Joint Aarhus Convention/Cartagena Protocol on Biosafety
Round Table on public awareness, access to information and public participation regarding genetically/living modified organisms
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PUBLIC AWARENESS, ACCESS TO INFORMATION AND PUBLIC PARTICIPATION WITH REGARDS TO GENETICALLY MODIFIED ORGANISMS/LIVING MODIFIED ORGANISMS: KEY PROVISIONS OF THE AARHUS CONVENTION AND THE CARTAGENA PROTOCOL ON BIOSAFETY

Background paper
Prepared by the secretariats of the Aarhus Convention and of the Convention on Biological Diversity

The document contains relevant information extracted from the original texts of the Aarhus Convention, the Cartagena Protocol on Biosafety, the Maastricht Recommendations on Promoting Effective Public Participation in Decision-making in Environmental Matters as well as information from reports and documents prepared by the secretariat to the Aarhus Convention and the Secretariat of the Convention on Biological Diversity, which services the Cartagena Protocol on Biosafety.

Delegates are invited to consult this document in advance of the meeting in order to gain an overview of the relevant provisions of the Aarhus Convention and the Cartagena Protocol on Biosafety in the context of public awareness, education and participation, including access to information regarding GMOs/LMOs.

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I. Extract from the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention)

Article 2

Paragraph 3 (a)

"Environmental information" means any information in written, visual, aural, electronic or any other material form on:

(a) The state of elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites, biological diversity and its components, including genetically modified organisms, and the interaction among these elements;

Article 6

Paragraph 11

"Each Party shall, within the framework of its national law, apply, to the extent feasible and appropriate, provisions of this article to decisions on whether to permit the deliberate release of genetically modified organisms into the environment".

Article 9

Paragraph 3

"In addition and without prejudice to the review procedures referred to in paragraphs 1 and 2 above, each Party shall ensure that, where they meet the criteria, if any, laid down in its national law, members of the public have access to administrative or judicial procedures to challenge acts and omissions by private persons and public authorities which contravene provisions of its national law relating to the environment".

II. Extract from Decision II/1 adopted by the Meeting of the Parties to the Aarhus Convention on Genetically Modified Organisms (ECE/MP.PP/2005/2/Add.2)

Article 6 bis

After article 6, insert a new article reading

Article 6 bis

PUBLIC PARTICIPATION IN DECISIONS ON THE DELIBERATE RELEASE INTO THE ENVIRONMENT AND PLACING ON THE MARKET OF GENETICALLY MODIFIED ORGANISMS

Paragraph 1

In accordance with the modalities laid down in annex I bis, 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.

Paragraph 2

The requirements made by Parties in accordance with the provisions of paragraph 1 of this article should be complementary and mutually supportive to the provisions of their national biosafety framework, consistent with the objectives of the Cartagena Protocol on Biosafety.

Annex I bis

After annex I, insert a new annex reading

Annex I bis

MODALITIES REFERRED TO IN ARTICLE 6 BIS

Paragraph 1

Each Party shall lay down, in its regulatory framework, arrangements for effective information and public participation 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.

Paragraph 2

In its regulatory framework, a Party may, if appropriate, 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 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 already approved within the regulatory framework of the Party concerned; or

(ii) It is intended for research or for culture collections.

Paragraph 3

Without prejudice to the applicable legislation on confidentiality in accordance with the provisions of article 4, each Party shall make available to the public in an adequate, timely and effective manner a summary of the notification introduced to obtain an authorization for the deliberate release into the environment or the placing on the market of a GMO on its territory, as well as the assessment report where available and in accordance with its national biosafety framework.

Paragraph 4

Parties shall in no case consider the following information 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) The methods and plans for monitoring the genetically modified organism or organisms concerned and for emergency response;

(c) The environmental risk assessment.

Paragraph 5

Each Party shall ensure transparency of decision-making procedures and provide access to the relevant procedural information to the public. This information could include for example:

(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.

Paragraph 6

The provisions made 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.

Paragraph 7

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

Paragraph 8

Parties shall provide that when a decision subject to the provisions of this annex has been taken by a public authority, the text of the decision is made publicly available along with the reasons and considerations upon which it is based.

III. Extract from the Guidelines on access to information, public participation and access to justice with respect to genetically modified organisms (Lucca Guidelines, KIEV.CONF/2003/INF/7, Kiev, 21-23 May 2003)

Paragraph 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.

