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MEETING OF THE SUB-WORKING GROUPS OF THE AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY
Bonn, 13-15 February 2012

REPORT OF THE MEETING

INTRODUCTION

1. At their fifth meeting, the Parties to the Cartagena Protocol on Biosafety (henceforth "the Protocol") decided to extend the ongoing Open-ended Online Expert Forum and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management with the view to achieving the following expected outcomes:[1]

(a) A revised version of the "Guidance on Risk Assessment of Living Modified Organisms";

(b) A mechanism, including criteria, for future updates of the lists of background materials;

(c) Further guidance on new specific topics of risk assessment, selected on the basis of the priorities and needs by the Parties and taking into account the topics identified in the previous inter-sessional period.

2. The AHTEG, at its third meeting, held in Mexico City from 30 May to 3 June 2011,[2] in discussing the expected outcome (c) above and based on a priority-setting process by Parties, agreed to establish two Sub-Working Groups (SWGs) to develop guidance on:

(a) Monitoring of living modified organisms released into the environment; and

(b) Risk assessment of living modified trees.

3. Following the generous offer by the Government of Germany to host a meeting of the SWGs and the kind offer of financial support from the Government of Norway, the Meeting of the Sub-Working Groups of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management was held in Bonn from 13 to 15 February 2012. The objective of the meeting was to advance the work of the SWGs on the two draft guidance documents with a view to reaching advance drafts to be used as a basis for online discussions under the Open-ended Online Forum in preparation for the fourth meeting of the AHTEG.

[1] Decision BS-V/12 available at http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=12325.

[2] Report available at http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4736.

/…

4. Thirteen participants from Parties (Austria, China, Croatia, Cuba, Egypt, Germany, Malaysia, Mexico, Netherlands, Niger, Nigeria, Norway and Republic of Moldova), as well as two observers from non-Parties (Canada and United States of America) and four observers from organizations (Bayer CropScience, Federation of German Scientists, Public Research and Regulation Initiative, and University of Canterbury) attended the meeting. The list of participants is attached hereto as annex I.

ITEM 1. OPENING OF THE MEETING

5. The meeting was opened at 9 a.m. on 13 February 2012 by Mr. Albert Herberg, Director of the German Federal Agency for Nature Conservation. In his opening remarks, Mr. Herberg welcomed the participants to Bonn and noted the importance of the guidance on "monitoring" and "living modified trees" as tools for achieving the objective of the Protocol and in accordance with the precautionary approach.

6. The Chair of the AHTEG, Mr. Helmut Gaugitsch, expressed his appreciation to all members of the AHTEG for their commitment and active input into the development of the guidance documents since the last meeting of the Group.

7. The Secretariat of the Convention on Biological Diversity, represented by the Head of the Biosafety Division, Mr. Charles Gbedemah, thanked the Governments of Germany and Norway for their specific provisions for the meeting and their continued support for the Protocol, in particular the process for elaborating on risk assessment and management issues under the international instrument.

ITEM 2. ORGANIZATIONAL MATTERS

2.1. Adoption of the agenda

8. The provisional agenda for the meeting (UNEP/CBD/BS/AHTEG-RA&RM/SWGs/1/1) was adopted without amendment.

2.2. Organization of work

9. The organization of work as proposed in the annex to the annotated provisional agenda for the meeting (UNEP/CBD/BS/AHTEG-RA&RM/SWGs/1/1/Add.1) was also adopted without amendment.

ITEM 3. SUBSTANTIVE ISSUES

10. In introducing this agenda item, the AHTEG Chair invited Mr. Charles Gbedemah to explain the rules of procedure for the AHTEG process. Recalling decision BS-IV/11, Mr. Gbedemah reiterated the mandate as stated in the decision by the Parties to the Protocol that the AHTEG included observers in accordance with the rules of procedure for meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol. He explained that members of the Group could refer to the two publications distributed earlier via email for further information on the participation of observers, i.e., the "Rules, Procedures and Mechanisms Applicable to Processes under the Cartagena Protocol on Biosafety"[3] and the "Guidelines for the Participation of Representatives of Observer Organizations at Meetings of the Conference of the Parties of the Convention on Biological Diversity and its Subsidiary Bodies".[4] Mr. Gbedemah further noted that, as stated in the report of its second meeting, the AHTEG was a multi-

[3] Available at http://bch.cbd.int/database/attachment/?id=10674.

[4] Available at http://www.cbd.int/doc/meetings/abs/icnp-01/other/icnp-01-guidelines-observer-en.pdf.

stakeholder consultative process led by the Parties and that the guidance documents produced by the Group must ultimately reflect the views of the Parties as taken from the body of knowledge put at their disposal and considered on the basis of its substantive merit. While the AHTEG would endeavour to reach consensus among its members from Parties, in cases where no consensus could be reached, the different views of the Parties would be reflected in the guidance document.

11. The AHTEG Chair explained that the fourth version of the draft guidance documents on "monitoring" and "trees" (version of 6 February 2012), respectively, which were developed by the AHTEG SWGs Chairs in consultation with the respective SWGs taking into account the input from the Open-ended Online Forum, and circulated by the Chairs of the SWGs prior to the meeting, would form the basis for deliberations during the meeting.

12. In an initial round of discussions, the AHTEG Chair invited participants to share their overall views on the two draft guidance documents. During the general discussions, issues that emerged were later taken up in more in-depth discussions, as appropriate.

3.1 Further development of the guidance on "Monitoring of Living Modified Organisms Released into the Environment"

13. Sessions under this agenda item were chaired by the Chair of the Sub-Working Group on Monitoring, Mr. David Quist. He explained how the process of developing the guidance on monitoring had been undertaken to date in collaboration with participants of the Open-ended Forum.

14. Mr. Quist invited participants to share their views on how to improve the draft of the document on monitoring. Participants commented on each section of the document, how they could be restructured or reformulated, and provided concrete text proposals for improving the draft. Mr. Quist further invited participants to share their views on the usefulness of including a graphical representation of the monitoring process and a table with various examples of monitoring as annexed to the guidance. Several participants were of the view that such annexes would be useful.

15. After intensive discussions during the first two days of the meeting and completion of the first reading of the document, the SWG Chair, in consultation with the AHTEG Chair and the Secretariat, prepared a revised draft which attempted, as appropriate, to incorporate all views and comments of members of the AHTEG. This revised draft was distributed to participants of the meeting for follow-up discussions.

