and distribution chain, with the words “This product contains genetically modified organisms” and the source of further more detailed information, for example a (toll-free) telephone line and/or Internet site. Where products, including bulk quantities, are not packaged and the use of a label is not possible, this information should be transmitted with the product along the production and distribution chain, in the form of, for example, accompanying documentation. Such a labelling scheme requires that the unique identifier(s) relating to the GMO(s) contained in the product should also be transmitted with the product along the production and distribution chain.

29. The public authorities should seek to harmonize, to the extent possible, national labelling schemes at supranational and international levels.

30. It is recommended that the public authorities should take steps to establish progressively, taking into account international processes where appropriate, a coherent, nationwide system of inventories or registers with information on the results of the monitoring of the effects on the environment and human health of activities with GMOs. The focus should be on deliberate releases of GMOs into the environment and placing GMOs on the market. The information should be put on a structured, computerized and publicly accessible database compiled through standardized reporting.

31. 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.

III. ACCESS TO JUSTICE

32. It is recommended that the public authorities at national and supranational levels should ensure that any member of the public or public-interest organization who considers that his or her request for information on activities with GMOs has not been dealt with in accordance with these guidelines has access to a review procedure before a court of law or another independent and impartial body established by national or supranational law.

33. If national or supranational law provides for such a review by a court of law, the public authorities should in any case ensure that such a person has access to an expeditious procedure

established by law that is free of charge or inexpensive for reconsideration by the public authorities or review by an independent and impartial body other than a court of law.

34. Final decisions should be binding on the public authorities holding the information on specific activities with GMOs. Reasons should be stated in writing, at least where access to information is refused.

35. It is recommended that the public authorities at national and supranational levels should ensure that any member of the public or public-interest organization who considers that in the decision by the public authorities due account was not taken of the outcome of the public participation procedure has access to administrative or judicial procedures to challenge the decision before a court of law or another independent and impartial body established by law.

36. If national or supranational law provides for such a challenge before a court of law, the public authorities should in any case ensure that such a person has access to an expeditious procedure established by law that is free of charge or inexpensive for reconsideration by the public authorities or review by an independent and impartial body other than a court of law.

37. Final decisions on whether or not to amend the decision on the proposed activity with GMOs by the public authorities should be binding on these public authorities. Reasons should be stated in writing.