Paragraph 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;

IV. Extract from the Aarhus Convention Implementation Guide (second edition)[1]

ARTICLE 6 BIS
PUBLIC PARTICIPATION IN DECISIONS ON THE DELIBERATE RELEASE INTO THE ENVIRONMENT AND PLACING ON THE MARKET OF GENETICALLY MODIFIED ORGANISMS

Article 6 bis lays down requirements for public participation in decisions on the deliberate release into the environment as well as the placing on the market of GMOs. Article 6 bis does not apply to the contained use of GMOs; however, this type of activity is covered by the Lucca Guidelines on GMOs.

Deliberate release, placing on the market, contained use

While neither the Convention nor the amendment define the terms "deliberate release", "placing on the market" or "contained use", annex I of the Lucca Guidelines provides the following definitions:

"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.

"Placing of GMOs on the market" is defined as making GMOs available to third parties, whether in return for payment or free of charge.

"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.

1. In accordance with the modalities laid down in annex I bis, 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.

Paragraph 1 of article 6 bis contains two main principles: early and effective information and early and effective public participation. The principle of early information is to be understood by public authorities responsible for decision-making concerning the deliberate release and the placing on the market of GMOs as the obligation to inform the public at the earliest stage of a decision-making

[1] Available from http://www.unece.org/index.php?id=35869&L=0

procedure. That means in practice that as soon as an appropriate notification has been submitted to the public authority, the public has to be informed, e.g., by public notice, about the proposed activities. The principle of effective information primarily means that the public should be provided with the relevant information in an easily accessible and comprehensible way. The principle of early and effective public participation should provide for a transparent decision-making process with the active involvement of the public. Of course the public has to be informed prior to decision-making so that early participation, when all options are open, can take place. In order to give the public the possibility to express an opinion it is therefore very important to include reasonable time frames in the public participation process.

2. The requirements made by Parties in accordance with the provisions of paragraph 1 of this article should be complementary and mutually supportive to the provisions of their national biosafety framework, consistent with the objectives of the Cartagena Protocol on Biosafety.

Article 6 bis, paragraph 2, requires Parties to implement paragraph 1 of that article in a manner which is complementary and mutually supportive to the provisions of their national biosafety framework and consistent with the objectives of the Cartagena Protocol on Biosafety. Ideally, in this regard, good practice would be to incorporate the requirements of article 6 bis, paragraph 1, directly into the national biosafety framework. Those Parties that do not yet have a national biosafety framework in place consistent with their international obligations should take these provisions into account when developing their national biosafety framework. In keeping with article 3, paragraphs 5 and 6, of the Convention, Parties are free to introduce, or to maintain, measures that provide for broader access to information and more extensive public participation in GMO decision-making than required under article 6 bis.

In general, biosafety frameworks comprise three essential elements that, in combination, are commonly referred to as risk analysis: risk assessment; risk management; and risk communication. The core activity is the so-called risk assessment, a multidisciplinary, scientific exercise. In the EU, the term “environmental risk assessment” is used, indicating its focus on potential impacts on the environment, taking also into account potential effects on human health. The second element of risk analysis is risk management. This means, on the one hand, any measures (e.g., isolation distances) intended to limit potential risks resulting from the use of a GMO, i.e., technical risk management, and, on the other hand, administrative risk management, in the form of decisions imposing possible conditions for the safe handling and use of a certain GMO. Finally, the third essential element of risk analysis is risk communication, which addresses public information and public participation. A thorough risk analysis requires communication and discussion about both the content of the risk assessment (e.g., results of the scientific evaluation) and the risk management (e.g., reasons and considerations a decision is based upon).

Considering the fact that GMOs are living organisms that may reproduce in the environment, their release may be irreversible. A fundamental principle derived from that reasoning that has found its way into almost all national biosafety frameworks around the world is the step-by-step principle. This means that the scale of release of a GMO is gradually increased only if evaluation of the earlier steps did not suggest potential negative effects for human health or the environment. At the legal level this is reflected in the classification and procedures concerning the different activities

regarding GMOs: contained use, deliberate release and placing on the market. As noted previously, the GMO amendment does not cover the contained use of GMOs; however, this activity is addressed in the Lucca Guidelines.