16. Participants welcomed the new draft version and noted that it embodied significant improvements in reflecting earlier discussions. The SWG Chair further invited participants to turn to the text document and to provide their feedback. To the extent possible and with a view to further improving the document, participants were invited to make specific comments in the form of concrete textual proposals to the document. At this point, the SWG Chair noted that, in view of the limited time, the annexes to the document had not been revised but that this would be done after the meeting, taking into account earlier discussions. The second reading of the draft guidance on monitoring was concluded in the night of the last day of the meeting.

17. The SWG Chair explained that, in collaboration with the AHTEG Chair and Secretariat, he would prepare a revised advance draft of the document to be used as a basis for online discussions under the Open-ended Online Forum planned to take place between 27 February and 11 March 2012. The resulting advance draft of the guidance on "Monitoring of Living Modified Organisms Released into the Environment" is attached hereto as annex II.

3.2. Further development of the guidance on "Risk Assessment of Living Modified Trees"

18. Sessions under this agenda item were chaired by the Chair of the Sub-Working Group on Living Modified (LM) Trees, Ms. Beatrix Tappeser. She introduced the draft guidance document on "Risk Assessment of LM Trees" and highlighted the main issues that emerged during the online discussions.

19. The SWG Chair invited participants to share their views on how to improve the draft document. After completion of the first reading, the SWG Chair in consultation with the AHTEG Chair and Secretariat prepared a revised advance draft document which was circulated among the participants of the meeting.

20. The SWG Chair explained that because of the limited time available, this revised draft would not be open for discussion at the meeting, but invited AHTEG members to take active part in the upcoming discussions under the Open-ended Online Forum.

21. The revised advance draft of the guidance on "Risk Assessment of Living Modified Trees" is attached hereto as annex III.

ITEM 4. OTHER MATTERS

22. Under this agenda item, the AHTEG Chair invited participants to indicate their availability for the fourth meeting of the AHTEG proposed for either in the week of 4 June or the week of 11 June 2012, in Montreal. In view of the significant number of participants that were available in the week of 4 June 2012, this option, 4 to 8 June 2012, was adopted as the date for the fourth meeting of the AHTEG.

23. A revised calendar of activities under the Open-ended Online Forum and AHTEG process, developed by the AHTEG Chair in collaboration with the AHTEG Bureau and the Secretariat, was distributed during the meeting. The revised calendar includes a timeline for tentative activities towards the achievement of the expected outcomes set out in decision BS-V/12 for consideration by the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol to be held in October 2012.

24. The revised calendar of activities is attached to this report as annex IV below.

ITEM 5. CLOSURE OF THE MEETING

25. The meeting was closed at 9.30 p.m. on Wednesday, 15 February 2012.

Annex I

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Annex II

MONITORING OF LIVING MODIFIED ORGANISMS RELEASED INTO THE ENVIRONMENT

Version of 22 February 2012

INTRODUCTION

This document complements and builds on the Roadmap for Risk Assessment of Living Modified Organisms.

In the context of this guidance, monitoring of LMOs refers to the systematic observation, collection, and analysis of data undertaken based on the risk assessment and following the release of an LMO into the environment, and in accordance with the objective of the Protocol.[5]

In the context of paragraph 8(f) of Annex III, which states that "where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment". As such, monitoring is one of the possibilities to reduce uncertainty related to the level of risk of an LMO. In accordance with the terms of reference for the AHTEG, this document provides guidance on "monitoring of the long-term effects of living modified organisms released in the environment".[6] In addition, recognizing the importance of in situ conservation, Parties to the Protocol may consider monitoring within the broader context of the provisions of Article 7, "Identification and Monitoring", of the Convention of Biological Diversity (CBD) (e.g., monitoring of protected areas or keystone species).[7] Article 16 of the Protocol and, in particular, paragraphs 2 and 4 may be relevant with respect to the implementation of monitoring.

Monitoring may help detect changes related to adverse effects, in a timely manner, before the consequences are realized, and inform the need for appropriate response measures (e.g., changes to risk management strategies, emergency response measures, a new risk assessment, or re-evaluation of prior decisions).

OBJECTIVE AND SCOPE

The present document aims at providing conceptual, science-based and practical guidance for monitoring changes that could be related to adverse effects of LMOs released into the environment and that could affect the conservation and sustainable use of biological diversity, taking into account risks to human health. This guidance may be applicable to all classes of LMOs, and scales of release into the environment (e.g., small- and large-scale releases).

Monitoring of potential adverse effects to human health in the context of environmental risk assessment is considered under this guidance (e.g., inhalation of pollen from LM plants).

Issues related to the decision as to whether or not monitoring should be implemented, or who bears the responsibility for its implementation and associated costs, are not addressed in this document.

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[5] See Article 1 of the Protocol.

[6] COP-MOP decision BS-IV/11 (http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=11690).

[7] See article 7(a) to (d).

MONITORING AND ITS PURPOSES

Monitoring can be done in a case-specific manner to address questions and uncertainties related to level of risk identified in a risk assessment. When recommended in step 5 of the Roadmap, the case-specific monitoring reflects the considerations in the earlier steps of the risk assessment and the considerations on uncertainty with regard to the overall risk of the LMO.

The implementation of case-specific monitoring in conjunction with an approved release may provide observational data about specific effects of the LMO on relevant components of the ecosystem.

Case-specific monitoring of the environmental release may be done for different purposes, depending on the type (e.g., experimental or commercial), duration (e.g., short- or long-term) and scale (e.g., small- and large-scale) of release, as well as on uncertainties regarding the level of risk or its management:

• *Monitoring during experimental, short-term and/or small-scale environmental releases*

Monitoring can generate data during experimental, short-term and small-scale releases in order to provide supporting data for future risks assessments that may involve a larger scale of release of the same LMO. When environmental releases of an LMO are conducted in a step-wise manner, monitoring at smaller scales may increase the scientific strength or certainty of risk assessments for subsequent larger scale releases.

• *Monitoring during long-term and/or large-scale environmental releases*

During long-term and large-scale releases of an LMO (e.g., for commercial purposes), monitoring may be conducted in order to address remaining uncertainties identified in the risk assessment, or to confirm that conclusions of the risk assessment are accurate once the environmental release has taken place.

• *Monitoring to evaluate the efficacy of specific risk management strategies*

In cases where risk management strategies are implemented along with an environmental release, monitoring may be used to evaluate the effectiveness of these risk management strategies.

Another type of a case-specific monitoring may be undertaken to detect changes related to potential adverse effects that were identified but not addressed in the risk assessment (e.g., effects such as long-term, tri-trophic, cumulative, as well as changes to management practices and effects to human health).

