MONITORING AND LONG-TERM EFFECTS OF LMOs RELEASED INTO THE ENVIRONMENT

PREFACE

(*Note: This preface is here only as orientation for the reader to the initial draft of this guidance document. It is not intended to appear in the final version)

The initial draft of this guidance was written on the basis of the original outline developed at AHTEG3 by the Sub-Working Group (SWG), and reference documents suggested by members of the SWG electronically. The original outline was a good start, yet the latter input of documents by the SWG offered substantially different conceptual ideas than originally discussed. Taking this information submitted by SWG members into consideration necessitated some reconceptualizing and restructuring that led to modifications from the original outline.

The title of the document was modififed slightly for greater readability, without changing the intent. Significantly, how the two issues in our working title, "monitoring" and "long-term effects" interact and are related needed further clarification. In consideration of the submitted background documents by the SWG member, it became germane to consider that in some instances these two would be intergrative, in other instances, complementary activities that where long-term effects research may inform monitoring needs, and vice-versa.

Lastly, the approach taken in this guidance was to provide the user with clear, well defined concepts and tools that faciltates its use as actionable guidance, with diagrams, tables and a reference guide as user aids. The intent is to give a conceptual foundation on monitoring in accordance with the Protocol, without lengthy descriptions. An attempt was made to utilize the "rationale/points to consider" structure of the related Roadmap documents, where appropriate, however some instances did not lend themselve easily to such a format. However, it was adopted where feasible. Lastly, the further development of the Appendices will need strong contributions from the AHTEG SWG and Open-ended Group.

BACKGROUND

Within the methodology laid out in Annex III of the Protocol, monitoring of LMOs is a tool to address uncertainties that may arise in the risk assesment, and may further be used in conjunction with risk management. However, despite the importance of monitoring for ensuring the objectives of the Procotol are achieved, no guidance is given in the Protocol intself concerning the criteria of when monitoring should be required, or how the monitoring should be conducted. Research on the long term effects of LMOs once released into the environment, is another area that is not addressed in the Protocol yet has been identified as an area of needed guidance[1].

As a result of the identified needs, the AHTEG decided in its third meeting to undertake the development of more detailed guidance for post-release monitoring and long-term effects of LMOs released into the environment[2].

1 See UNEP/CBD/BS/AHTEG-RA&RM/3/4 (http://www.cbd.int/doc/meetings/bs/bsrarm-03/official/bsrarm-03-04-en.doc).

2 ibid.

Comment [O1]: This is a general comment: I see some merites in having separate sections relevant to CSM and GS and not to mix both subject in single paragraphs

Comment [O2]: A linkage with the monitoring and identification requiremen under the CBD (article 7) and the insitu conservation (article 8) should be established here. This is higly inportant in this section as well as the following sectio introduction. Noting that the cartagena protocol originated from article 8.g of the convention

INTRODUCTION

Under the Protocol, any approval for transboundary and enviromental release of an LMO should be preceded by a case-specific risk assessment. This is specified in order to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking also into account risks to human health. When there is uncertainty regarding the level of risks that may exist with the use of an LMO, monitoring of the LMO in the receiving environment is suggested as a potential means to verify that the conclusions of the risk assessment are correct[3]. The "Roadmap on Risk Assessment" specifies further the instances when monitoring may be useful, stating

"Monitoring can be applied as a tool to detect unexpected and long-term adverse effects. Monitoring can also be a means to reduce uncertainty, address assumptions made during the risk assessment and to validate its conclusions on a wider (e.g. commercial) level of application and to establish a causal link or pathway between LMOs and adverse effects. Monitoring may also be used as an instrument providing for effective risk management, including the detection of adverse effects before the consequences are realized."[4]

In the cases where LMO monitoring is considered in relation to the adverse effects anticipated in the risk assessment, it may serve three main functions, when properly implemented:

First, monitoring can be a science-based means for confirming the outcomes of the risk assessment. The nature of the information provided in the risk assessment may have inherent limitations for approximating real-world adverse effects (e.g. given the complexity of the receiving environment under evaluation, effect sizes under investigation, or ability to extrapolate from limited temporal and spatial scales of field trials). As a result, important adverse effects may erroneously underestimated, or deemed irrelevant. Monitoring can, therefore, work to reduce anticipated adverse effects, including those that may have been anticipated, but were understated in their level of potential risk in the conclusion of the risk assessment.