Synergies with the CBD and its Cartagena Protocol on Biosafety

In decision II/1 adopting the GMO amendment, the Parties to the Aarhus Convention recognized the need to cooperate with other international organizations and forums, in particular the Cartagena Protocol on Biosafety, with a view to maximizing synergies and avoiding duplication of efforts, including through encouraging the exchange of information and collaboration between the respective secretariats. The Riga Declaration, adopted at the third session of the Meeting of the Parties, recognized the value of further collaboration with bodies of the Cartagena Protocol in activities aimed at supporting the application of the Lucca Guidelines on GMOs and the implementation of the Almaty amendment on GMOs.

The Cartagena Protocol on Biosafety to the CBD was drafted by the Parties to the CBD in the same period as the Aarhus Convention was being negotiated. The Cartagena Protocol was adopted on 29 January 2000 after long and intense negotiations, and entered into force on 11 September 2003. The Conference of the Parties to the CBD serves as the Meeting of the Parties to the Protocol.

Like the CBD, the Cartagena Protocol does not use the term “genetically modified organism”. Instead, it refers to “living modified organisms resulting from biotechnology”. The extent of any difference in the scope of these two terms has not been settled in practice.

The objective of the Cartagena Protocol, in accordance with the precautionary approach, is “to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movements” (Protocol, article 1). According to article 23 of the Protocol, Parties are required to “promote and facilitate public awareness, education and participation”, “to consult the public in the decision making process regarding living modified organisms”, and to “make the results of such decisions publicly available”. These provisions are kept rather general, supplemented by obligations concerning the exchange of information within the Biosafety Clearing-House mechanism.

At their fifth session (Nagoya, Japan, October 2010), the Parties to Cartagena Protocol adopted the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress. The objective of the Supplementary Protocol is to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to living modified organisms. Being a Supplementary Protocol, the provisions of the Cartagena Protocol on public awareness and participation, including article 23, apply to processes

under the Supplementary Protocol.

While the objective of the Aarhus Convention is "to contribute to the protection of the right of every person of present and future generations to live in an environment adequate to his or her health and well-being" (article 1), the CBD and the Cartagena Protocol focus more particularly on the protection of biological diversity for its own sake. However, despite their different foci, the provisions of the Cartagena Protocol and the GMO amendment to the Aarhus Convention overlap on the issue of public participation in decision-making. In this regard, the two instruments should not be seen as contradicting, but rather as complementing one another. In the light of the GMO amendment, the Aarhus Convention might be considered as the more elaborated instrument in respect of the modalities for public participation, for which it lays down detailed requirements; whereas article 23 of the Cartagena Protocol on public participation is of a more framework nature (although at their fifth session the Parties to the Protocol adopted a Programme of Work on Public Awareness, Education and Participation Concerning the Safe Transfer, Handling and Use Of Living Modified Organisms which envisages activities addressing, inter alia, the issue of public participation). Conversely, regarding access to information, the Cartagena Protocol, in its article 20 establishing the Biosafety Clearing-House mechanism, defines more clearly than the Aarhus Convention what kind of scientific, technical, environmental and legal information and information has to be made publicly available.

In accordance with the recognition, in decision II/1 adopting the Aarhus Convention's GMO amendment, of the need to cooperate with the Cartagena Protocol, the two instruments have subsequently collaborated in a number of respects. This collaboration has included the convening of joint workshops on access to information and public participation with respect to GMOs back to back with the fourth and fifth sessions of the Meeting of the Parties to the Cartagena Protocol (Bonn, Germany, May 2008 and Nagoya, Japan, October 2010). The secretariats of the two instruments have also collaborated in the intersessional periods in various respects. For example, at the invitation of the Cartagena Protocol secretariat, the Aarhus Convention secretariat provided comments on the draft work programme on public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms prior to the finalization of its text.

ANNEX I BIS
MODALITIES REFERRED TO IN ARTICLE 6 BIS

1. Each Party shall lay down, in its regulatory framework, arrangements for effective information and public participation 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.

Paragraph 1 of annex 1 bis more or less summarizes the basic requirements on public participation laid down in article 6 of the Aarhus Convention for decisions on GMOs. These are, in particular, the principle of effective information and the basic elements of public participation (further elaborated under paras. 4–8 of annex 1 bis). The latter imply that within public participation procedures, whatever forms these may take (e.g., public hearings, stakeholder dialogues and consensus conferences), the public are granted adequate time frames to prepare and to participate effectively during the decision-making process. Access to relevant information is thus considered a prerequisite to the opportunity for the public to provide opinions. The time frame admitted may vary between decisions on the deliberate release of GMOs and decisions on the placing on the market of GMOs, and also among countries.