Broader environmental monitoring for unanticipated adverse effects that were not identified in the risk assessment may be conducted to address more general questions related to the conservation and sustainable use of biological diversity, taking into account risks to human health. Monitoring for unanticipated effects starts with general observations of changes in indicators and parameters, which are often defined within national protection goals, and that could be related to adverse effects. Should monitoring for unanticipated adverse effects that were not identified in the risk assessment detect changes that could be related to an adverse effect, a more specific hypothesis may be formulated to establish a causal relationship between the LMO(s) and the adverse effect, and be followed up by case-specific monitoring or further research. When monitoring for unanticipated adverse effects that were not identified in the risk assessment, programmes already established for the surveillance of broader protection goals may be used in order for the monitoring to be more cost-effective.

Annex 1 provides a diagram outlining the purposes of monitoring in the risk assessment process under the Protocol.

DEVELOPMENT OF A MONITORING PLAN

A monitoring plan is developed when the recommendation of a risk assessment and/or the national biosafety policy calls for monitoring activities to be carried out in conjunction with the environmental release of the LMO. In such cases, the competent authority(ies) or the entity responsible for the risk assessment may outline the requirements of the monitoring strategy (including the reporting of monitoring data). The monitoring plan should be transparent, of scientific quality and presented in sufficient detail so that the relevance of the data can be appraised.[8]

If the monitoring plan is to be developed by the notifier, it may be evaluated by the competent national authority and may be subject to modification before a decision for release is granted. It is important to consider that the proposed monitoring activities should be commensurate with the uncertainty regarding the level of risk posed by the LMO under consideration.[9]

Information relevant for developing the monitoring plan may be available from the risk assessment and, if applicable, from previous monitoring activities, including those from other countries. For example, the choice of protection goals, as well as of indicators and parameters, may often be derived from the context and scoping phase of the risk assessment (See Roadmap, "Setting the context and scope"). The scientific and technical details of the specific LMO, including detection methods, would be available from the information required for conducting the risk assessment as outlined in Annex III.[10]

This guidance focuses on the development of a monitoring plan to address uncertainty regarding the level of risk of an LMO in the context of (i) the results and recommendations of the risk assessment, including adverse effects that were identified but not addressed in the risk assessment and (ii) unanticipated adverse effects that were not identified in the risk assessment. When both types are to be undertaken, separate plans may be developed. When developing (or evaluating) a monitoring plan, the following may be considered:

1. Description of how monitoring data would address the uncertainty regarding the level of risk of an LMO ("why monitor?");

2. Choice of indicators and parameters for monitoring ("what to monitor?");

3. Monitoring methods, including the establishment of baselines and the duration of monitoring ("how to monitor?");

4. Monitoring sites and regions ("where to monitor?");

5. Reporting of monitoring results ("how to communicate?").

The sections below address these issues in terms of rationales and points to consider.

1. Description of how monitoring data would address the uncertainty regarding the level of risk of an LMO ("why monitor?")

Rationale:

The monitoring plan may differ according to the uncertainties regarding the level of risk of an LMO, including (i) risks that were identified but either not addressed or resolved in the risk assessment, as well

[8] See Roadmap "Overarching issues", "Quality and relevance of information".

[9] See Roadmap "Overarching issues", " Identification and consideration of uncertainty".

[10] See Annex III paragraph 9 (a through h).

as monitoring of the efficacy of risk management measures, and (ii) risks that were not identified in the risk assessment and, therefore, related to unanticipated adverse effects. The monitoring plan should be described in such a way that it will contribute to achieving its expected outcomes.

Points to consider:

a. Uncertainties regarding the level of risk of the LMO;

b. Identified causal pathways from the LMO to potential adverse effects, if applicable, in relation to the risk hypothesis;

c. Uncertainties related to the duration and scale of the release;

d. Uncertainties related to the effectiveness of the implementation of risk management measures.

2. Choice of indicators and parameters for monitoring ("what to monitor?")

Rationale:

The selection of indicators and parameters to be monitored will vary from case to case, depending on the LMO, characteristics of the receiving environment, specific risk scenarios established during the risk assessment (see the Roadmap), and on the protection goals and biosafety legislation or policies of each country.

The indicators (e.g., species, populations, groups of species, environmental processes, etc.) and parameters (i.e., a component to be measured in the observation of an indicator) chosen are ideally those that can reliably signal potential adverse effects and address uncertainties in the level of risks.

Annex 2 provides examples of indicators and parameters that may be part of a monitoring plan.

Points to consider:

a. The potential of the indicators and parameters to signal potential adverse effects, in particular, before the consequences are realized;

b. Characteristics of the indicators, as well as the distribution and abundance of those indicators that are species and, if applicable, their level of exposure to the LMO;

c. Variability of the parameters to be measured;

d. The usefulness of the chosen indicators and parameters to establish relevant baselines, including reference points;

e. The importance of the indicators and parameters to relevant key ecological processes and functions or to the identified protection goals;

f. Whether sampling and analysis would be easy or difficult and how these would affect the choice of indicators and parameter.

3. Monitoring methods, baselines and duration of monitoring ("how to monitor?")

a) Selecting monitoring methods

Rationale:

Monitoring methods are largely dependent on the indicators and parameters chosen in the preceding step and their ability to address uncertainty regarding the level of risk and to signal adverse effects. The

selection of monitoring methods should also take into account their level of sensitivity and specificity needed to detect changes in the indicators and parameters.

The description of the monitoring methodology includes the means for sampling and observing indicators and parameters, and analysing the resulting data. Appropriate methods, observations, descriptive studies, or questionnaires may be useful in the collection of data for monitoring, including questionnaires addressed to those who are exposed to the LMO. For ecological issues, or effects occurring outside of the receiving environment, additional knowledge and tools may be required to gather relevant data.

Harmonization of methods, data formats, and analytical approaches facilitates the comparison of results from monitoring. When the use of existing monitoring networks is to be considered, the monitoring plan should specify the criteria for their selection and utilization.