Second, monitoring can survey for adverse effects that were not anticipated, identified in, or could not have been identified in, a singular risk assessment. This is particularly the case where indirect, delayed, cumulative, combinatorial and long-term adverse effects of LMOs or their products on the environment or human health may occur. In this way, monitoring can serve as an early detection system for ~~any~~ potential adverse effects of an LMO or its products arising from an environmental release. Monitoring and ~~research~~ investigation for such effects is generally considered in the context of ensuring critical protection goals more broadly, rather than just monitoring for a specific effect.

Third, monitoring may provide informational feedback by generating data over longer time scales and larger spatial scales of a release than was originally assessed, which may lead to an adjustment in the risk assesment, modification in appropriate risk management options (including contingency plans), or decision making.

In addition to specific applications of monitoring as a tool in the context of a risk assessment, monitoring may be an effective risk management measure (but not a risk mitigation strategy in itself). The provision for such measure is made not only to address concerns or uncertainties related to environmental issues, but also social and economic issues[5] that exist at

Comment [O3]: Comment o1 : applies here also. Please reflect the ideas in the following articles of the convention:
Each Party shall
(a) Identify components of biological diversity important for its conservation a sustainable use having regard to the indicative list of categories set down in Annex I:
(b) Monitor, through sampling and other techniques, the components of biological diversity identified pursuant to subparagraph (a) above, paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use; (c) Identify processes and categories activities which have or
are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity, and monitor their effects
through sampling and other techniques;

Comment [O4]: evaluate

3 Annex III (8f) "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."

4 See Roadmap for Risk Assessment, Rationale, Step 5.

5 See article 26 of the Protocol.

the nexus of the conservation and sustainable use of biological diversity in the context of decisionmaking. Further, monitoring can provide valuable assurance that risk mitigation strategies are indeed effective towards declared protection goals.

Thus, while provision for monitoring within the Protocol arises in relation to both risk assessment and risk management, the determination of when monitoring is needed and appropriate must be made by the Competant Authority in the Party of import as part of the decision-making process. The duration of any monitoring requirement should be specified, yet may be a continuous activity over the period of approved release of the LMO.

It should be recognized that beyond the use of monitoring as a information generating tool to deal with uncertainty, monitoring may serve as a valuable policy-learning function that will enable more robust, effective and efficient risk assessment, risk management or decisonmaking in the future. This underscores the value of the interative approach for taking into consideration new knowledge arising on LMOs.

In summary, monitoring, in a very broad sense, is therefore a tool for addressing uncertainty within the entire risk appraisal and decisonmaking processes. Monitoring outcomes may interact and inform between the risk assessment, risk management and decisionmaking. (See Annex I "LMO Monitoring in the context of the Protocol".) [NB: This Annex (diagram) is to be developed during subsequent work of the Monitoring Sub-Working Group.]

The guidance here, while focused on the provisions for monitoring in relation to the risk assessment in accordance with Annex III of the Protocol, also reflects complimentary needs for long-term effects research, for monitoring under risk management, and decision procedures that are not provided for in the methodology of Annex III. The general principles and rationale, and specific concepts for monitoring (included those that may be necessary in the development of a Monitoring Strategy) presented here are developed from current research on LMO monitoring.

OBJECTIVE AND SCOPE

The aim of this guidance document is to provide for the user a conceptual framework for the monitoring of LMOs released into the environment, which includes the consideration of long term effects research. The framework presented here is consistent with the objectives of the Protocol and article 7 c of the convention, and give recommendations on general principles and specific points that should be considered in the design of a comprehensive Monitoring Strategy. The fundamental aim of a Monitoring Strategy—which may be called for by the Party of import within an application for any environmental release—is twofold. First, is to devise a scientifically robust Monitoring Plan for the conduct of monitoring activities, to detect any adverse effects of LMOs short- or long-term, immediate or delayed, direct or indirect. This includes both those anticipated in the risk assessment and those not unanticipated, and to set in place a system for review and reporting of the results of the monitoring activity to ensure the outcomes are efficient and effective in their use. Second, the means for reporting, review, and use of outcomes from monitoring should be fully specified to ensure effective use.