In the EU, for instance, the public has 30 days to comment on the opinion of the European Food Safety Authority (EFSA), which constitutes the assessment report of a notification concerning the placing on the market of GMOs. In Norway, where specific legislation on access to GMO information is in place, the public generally has six weeks for comments. In Austria, after the public announcement of a notification for the deliberate release of a GMO, the public may submit written comments to the competent authority within three weeks, during which the public has the right/possibility of access to the notification. If the public provides comments, the competent Austrian authority has to hold a public hearing within three weeks after the end of the commenting period.

The use of an annex to set out the prescribed modalities is interesting. While annexes are considered an integral part of the Convention (article 13), the process for amending them is much less onerous than for amending a provision in the main body of the Convention (article 14, paras. 4, 5 and 6).

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

For many of the activities listed in annex 1 of the Convention a threshold is established regarding the applicability of the provisions of article 6. The notion behind this provision is that the potential impact of a given activity on the environment is generally proportional to the size of the venture. As balancing potential risks for the environment against potential benefits for the society always results in a compromise depending on the case, each exemption demands a detailed statement of grounds.

Similarly, annex I bis specifying modalities for public participation regarding the deliberate release and the placing on the market of GMOs provides the possibility for exemptions to this procedure. However, these exemptions are not mandatory and can be applied at each Party's own discretion. As the two activities of GMOs covered by article 6 bis — deliberate release and placing on the market — differ in scope, exemptions are specifically defined for each of them (see below).

(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:

Article 6 bis, paragraph 2 (a), entitles a Party to provide for exemptions to the public participation procedure laid down in the annex regarding the deliberate release of a GMO (other than its placing

on the market) if (a) such a release under comparable biogeographical conditions has already been approved within the Party's regulatory framework and (b) sufficient experience has already been gained with the release of the GMO in question in comparable ecosystems. Both of these conditions are required before a Party is entitled to rely on this exception.

(i) Such a release under comparable bio-geographical conditions has already been approved within the regulatory framework of the Party concerned; and

Except as otherwise provided for in the national biosafety framework of a Party, a Party may make an exemption to the obligation for a public participation procedure required for decisions on the deliberate release of GMOs, if under comparable biogeographical conditions such a release has already been approved. It is important to note, however, that a relevant release would have had to be performed within the territory of the Party. Any deliberate release that took place in a comparable biogeographical region in a neighbouring country, for instance, would not represent an adequate basis for granting such an exemption.

The wording "comparable biogeographical conditions" should be seen against the background that potential effects of GMOs on the environment depend not only on the type of GMO, but also on the prevailing environmental conditions (e.g., climatic factors, number of generations of target pest, occurrence of non-target organisms, wild relatives, agricultural practices, etc.). Data gained in a field trial with a GMO in a region under a particular set of conditions cannot substitute experimental releases in environments with differing conditions. So any decision to grant an exemption has to be judged on a case-by-case basis and the concept of biogeographical regions may provide basic guidance in this respect.

(ii) Sufficient experience has previously been gained with the release of the GMO in question in comparable ecosystems;

The biosafety frameworks of many countries, and also the EU biosafety framework, provide for so-called simplified or differentiated procedures. The idea behind this is to streamline the regulatory procedures, if sufficient experience has been obtained with the release of a particular type of GMO in particular ecosystems. Consequently, if a GMO notification is subject to a differentiated procedure in a country, but not necessarily only in such cases, paragraph 2 (a) (ii) of annex 1 bis allows for exemptions to the public participation procedure.

What "sufficient experience" means may in practice vary from country to country. As one example, according to EU Directive 2001/18/EC certain criteria, specified in its annex V, have to be met before a proposal for a differentiated procedure can be submitted. According to annex V, for instance, sufficient information on any interaction of particular relevance for the risk assessment needs to be available and the GMO may not present additional or increased risks to human health or the environment under the conditions of the experimental release. Under the Directive, the public has 60 days to comment on the reasoned proposal for the application of a differentiated procedure.