Points to consider:

a. Relevance of the monitoring methodology to generate information to address uncertainty related to the level of risk;

b. The nature of the effect to be monitored (e.g., whether short- or long-term, delayed or indirect, cumulative, etc.);

c. Relevance, suitability and adaptability of existing broader monitoring schemes, as well as the accessibility to those data, in the context of broader environmental monitoring for unanticipated adverse effects that were not identified in the risk assessment;

d. The specification of the ranges or degrees of changes in a parameter or indicator to signal an adverse effect;

e. The scientific quality of the sampling, analytical and statistical methods to be employed;[11]

f. The availability of relevant standardized methods, and whether and how these could be taken into account;

g. Whether methods are adequate to meet the objectives of the proposed monitoring plan;

h. The use of descriptive studies or questionnaires, taking into account their replicability and verifiability;

i. Findings of the ongoing and/or other monitoring activities, if relevant;

j. Relevant local, regional and international monitoring practices.

b) Establishing baselines, including reference points

The establishment of relevant baselines, including reference points, is necessary for observing and analysing changes during monitoring. In practice, the baseline is a measurement of the relevant indicators and parameters in the likely potential receiving environment, or in a comparable environment. Therefore, the baseline should be described in the monitoring methodology in order to verify that it accurately represents the environment where the LMO will be released. Natural and human induced variation that may occur in baseline data should be taken into account when analysing monitoring data.

[11] See also considerations on "Quality and relevance of information" in the Roadmap.

Points to consider:

a. The scientific quality of methods used for generating baseline data;

b. The appropriate spatial scale over which to establish the baseline;

c. Effects of temporal and spatial variation (i.e., human induced or natural variation);

d. The scale of potential spread of the LMO.

c) Establishing the duration of monitoring

Rationale:

The duration of the monitoring, including the frequency of observations necessary, is chosen on a case-by-case basis and will depend on the type of adverse effects that are to be monitored (e.g., immediate or delayed, short- or long-term), type of LMO (e.g., short or long life cycles,[12] transgenic traits introduced), or duration of proposed environmental release. The duration of monitoring may be changed, if appropriate, on the basis of the results of ongoing monitoring activities.

Points to consider:

a. The duration necessary for changes in a parameter related to the adverse effects to likely become apparent;

b. Life-cycle and generation time of species to be used as indicators;

c. Life-cycle and generation time of the LMO as being used in the environment;

d. Whether variability in the monitored parameters over time could affect the results of the monitoring;

e. Potential for environmental changes.

4. Choice of monitoring sites ("where to monitor?")

Rationale:

Monitoring sites are selected on a case-by-case basis depending on the parameters and indicators that will be used in the monitoring and the likely potential receiving environment, as well as the intended use of the LMO, and taking into account the associated management practices. The likely potential receiving environment may include areas that extend beyond the intended receiving environment where the LMO may be introduced.

Relevant information regarding the sites to be monitored include, for example, specific locations, their size and relevant environmental characteristics.

Points to consider:

a. Dissemination and establishment of the LMO in the likely potential receiving environment;

b. The type of LMO as well as indicators and parameters to be monitored and, in case of indicator species, their biological or ecological characteristics and life cycles;

[12] See Article 16(4) of the Protocol.

c. Appraisal of suitable, relevant reference sites where the LMO is not present for a comparison over the duration of the monitoring, if applicable;

d. Pathways through which the environment is likely to be exposed to the LMO(s);

e. The distribution patterns, including seasonal distribution (e.g., migration), of the selected indicator species in the receiving environment for consistent detection and observation;

f. Appraisal of protected areas and centres of origin and genetic diversity or ecologically sensitive regions, particularly in the context of monitoring the presence of LMOs;

g. The appropriate number of monitoring sites sufficient to support meaningful statistical analysis;

h. The continued availability of the monitoring sites throughout the duration of monitoring;

i. Current management practices and possible changes to those practices over the duration of monitoring.

5. Reporting of monitoring results ("how to communicate?")

Rationale:

Reporting of monitoring results serves four main objectives: (i) to inform competent authorities of any changes that could be related to adverse effects, (ii) to provide feedback as to whether the monitoring activities have been carried out in a manner that meets the intended objectives set out in the monitoring plan, (iii) to indicate, if appropriate, the need for changes to the monitoring strategy and/or other risk management strategies (or for follow-up studies or risk assessments), and (iv) to recommend, if appropriate, the re-evaluation of a decision and the necessity of any emergency measures.

The reporting of monitoring activities may be communicated in different forms depending on the target audience. Since monitoring is both a scientific and regulatory activity, the report should clearly describe how the scientific results relate to the original regulatory need for monitoring. From the report, the regulatory authority should be able to interpret the results and decide whether or not a specific action is required.

Points to consider:

a. Reporting requirements set out by the competent authority(ies) or in national biosafety regulations, if available;

b. The completeness of the report, including transparency in presentation of methods, data and analytical tools used to draw conclusions;

c. Accessibility to raw data accrued during the monitoring activities, taking into account information that may be confidential.[13]

CHALLENGES IN THE IMPLEMENTATION OF A MONITORING STRATEGY

In the development (or evaluation) of a monitoring plan, it may become apparent that resource limitations or technical and scientific challenges may affect its effective implementation. Therefore, an analysis of the capacities and resources, human and financial, helps to ensure the maintenance and completion of the proposed monitoring strategy. Amendments to the strategy may be required in some cases to ensure the monitoring strategy is efficient and cost-effective in relation to monitoring needs and expected outcomes.

[13] See Article 21 of the Protocol.

Because changes or effects observed through monitoring may be a consequence of complex interactions of various biological and non-biological factors within the environment, it is essential that the monitoring activities are designed in a way to give meaningful information towards determining whether the observed effects and an LMO have a causal link (which may require further monitoring information or data).

Examples of challenges that may be encountered during the implementation of monitoring may include (i) lack of capacity for the establishment of robust detection or identification methodologies, (ii) determination of cause-effect relationships (causalities) between the LMO(s) and observed changes in the indicator(s) or parameter(s); and (iii) the interpretation of monitoring results and relating them to further specific actions.