Regulation of public participation in decision-making on GMOs in the EU

In the EU one important legal instrument concerning GMOs is Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. The Directive has been complemented by Commission decisions with guidance notes on risk assessment and monitoring. Additionally, there are relevant EU regulations that are directly applicable in EU member States, for instance, Regulation 1829/2003/EC on genetically modified food and feed. These pieces of legislation also contain provisions on public participation.

Council Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC defines GMO as "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". All EU member States and a number of other ECE member States have passed GMO legislation. Some of them have taken legal measures against the placing on the market of GMOs in recent years, including Austria, France, Greece, Hungary, Luxembourg and Norway.

According to Directive 2001/18/EC "deliberate release means any intentional introduction into the environment of a GMO … for which no specific containment measures are used", whereas "placing on the market means making available to third parties". Consequently, a GMO, by itself or contained in products, must be subject to field testing at the research and developmental stage before it can be considered for placing on the market.

Directive 2001/18/EC mandates human health and environmental impact assessments. Article 4 of the Directive states that "member States shall ensure that all appropriate measures are taken to avoid adverse effects to human health and the environment which might arise from the deliberate release and placing on the market of GMOs". Article 9, though, holds that if member States consider it appropriate they may consult groups or the public on such aspects of the proposed deliberate release. Article 24 foresees a public information and participation procedure also in case of GMO product notifications.

The provisions of Directive 2001/18/EC on public information and public participation regarding GMOs differ depending on the scope of the notification. For a deliberate release of a GMO, an EU member State is required to "consult the public, and where appropriate groups"; whereas, for the placing on the market of a GMO, "the public may make comments to the Commission" on the assessment report provided. In practice, the provisions regarding the deliberate release of GMOs implemented by each member State also differ in detail concerning the public information and participation.

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

(i) It was already approved within the regulatory framework of the Party concerned; or

Authorizations to the placing on the market of GMOs are normally not granted in an unlimited manner, but usually define a period of validity. In Regulation 1829/2003/EC on genetically modified food and feed, for example, it is arranged that consent has to be renewed every 10 years (article 11, para. 1), at the latest one year before the expiry date of the authorization. In cases where an authorization is due to expire and a renewal has been applied for, the GMO amendment to the Aarhus Convention allows for exemptions to the public participation procedure.

(ii) It is intended for research or for culture collections.

The GMO amendment provides for the possibility of exempting GMO notifications from the public participation procedure if they are exclusively used for research purposes or culture collections, in order not to interfere with the principle of freedom of science and research.

For example, the EU Directive 2001/18/EC provides that some operations with GMOs are not regarded as "placing on the market". These, inter alia, concern operations with genetically modified micro-organisms in contained systems regulated under Directive 90/219/EEC (amended by Directive 98/81/EC), including culture collections, as well as making available GMOs other than genetically modified micro-organisms to be used under contained conditions (e.g., greenhouses).

3. Without prejudice to the applicable legislation on confidentiality in accordance with the provisions of article 4, each Party shall make available to the public in an adequate, timely and effective manner a summary of the notification introduced to obtain an authorization for the deliberate release into the environment or the placing on the market of a GMO on its territory, as well as the assessment report where available and in accordance with its national biosafety framework.

A prerequisite for effective public participation is access to information, i.e., the public is provided with the relevant information in a timely manner. As a good practice, "timely" in this respect means that the public is granted sufficient time to deal with the information provided and to develop an opinion about the existing application. As an example of good practice in this respect, the Lucca Guidelines propose that public authorities should encourage potential applicants to enter into discussion with the public concerned and to provide information even before entering the authorization procedure. The Guidelines are consistent in this regard with article 6, paragraph 5, of the Aarhus Convention. Additionally, annex IV of the Lucca Guidelines provides examples concerning the question of how information should be made available, for instance, recommending that information for the public is provided free of charge. Moreover, not only passive access to information (e.g., on a website, in registers), but also active dissemination of information using a variety of media is of importance (e.g., reports, labelling of genetically modified products).

In summary, the information that needs to be available in the course of a participation procedure should include information on the content of the notification (see also annex I bis, para. 4 (a)–(c)), as well as procedural information (see annex I bis, para. 5 (i) (v)). The Aarhus Convention is not very explicit as to what constitutes GMO information, thus the GMO amendment provides a more concrete interpretation. The two most important elements of such information are mentioned in paragraph 3 of annex I bis: the summary of the notification and the assessment report.

By way of example, in the EU, the content of the summary of the notifications — the so-called summary notification information format — is clearly defined in two Commission decisions, for the placing on the market of GMOs themselves or in products and for the deliberate release of GMOs, respectively. The Lucca Guidelines recommend that a non-technical summary be made available to the public, in order to assist the public's understanding of the matter.

In general, the assessment report is based on the scientific evaluations of the intended use of the GMOs, and includes an environmental risk assessment (ERA), a food safety evaluation, etc. Where the competent authorities do not compile the assessment report themselves, they generally rely (as much as possible) on the respective assessment reports compiled by regulatory experts or scientific committees when reaching a decision.

While in EU Directive 2001/18/EC the term "assessment report" is used, Regulation EC/1829/2003 refers to the "opinion of the Authority", i.e., EFSA. According to the Regulation, the placing on the market of genetically modified food and feed is governed by a community-wide procedure. The task of compiling an assessment report, or "overall opinion", according to the Regulation, is assigned to EFSA while the decision-making rests with the member States on the basis of a proposal for a Council decision presented by the European Commission. The EFSA overall opinion contains the scientific opinion of the EFSA GMO panel and, in the case of applications which cover the cultivation of a genetically modified plant, also the ERA by the national competent authority assigned by EFSA to conduct it according to article 6, paragraph 3 (c), of Regulation EC/1829/2003.

4. Parties shall in no case consider the following information as confidential:

It is common practice under many countries' regulatory frameworks that certain commercial and industrial information, the disclosure of which may harm a company or research institution's competitive position, may be treated as confidential. However, in the same manner as article 4, paragraph (4) (d), of the Convention requires information on emissions relevant for the protection of the environment to always be disclosed, paragraph 4 of annex I bis lists certain information which can never be kept confidential.

Paragraph 4 of article 25 of Directive 2001/18/EC lists certain pieces of information that must never be regarded as confidential. Together with article 6, paragraphs 2 and 6, of the Aarhus Convention and annex III of the Lucca Guidelines, the Directive 2001/18/EC provisions served as a model for paragraph 4 (a)–(c) of annex I bis of the GMO amendment to the Aarhus Convention (see below).

It should be noted that each of the provisions referred to in the previous paragraph depict minimum requirements for information that has to be made public in the course of a public participation

procedure. In a number of EU countries, e.g. Austria and the Czech Republic, it is common practice to disclose the whole notification except for its confidential parts.

(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:

Here the basic pieces of information are mentioned which ought to be communicated to the public in an early and effective manner during an environmental decision-making procedure. This includes, first of all, a description of the GMO and the name and address of the applicant responsible for proposed activity with the GMO. Moreover, the intended use of the GMO, i.e., the scope of the notification, needs to be part of this information. If the GMO in question is intended to be deliberately released for research purposes, the location of the release should also be made public. Depending on the legal and administrative practice in a country the term “location” may be interpreted with different degrees of detail or precision. In the 2009 case of Commune de Sausheim v. Pierre Azelvandre, the ECJ held that the requirement in article 25, paragraph 4, of Directive 2001/18/EC not to keep confidential the location of the release meant that the disclosure of the information concerning the specific location of the site of the release, including grid reference, is mandatory. Exemptions relating to public order or other interests are not allowed.

To know where a certain type of GMO is grown is essential for the monitoring of GMOs, such as that required under articles 19 and 20 of Directive 2001/18/EC. According to article 31, paragraph 3, of that Directive, member States are required to establish public registers not only to record the locations of deliberate releases of GMOs, but also to record the locations of GMOs grown commercially “in the manner deemed appropriate to the competent authority”. In Austria, for example, the local community in which a GMO product may be cultivated has to give notice of the cultivation to the national competent authority, which is obliged to maintain this information in a register.

(b) The methods and plans for monitoring the genetically modified organism or organisms concerned and for emergency response;

Methods and plans for monitoring of potential adverse effects resulting from the activities specified in annex I, as well as emergency response plans, cannot be kept confidential.

As noted in Directive 2001/18/EC, monitoring helps both to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the ERA is correct, and also to identify the occurrence of adverse effects of the GMO or its use on human health or the environment that were not anticipated in the ERA.

(c) The environmental risk assessment.