Annex 1

[Add graphic representation of the revised text]

Annex 2

EXAMPLES OF MONITORING IN RELATION TO PROTECTION GOALS/OBJECTIVES[14]

Objectives	Indicator(s)/Parameter(s)	Example(s) of monitoring
Reduction of levels of significant uncertainty of potential effects identified in the RA	Target organisms, non-target organisms, environmental parameters, etc.	• Confirming host-range effects of target transgenic proteins, resistance development • Confirming exposure routes or levels, if not maximized in the considerations of the risk assessment (worst case approach)
Impact on assessment endpoints or related indicators identified and evaluated in the RA	Target organisms, non-target organisms, environmental parameters, etc.	• Presence and population levels of key selected NTOs • Food web and predator/prey interactions of key selected NTOs at different trophic levels
Confirmation of *in vivo* exposure levels	Non-target organisms, etc.	• Direct or indirect uptake/exposure of NTOs to transgenic pesticidal proteins • Existence of weed species in herbicide tolerant (HT) fields • Accumulation of transgenic products in the soil
Impact on production systems in relation to sustainability	Functional organisms, key environmental services, etc.	• Pollination impacts • Pest control efficacy
Monitoring for scale-dependent effects	Wild and weedy relatives, HGT candidates	• Persistence of DNA or transgenic products in the soil • Frequency of gene transfer potential
Efficacy of risk management strategies	Weed populations, resistance development	• Efficacy of refugia strategies to delay resistance development of pesticide-producing crops by testing susceptibility of target pests • Recording weed populations in HT crop fields or adjacent areas

[14] This table includes a non-exhaustive list of examples that may be taken into account on a case-by-case basis, as appropriate, when developing a monitoring strategy.

Conservation of biodiversity (including genetic diversity) and ecosystems	Primary producers (e.g., plants) and vertebrates (mammals, birds, fish, etc.), invertebrates (arthropods, fungi) with a focus on beneficial/functional organisms, important sources of genetic diversity or protected species	• Abundance and population changes • Resistance development, changes in pest prevalence or pathology • Effects of agrochemical usage associated with the LMO in indicator species • Developmental and fitness changes (direct and indirect) in indicator species • Host range or key behavioral changes in indicator species • Changes in dispersal, establishment and persistence in the LMO compared to the non-modified recipient organism • Landscape alterations • Outcrossing/hybridization with wild or weedy relatives
Soil quality and functional processes	Soil microbes and invertebrates (e.g., bacteria, fungi, and arthropods) particularly those providing key soil ecological services (nutrient cycling and decomposition)	• Population changes • Gene transfer frequencies • Organic compound changes • Effects of agrochemical usage associated with the LMO • Soil fertility changes • Changes to degradation processes • Soil erosion and compaction changes
Water quality and water pollution prevention	Physical and chemical pollutants in water, etc.	• Nutrient levels • Pollutants: pesticides, herbicides, etc. • Emission of transgenic product to water • Anoxia
Plant health	Plant diseases, pests and weeds, etc.	• Incidence of disease, pests and weeds • Pesticide usage

Human health (e.g., LMO handlers)	Handlers of LMOs or their products (e.g., farmers, research technicians, mill workers, etc.)	• Exposure analysis • Screens for toxic or immunogenic effects • Epidemiological surveys
Agroecosystem services	Floral and faunal indicators of functionality (pollinator populations, beneficial plant communities)	• Abundance • Foraging behaviors and pollination levels • Soil indicators

Sources:

Food and Agriculture Organization of the United Nations. (2011). Biosafety resource book. Rome: FAO, Module B: Ecological Aspects and Module D: Test and Post-Release Monitoring of GMOs.

VDI-Guideline 4330 Part 1: Monitoring the ecological effects of genetically modified organisms, Genetically modified plants, Basic principles and strategies, 2006.

EFSA Panel on GMO; Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011;9(8):2316. [40 pp.]

Annex III

RISK ASSESSMENT OF LIVING MODIFIED TREES

Version of 15 February 2012

The considerations in this guidance complement the Roadmap for Risk Assessment of LMOs and aim to provide additional guidance on the risk assessment of LM trees in accordance with Annex III to the Cartagena Protocol on Biosafety.

BACKGROUND

Forest biodiversity is a core area of work in the Convention on Biological Diversity (CBD). During its eighth and ninth meetings, the Conference of the Parties to the CBD recognized "the uncertainties related to the potential environmental and socio-economic impacts, including long-term and transboundary impacts, of genetically modified trees on global forest biological diversity", recommended "Parties to take a precautionary approach when addressing the issue of genetically modified trees" and urged Parties to undertake a number of actions with regard to LM trees, such as "to develop risk-assessment criteria specifically for genetically modified trees".[15]

Given the above decisions and the mandate by the COP-MOP to develop "further guidance on new specific topics of risk assessment, selected on the basis of the priorities and needs by the Parties and taking into account the topics identified in the previous intersessional period",[16] and on the basis of the priority-setting exercise conducted in the Open-ended Online Expert Forum on Risk Assessment and Risk Management, the AHTEG agreed to develop additional guidance for the environmental risk assessment of LM trees.

INTRODUCTION

Tree species belong to many different taxonomic orders and families of angiosperms (flowering plants; e.g., mahogany, poplar, apple) and gymnosperms ("naked seed" plants; e.g., pine, spruce, cedar). Trees differ from annual crop plants by characteristics such as size, perennial growth habit with a long lifespan, and delayed onset of reproductive maturity.

High fecundity together with seed dormancy, multiple pathways for dispersal of propagules, and high seed viability are important aspects for the highly adaptive reproductive capacity of many, although not all, tree species. By using cuttings from some tree species, in particular some fruit trees, grafting of a desirable selected genotype onto rootstock of a different genotype may be done. For many forest and fruit tree species, clonal multiplication of identical individuals can be achieved through regeneration of entire trees from vegetative propagules such as cuttings or somatic embryos.

Compared to annual crop plants, perennial growth and long lifespan of trees may lead to the development of a higher level of complexity and multi-level ecological interactions in the environment. This can involve, directly or indirectly, organisms ranging from decomposers to birds, from insect pollinators to

[15] See COP decisions VIII/19 paragraphs 2 and 3 (http://www.cbd.int/decision/cop/?id=11033) and IX/5 paragraphs 1(s)-(z) (http://www.cbd.int/decision/cop/?id=11648) "*Recognizing* the uncertainties related to the potential environmental and socio-economic impacts, including long-term and transboundary impacts, of genetically modified trees on global forest biological diversity, as well as on the livelihoods of indigenous and local communities, and given the absence of reliable data and of capacity in some countries to undertake risk assessments and to evaluate those potential impacts, [...] *Recommends* Parties to take a precautionary approach when addressing the issue of genetically modified trees;"

[16] See paragraph 3(c) of the annex to decision BS-V/12.

large wild animals. The root systems of trees are extensive and usually associated with microorganisms and fungi, such as mycorrhiza (symbiotic associations).

Concerning reproductive maturity and breeding systems, many tree species undergo a distinct juvenile phase which may last for several years to more than a decade before the onset of reproductive maturity. As a result, some commercialized tree species have gone through only a limited number of breeding cycles. Additionally, some trees species (as well as some non-tree species) are dioecious (plants that are either male or female) so that backcrossing or selfing (common approaches for many annual crops) are impractical or even impossible, which has led to greater interest in vegetative propagation in trees.