Here, the GMO amendment substantiates the provision of article 6, paragraph 6, of the Aarhus Convention with regard to GMOs. The disclosure of the ERA to the public guarantees that the public is provided with extensive information on all environmental aspects associated with the proposed activity concerning the GMO in question.

There might be a lack of clarity regarding the question what the term ERA means in practice. The EU, for instance, defines ERA as "the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose" (Directive 2001/18/EC, article 2, para. 8). With the principles laid down in Directive 2001/18/EC and the legally binding Guidance Notes on risk assessment, the EU has established a common methodology for carrying out the ERA of GMOs. In 2010 EFSA published updated guidance for the ERA of genetically modified plants.

5. Each Party shall ensure transparency of decision-making procedures and provide access to the relevant procedural information to the public. This information could include for example:

(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.

Besides information on the content of the GMO notification (see annex I bis, paras. 3 and 4), the public has to be provided with information on the envisaged environmental decision-making procedure. The annex refers to "the public" generally, rather than using the narrower term "the public concerned", which is used in article 6, paragraph 2, of the Convention. By using the term "the public", Parties to the Convention recognize that the mobility of GMOs, including when they are placed on the market, means that it is not possible to identify a discrete subsection of the public as the "public concerned".

First of all, the public authority responsible for the decision-making should find effective means to inform the public about the proposed activity with GMOs by public notice (e.g., in an appropriate national, regional or local newspaper; in the official government gazette; on their Internet site; via any existing clearing-house mechanism, etc.). From this information it should be clear to the public what kind of activity with GMOs is submitted for decision and what types of decisions may be made (para. 5 (i)), and which public authority is responsible for taking the decision (para. 5 (ii)). Moreover, it is important that the public is made aware of their rights and opportunities to participate in the decision-making process. Therefore, such a public notice should also contain information on the envisaged process according to the provisions of national legislation (para. 5 (iii)), for instance, the start of the procedure, any time limits for public consultation and any opportunities for participation (e.g., time and venue of a public hearing). Another very important piece of information for the public is the indication of the public authority or any other official body from which relevant information can be obtained from (para. 5 (iv)). Relevant information may include not only information on the notification, but also any other information that may be relevant

in this respect (e.g., reports and advice issued by expert committees or advisory bodies, international and national legislation and policy documents, etc.). The obligations of public authorities to collect and disseminate further information on GMO activities (e.g., in registers, databases and reports) are addressed. Last but not least, the public should be informed about the public authority to which comments or questions can be submitted and the respective time schedule and modalities for doing so (para. 5 (v)). The public's right to submit comments is addressed further in paragraph 6 of annex I bis.

6. The provisions made 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.

Paragraph 6 states that a public authority has to ensure the possibility for proper input from the public. In keeping with article 6, paragraph 7, of the Convention, the annex gives this right to the public generally, rather than the narrower "public concerned". Not only written comments are to be taken into account by the public authority, but, for instance, also oral questions and opinions put forward at a public hearing or enquiry. Attention should be paid to any point raised in the course of the public participation procedure (see the commentary to article 6, paragraph 7, and in particular the discussion of the Compliance Committee's findings in ACCC/C/2006/16 (Lithuania) above). In Norway, the relevant legislation expressly provides for ethical considerations to be taken into account in decisions on activities with GMOs.

Regarding good practices in this area, the Lucca Guidelines encourage public authorities to explore other mechanisms and measures, including consensus conferences, round-table discussions, stakeholder dialogues and citizens' juries on issues relating to, for example, the risk assessment and risk management of GMOs, in order to improve public knowledge, public participation and awareness of activities involving GMOs.

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

Paragraph 7 requires the competent authority to take due account of the outcome of the public participation procedure in taking the final decision on a GMO notification. For a more general discussion of what is meant by taking "due account" of the outcome of the public participation procedure, see the commentary to article 6, paragraph 8, above.

8. Parties shall provide that when a decision subject to the provisions of this annex has been taken by a public authority, the text of the decision is made publicly available along with the reasons and considerations upon which it is based.

This paragraph is consistent with article 6, paragraph 9, of the Convention. Accordingly, each Party has to make sure that the text of the final decision and the reasons and considerations on which it is based are made publicly available, for instance, at a public building and on the Internet.

Additionally, the decision should contain a description of how due account has been taken of the outcome of the public participation procedure.

In the Netherlands, the public may make comments on a draft decision prior to its being finalized. Comments by the public have to be answered individually and are taken into account in the final decision. The entire process is available to the public on the Internet.