Trees as a group represent a vast diversity in distribution, organismic networks, species and genotypes and have significant ecological, economic, environmental, climatic and socio-economic values. Fruit, ornamental, and forest tree species of economic interest grow in various regions of the world from temperate to tropical climates. Thirty one per cent of the total global land area or more than 4 billion ha are covered by forests. Minimally managed forest habitats and non-managed forests like tropical rainforests or boreal forests in the northern hemisphere are of high conservation value. Accordingly they represent important protection goals which should be taken into account when assessing the possible impact of LM trees and emphasis should be given to the precautionary approach.

Both fruit and forest trees, especially those suited for plantations, are the focus of advanced breeding strategies including genetic modification through modern biotechnology as defined by the Cartagena Protocol on Biosafety. Currently about 30 to 40 different tree species have been modified through modern biotechnology, mainly through the insertion of transgenes, and have been introduced into the environment for small scale releases (FAO 2004, Verwer et al. 2010, IUFRO 2011[17]). The majority of these LM trees are species of economic interest used in managed forests and plantations. The genetic modification has focused on traits related to herbicide tolerance, wood composition (e.g., lignin), growth rates and phenology (including flowering and fruiting), resistance to pests and diseases, or abiotic stress tolerance. By far, poplars make up most of the LM trees that were developed and subjected to field trials to date, (Canada Norway Workshop 2007), followed by eucalypts and pines. LM apples and papaya[18] make up most of the fruit trees approved for field trials (Gessler & Patocchi 2007; Hanke & Flachowski 2010) or commercial cultivation. Poplars are the only transgenic forest trees planted not only for field trials though to date only on small scale in China (Ewald et al. 2006). Examples of risk assessments in LM trees or other woody perennials including small and large scale experimental releases are available online from a number of sources (Australia, New Zealand and the USA,[19] EU,[20] Canada[21]). Other countries have approved field trials, including Brazil, China, Malaysia, Mexico and Japan, but only limited information is available.

[17] IUFRO Tree Biotechnology 2011 - http://www.treebiotech2011.com/. Full proceedings available at http://www.biomedcentral.com/1753-6561/5?issue=S7.

[18] See http://www.isb.vt.edu/search-petition-data.aspx.

[19] Australia: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1 (papaya, plus sugarcane, rose and banana). New Zealand: http://www.epa.govt.nz/new-organisms/Pages/default.aspx (Radiata pine). USA: Commercial releases - http://www.aphis.usda.gov/biotechnology/not_reg.html (papaya (2), plum); field trials - http://www.isb.vt.edu/search-release-data.aspx (Eucalyptus, poplar, apple, sugarcane, sweetgum, cranberry, poplar/white spruce, plum, papaya, Amelanchier laevis, walnut).

[20] http://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx.

[21] http://www.inspection.gc.ca/english/plaveg/bio/dt/term/2010/2010e.shtml.

The OECD Working Group on Harmonisation of Regulatory Oversight has published consensus documents on the biology of most tree species of economic interest that have been modified through modern biotechnology.[22]

SCOPE OF THIS GUIDANCE

According to the Food and Agriculture Organization of the United Nations (FAO), a tree is: "a woody perennial with a single main stem, or, in the case of coppice, with several stems, having a more or less definite crown".[23] This guidance focuses on true botanical trees and does not cover any additional species such as palms, bamboos and shrubs.[24] Although not addressed specifically in this guidance, where some of the characteristics of trees are shared by other plant species, such as perennial growth or vegetative propagation, this guidance may provide some insights useful for the evaluation of LMOs of those species.

OVERARCHING ISSUES IN THE RISK ASSESSMENT PROCESS (*see "Overarching issues in the risk assessment process" in the Roadmap)*

Transboundary movements of LM trees and the Cartagena Protocol

According to the Protocol, risks associated with LMOs or products thereof[25] should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment. Therefore, in the case of LM trees, when characterizing the likely potential receiving environment, risk assessment should take into account not only the movement of seeds for intentional introduction into the environment, but also of vegetative propagules since, for selected tree species such as some poplars and eucalypts that is the preferred way of propagating them. Issues related to unintentional transboundary movements (Article 17) may also be taken into account in cases where LM trees could cross national boundaries through, for example, pollen or seed dispersal by physical and biological vectors, including the international trade of fruits with seeds.

PLANNING PHASE OF A RISK ASSESSMENT OF TRANSGENIC TREES

The comparative approach - aspects of implementation *(see "Planning Phase of the Risk Assessment", "The choice of comparators" in the Roadmap)*

Rationale:

As for risk assessments of any other type of LMO, a comprehensive planning phase is needed in order to define, among other things, how a comparative approach can be carried out in the risk assessment of an LM tree. For those tree species for which there is little or no information the assessment may be challenging. In such situations the use of closely related lines may provide a good alternative for the comparative risk assessment.

For both annuals and perennial plants the characteristics of the receiving environment must be considered as it often changes over time, including interactions and interactive networks with other organisms as well as biotic and abiotic conditions. Annuals, which must germinate and re-establish each year, are likely to be more sensitive to such variations than perennial plants, including trees [requires citation].

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[22] Up to now for 13 tree species consensus documents on their biology have been developed to support an environmental risk assessment. These documents can be found at http://www.oecd.org/document/15/0,3746,en_2649_34385_37336335_1_1_1_1,00.html.

[23] http://www.fao.forestry/site/24690/en.

[24] Some Parties to the Protocol are of the view that fruit trees should not be addressed by this guidance.

[25] "…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..." (see Protocol, Annex III, paragraph 5).

Indeed, to survive for many years, trees must be robust to a wide range of environmental factors resulting among others from human induced effects.

In all forms of forestry the use of well adapted provenances,[26] those which have evolved or been bred within the region where they will be grown commercially, is of great importance because they may show better adaptive capabilities and consequently better performance than unselected germplasm (Hubert & Cundall 2006).[27] These regional provenances and their management—whether part of the local flora, domesticated species or introduced but bred and adapted varieties, may provide appropriate comparators for LM trees in accordance with national protection goals and good forest management practices.

Due to the large physical size of trees only limited data may be obtained from glasshouse experiments. Not only can glasshouses be limiting with respect to the height of the tree, but the area or footprint required for each individual tree can quickly fill the available space thus limiting the practicality of replicated samples. This may be particularly challenging when obtaining data over a number of growing seasons to address the perennial growth nature of trees.

In instances where LM tree species have a long lifespan and a high potential for dispersal, outcrossing and establishment beyond the intended receiving environment (e.g., into natural or less managed ecosystems), should be taken into account when considering any limitations in the predictive power of the comparative environmental risk assessment.

Points to consider:

(a) Availability of data from glasshouse experimentation (including exposure to abiotic and biotic stresses);

(b) Availability of information and knowledge of the biology of the species and/or genotype (including regional provenances or ecotypes as appropriate) to be used as a comparator;

(c) Whether one or more suitable comparators are available and the possibility of their use in the appropriate experimental design;

(d) Design of field trials in relation to established methodologies for the non-modified trees, including for example the length of the period before flowering, the length/age of trials, testing in different environments and exposure to multiple biotic and abiotic stresses.

CONDUCTING THE RISK ASSESSMENT

The information provided aims to cover different tree species and management practices and may therefore be relevant or needed according to the specific case.

Transformation and propagation methods *(see "Step 1", "Point to consider (b)" in the Roadmap)*

Rationale:

The cross-breeding process of LMOs (including back-crossing) may be an option to reduce the presence of any parts of the transformation vector and marker genes[28] if appropriate. Crossing may not be a viable option for many species of LM trees which have a long juvenile period. Consequently the multiplication

[26] A comparable concept for crop plants would be regionally adapted crop varieties.

[27] For example the Ministerial Conference on the Protection of Forests in Europe recommended "Native species and local provenances should be preferred where appropriate. The use of species, provenances, varieties or ecotypes outside their natural range should be discouraged where their introduction would endanger important/valuable indigenous ecosystems, flora and fauna…".

[28] See Roadmap lines 319-320 (version of 15 Sept 2011).

of trees is likely to be done through clonal and vegetative propagation, which does not allow for simple removal of vector fragments or marker genes.

The stability of the modified genetic elements over successive generations may be an important issue, *inter alia*, when containment strategies are used in risk management. However, verification of stability through successive crosses may not be meaningful for risk assessment of vegetatively propagated species. In many cases human intervention is required for successful vegetative propagation:

i. Rooted cuttings. In some tree species mass propagation of selected genotypes is accomplished through the preparation of rooted cuttings from stocks maintained as hedges or in tissue culture.
ii. Grafting. Notably in fruit trees a selected variety with desirable traits can be propagated by grafting material, the scion, on to rootstocks of a different genotype. In such cases the scion, the rootstock, or both may be transgenic.
iii. Somatic embryogenesis. In several conifers and other species methods have been developed to mass produce selected genotypes in tissue culture through somatic embryogenesis.

Points to consider:

(a) Propagation method(s) used – cross-breeding (including degree of back-crossing if possible in that species) and/or vegetative propagation;

(b) Transformation methods used (possibly leading to the presence of vector fragments or marker genes).

Long lifespans and genetic and phenotypic characterization and stability *(see "Step 1", "Point to consider (d) and (e)" in the Roadmap)*

Rationale:

For tree species, lifespan can range from several decades to several hundred years or longer (Matyssek et al. 2010, Roloff 2004) and therefore they may need an extended time period of observation.[29] They have the capability (like other perennial plants) to adapt to the different abiotic and biotic conditions they encounter during their often long lives. Phenotypic characterization during risk assessment should consider the developmental stage, environmental conditions and the anticipated changes in the management practices used for the tree at the time of the characterization.

In consideration of the long lifespan of trees, transgene instability including those causing gene silencing and variable expression levels should be considered (Ahuja 2009; Harfouche et al. 2011). On the same basis, gene/environment interactions, that play an important role for expression level of the transgenes (Strauss et al. 2004), should be duly considered. Consequently, an assessment of the stability of the transgenes and their levels of expression at different points during the lifespan of the LM tree may be important considerations, in particular where transgenic approaches are used for containment strategies (e.g., male sterility or ablation of floral organs).

Points to consider:

(a) Phenotypic changes over time in response to different stressors and different developmental stages;

(b) Potential for variability of transgene expression levels, including gene silencing over time;

[29] See Article 16(4) of the Cartagena Protocol.

(c) Changed interaction with other organisms, and changed ability to maintain role and function in ecosystems.

Dispersal mechanisms *(see "Step 1", "Step 2", "Point to consider (e) and (f)" in the Roadmap)*

Rationale:

Trees, like other plants, have developed a variety of ways to reproduce and disseminate via seeds, pollen and/or vegetative propagules. Trees often produce large amounts of pollen and seed per individual and propagules are often designed to spread over long distances (e.g., by wind, water, or animals including insects) (e.g., Williams 2010). The potential for vegetative propagation in certain trees raises consideration of the possibility of establishing new individuals from branches or root parts. Seeds inside fruits may travel as commodities around the globe and be released at the place of consumption such as road margins, railways or touristic areas, as well as in farmers' fields and local gardens.

Points to consider:

(a) Available information on the mechanisms and viability of pollen and seed dispersal for the non-LMO and LM tree species;

(b) Potential for and mechanisms of vegetative propagation in the non-LMO and LM species;

(c) Potential for dispersal mechanisms from anthropogenic activities (e.g., trade and consumption of fruits).

The likely potential receiving environment(s) *(see "Step 1", "Points to consider (f) and (g)", "Step 2", "Points to consider (b), (d) (f) and (g)", and "Step 3", "Points to consider (a) and (e) in the Roadmap)*

Rationale:

The identification and characterisation of likely potential receiving environment(s) may be dependent on the species in question, their habitats, the traits and modified characteristics and its mechanisms for dispersal. With some trees the intensity of management in the receiving environment is likely to be less than for annual plants. Given that the domestication level of some forest trees may be low and trees can often survive without human intervention, the dispersal of propagative material (e.g., seeds, branches) may lead to persistence and spread of the LM tree in question. Therefore, the potential for dispersal of propagative material into environments other than the intended receiving environment is an important consideration during the risk assessment.

Points to consider:

(a) Environments (e.g., forests) which offer the potential for seeds and/or vegetative propagules to establish;

(b) Degree of management of these environments;

(c) Presence and proximity of species including in orchards and gardens in the receiving environment with which the LM tree may hybridize;

(d) Occurrence of protected areas according to national legislation, centres of origin and genetic diversity or ecologically sensitive regions nearby;

(e) Impacts on water tables and watersheds in or linked to the potential receiving environment compared to that of non-LM comparators;

(f) Changes in landscape patterns (e.g., because of new plantations or afforestation);

(g) Ecosystem function and services of potential receiving environment;

(h) Impacts on organismic food chains and cascade effect;

(i) Sensitivity of the receiving environment to human changes (e.g., climate changes).