V. Extract from the Maastricht Recommendations on Promoting Effective public Participation in Decision-making in Environmental Matters (the Maastricht Recommendations, ECE/MP.PP/2014/2/Add.2)[2]

M. Public participation in decision-making regarding genetically modified organisms (article 6, paragraph 11, and article 6 bis)

145. The recommendations regarding article 6 should be applied mutatis mutandis and as appropriate to public participation in decision-making regarding genetically modified organism (GMOs) under article 6, paragraph 11, and article 6 bis.

146. In order to ensure effective public participation, it is recommended as a good practice that the provisions of article 6bis should be applied not only to decisions on whether to permit the deliberate release into the environment and placing on the market of GMOs but also, as appropriate, to decisions regarding the contained use of GMOs.

147. When designing and implementing the regulatory framework to facilitate public participation in decision-making regarding GMOs, it should be recalled that the exemptions listed in annex I bis to the Convention are not mandatory and may be incorporated into the regulatory framework, or not, on a discretionary basis.

148. The public may 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.

149. As a good practice, in order to improve public awareness and participation regarding GMOs, in addition to public hearings or public inquiries, other mechanisms that allow the public to be heard, for example round-table discussions, consultative bodies involving members of the public, stakeholder dialogues and citizens' juries, among others, may be considered.

150. Attention should be given to ensuring that measures to promote public participation in decision-making regarding GMOs within the context of article 6, paragraph 11, and article 6 bis are in line with relevant elements of the national biosafety framework and further the implementation of article 23 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

[2] Numbering of paragraphs follows the original document

VI. Extract from the Cartagena Protocol on Biosafety[3]

A. Article 23 and other relevant articles under the Cartagena Protocol on Biosafety

Article 1

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Article 3

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;
(i) "Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. 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;

Article 20

Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:
(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;
(b) Any bilateral, regional and multilateral agreements and arrangements;
(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;
(d) Its final decisions regarding the importation or release of living modified organisms; and
(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

Article 21

Paragraph 5

[3] Numbering of paragraphs follows the original document

If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

Paragraph 6
Without prejudice to paragraph 5 above, the following information shall not be considered confidential:
(a) The name and address of the notifier;
(b) A general description of the living modified organism or organisms;
(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
(d) Any methods and plans for emergency response.

Article 23
Paragraph 1
Public Awareness and Participation
The Parties shall:
(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

Paragraph 2
The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

Paragraph 3
Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

B. Decisions by the Meeting of the Parties

Decision BS-V/13

Paragraph 1

Adopts the programme of work on public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms, as contained in the annex to the present decision, to facilitate implementation of Article 23 of the Protocol;
The Conference of the Parties serving as the meeting of the Parties to the Protocol invited Parties, other Governments and relevant organizations, as appropriate, to make use of the Programme of Work and share their experiences and lessons learned through the Biosafety Clearing-House, and decided to review the Programme of Work at its eighth meeting in the light of experiences gained by Parties.

Paragraph 3
Underlines the importance of ensuring coherence among the programme of work and relevant activities of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters and other relevant conventions and organisations to maximize opportunities for cooperation in the promotion of public awareness, education and participation concerning living modified organisms.

Paragraph 4
Decides, in the light of experiences gained by the Parties, to review the programme of work at its eighth meeting, within the available resources.

Paragraph 5
Urges developed country Parties and other Governments and relevant organizations to provide additional support to developing country Parties and Parties with economies in transition to implement relevant activities contained in the programme of work.

C. Documents and the Priority Areas/Activities of the Programme of Work for the eighth meeting of the Parties

Official Documents
UNEP/CBD/BS/COP-MOP/8/15
Public Awareness, Education and Participation (Article 23)
https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-15-en.pdf

Informal Documents

UNEP/CBD/BS/COP-MOP/8/INF/9
Reports of the two joint Aarhus Convention/CBD round tables on public awareness, access to information and public participation regarding living modified organisms and genetically modified organisms

UNEP/CBD/BS/COP-MOP/8/INF/10
Summaries and recommendations of online discussions on public participation and access to information on living modified organisms

UNEP/CBD/BS/COP-MOP/8/INF/11

Capacity-building workshops on public awareness, education and participation concerning living modified organisms

https://www.cbd.int/doc/?meeting=MOP-08