Exposure of the ecosystem to LM trees *(see "Step 2", "Points to consider (e) to (h)" in the Roadmap)*

Rationale:

As trees may be relatively undisturbed for much of their life cycle they may engage in a variety of ecological interactions, such as providing habitat for other organisms and functioning as part of complex and elaborate food webs. In determining the likelihood of an adverse effect to occur, an assessment of the exposure to the LM tree should take into account the expected duration of the trees' presence in the receiving environment together with the transgenic traits and the intended use (e.g., processing, trade routes) as well as dispersal mechanisms. Given the late onset of reproductive maturity of a number of tree species pollen and seed production may not be relevant for several years of a field trial. A number of species (including some trees) under exploration as bioenergy crops have the potential of becoming invasive[30] (Gordon et al. 2011) which could greatly increase the potential for exposure. Genetic modification has been proposed as a strategy to mitigate the potential invasiveness of new bioenergy crops (Kausch et al. 2010).

Points to consider:

(a) Duration of the presence of the LMO trees in the receiving environment and their impact;

(b) Persistence and long-term effect of the LM trees in the environment including potential for the non-LMO and LM species to be invasive;

(c) Possible impacts from the modified trait on invasive characteristics;

(d) Long-term interactions with other organisms including in the food webs;

(e) Modifications, climatic conditions, or management practices that effect reproductive biology;

(f) Possible impacts of the modified trait on loss of biodiversity and ecosystem stability.

Risk management strategies *(see "Step 4", "Point to consider (d)" and "Step 5" in the Roadmap)*

Rationale:

Risk management strategies designed for LM trees will depend on the result of the risk assessment, and may vary depending on the LM tree and conditions under which it is grown. When indicated by the risk assessment, limiting or preventing dispersal for forest or plantation trees may utilize strategies for

[30] The Convention on Biological Diversity (CBD) defines the term "invasive alien species" as "species whose introduction and/or spread outside their natural past or present distribution threatens biological diversity". Since this document is not limited to consideration of alien species, the following definition is being used for "invasive species": "a species whose introduction and/or spread threatens biological diversity". This definition was chosen in consideration that the Cartagena Protocol on Biosafety is a protocol to the CBD. [This footnote may be supplemented according to the text referenced in: a) Committee on the Biological Confinement of Genetically Engineered Organisms, NRC (2004): Biological Confinement of Genetically Engineered Organisms (Washington, DC, National Academies Press) and b) Committee on Environmental Effects of Transgenic Plants, NRC (2002): Environmental effects of transgenic plants: the scope and adequacy of regulation (Washington, DC, National Academies Press).]

delaying or avoiding flowering (e.g., fast-growing trees for pulp or biomass/bioenergy production being cut before reaching the reproductive phase) and strategies for bioconfinement (e.g., induction of male sterility or flower ablation). Complete flower ablation would not be workable for many tree species. Male sterility may be appropriate in some species (e.g., apples) where pollen from a different variety (which could be non-LMO) is usually required. However this containment strategy does not take care of transgene spread by seed. Where applications involve genetic modification of only the rootstock in grafted trees, dispersal may be managed by ensuring that the rootstocks do not produce shoots or flowers [reference needed].

Points to consider:

(a) Risk as identified in the risk assessment;

(b) Type and intended use of the LM tree;

(c) Degree and type of management (e.g., grafting of fruit trees, rotation period of forest trees);

(d) Specific effects and risks of any containment strategy achieved through the use of modern biotechnology.

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Annex IV

TENTATIVE CALENDAR OF ACTIVITIES FOR 2012 UNDER THE OPEN-ENDED FORUM AND AHTEG

DATES	LOCATION	DESCRIPTION OF THE ACTIVITY		MAIN RESPONSIBILITY
		Revision of the Guidance on Risk Assessment of Living Modified Organisms	***Development of new guidance ("monitoring" and "LM trees"***	
16 – 31 January	0nline		Online discussions on the third draft documents on "monitoring" and "LM trees"	Open-ended Group
31 January – 15 February	0nline	Final round of online discussion for editorial improvement of the "Guidance on Risk Assessment of LMOs"		Open-ended Group
1 – 6 February			Consolidation of comments from the online discussions on "monitoring" and "LM trees" and circulation among SWGs members in preparation for face-to-face meeting	AHTEG SWG Chairs in consultation with AHTEG Chair and Secretariat
13 – 15 February	Bonn		Face-to-face meeting of the AHTEG SWGs on "monitoring" and "LM trees"	AHTEG SWGs
16 – 24 February	Online	Consolidation of comments on the "Guidance on Risk Assessment of LMOs" from the online discussions		AHTEG Chair in consultation with the AHTEG Bureau and Secretariat
20 February			Revised draft documents on "monitoring" and "LM trees" made available to the Open-ended Group	Secretariat
27 February – 11 March	0nline		Final round of online discussions of the revised draft documents on "monitoring" and "LM trees"	Open-ended Group
27 February – 16 March	n/a	Scientific editing of the "Guidance on Risk Assessment of LMOs"		External consultant, AHTEG Chair & AHTEG Bureau
12 – 18 March	0nline		Consolidation of comments from the online discussions	AHTEG SWG Chairs
19 – 25 March	0nline		Comments on the draft documents by SWGs	AHTEG SWGs
26 March – 1 April	0nline		Revision of the draft documents on "monitoring" and "LM trees" on the basis of comments from SWG members and submission to Secretariat	AHTEG SWG Chairs in consultation with SWGs, AHTEG Chair and Secretariat
2 April	0nline	Edited "Guidance on Risk Assessment of LMOs" and revised draft guidance on "monitoring" and "LM trees" made available to the Open-ended Group and AHTEG		Secretariat
9 – 27 April	**Online**	**Regional Real-time Online Conferences**		**Open-ended Group**
30 April – 18 May	0nline	Synthesis of the real-time online conferences made available to AHTEG members in preparation for AHTEG-4		Secretariat
4 – 8 June	**Montreal**	**Fourth meeting of the AHTEG (AHTEG-4)**		**AHTEG**
11 – 29 June	n/a	Final scientific editing of the "Guidance on Risk Assessment of LMOs", including "monitoring" and "LM trees"		External consultant, AHTEG Chair & AHTEG Bureau

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