Comment [O5]: also combinatorial effects

In order to achieve these aims, the duration of monitoring necessary to fulfill them, will vary depending on the case, the aims of the activity, and the regulatory requirements under which the monitoring was conducted. The monitoring duration should be specified within the Monitoring Plan, yet it should be noted that the timeframe for monitoring may continuous over the period of approved release of the LMO, and/or consistent with the timeframe which policies regarding the LMO is applicable.

While this guidance may be useful to complement the LMO monitoring requirements in existing national biosafety regulations, it is targeted for use by the less experienced user, or Parties without elborated monitoring requirements within their domestic legislation. To facilitate the conceptual understanding and use of this guidance, a variety of user aids are presented as annexes at the end of the document.

The scope of this guidance applies to all LMOs and all types of effects from LMOs released into the environment, regardless of scale or duration. It should be explicitly noted that post-release monitoring is by definition an activity to be performed after the approval of an LMO, the plans on how to monitor the LMO should be specified prior to the release being approved (or may be a pre-condition of approval for release), and in some instances, monitoring data may need to be collected (e.g. for establishing baseline data) before the release actually takes place. The term "post-release" does not indicate a specific scale or duration of release for any approval, but merely signifies that an LMO at some scale been ~~been~~ liberated into the environment after approval. LMO releases that are approved may extend into unintended receiving environments also fall under the scope of this guidance[6]. Further, the term "monitoring" when used in this document refers also to the consideration of short and long-term effects of LMOs in the receiving environment.

The general provisions outlined here should be broadly applicable, yet not all specific provisions in this guidance will apply in each scenario. This guidance should be seen as a "living" document, to be amended as needed.

GENERAL PRINCIPLES FOR MONITORING IN ACCORDANCE WITH THE PROTOCOL

1. The provision for monitoring in the Protocol aims to address relevant uncertainties

As risk assessment will always result in some level of uncertainty, the Protocol allows Parties to determine a range of appropriate actions, including the use of monitoring, in order to avoid or minimize potential adverse effects. In this way, a comprehensive, well designed monitoring plan is an essential tool to provide decisiomakers with science-based data on the potential adverse effects, including long-term and unforseen effects, and support decisions when corrective measures will be necessary in order to avoid or reduce environmental damage.

This is in contrast to other biosafety frameworks that are not based on the Precautionary Approach, which may lack provision for other measures, such as monitoring, to be enacted when there exists a lack of full scientific certainty with regards to risks of the LMO. In these cases, such frameworks restrict requirments for monitoring only to instances where specific adverse effects have been identified. Recognizing that the assessment of risk is largely based on the questions asked and the extent that time and scale of release of experiements (including laboratory studies) and may rely on untested assumptions in concluding the level of risk present, such frameworks would not be appropriate under the pretext of the Precautionary Approach provided for in the Protocol.

Although the Protocol does not specifically require monitoring of LMOs for a decision to approve an LMO for release, monitoring (or other forms of risk management) may be deemed appropriate on a case by case basis as a condition of consent for release, in accordance with the Precautionary Approach. Ideally, the requirements for monitoring are laid out in countries' legislation. Where provisions for monitoring are lacking, or in need of

6 See Article 17 of the Protocol

Comment [O6]: products?

Comment [O7]: In some instance ? Ma
This is a requirement under the CBD

Comment [O8]: Please note that monitoring is not covered extensively und the protocol since it is covered under 2 articles (7 and 8)of the convention and those articles applies here as per the protocol article 32. Relationship with the convention

Comment [O9]: Mitigation?

Comment [O10]: Please highlight the issue that those system are not in compliance with the convention as well, n only the precautionary approach, since parties are mandated to "Identify processe and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainal use of biological diversity, and monitor th effects through sampling and other techniques" and this is not limited only to LMOs

Comment [O11]: Not totally true since the protocol, which originated from the article 8.g of the convention , and monitoring both aim for in-situ conservation

augmentation, the Precautionary Approach provides the basis for monitoring requirements under uncertainty, as elaborated in the guidance.

See background documents [NB: To be developed. Please include suggestions of background documents to be added to the list indicating to which section(s) of this guidance each background document is relevant]

2. Monitoring of *specific* adverse effects should be based on the environmental risk assessment of GMOs

The decision procedure for the transboundary movement an LMO under the Protocol requires that the Party ensures that risk assessments were carried out on a case by case basis, "in accordance with Annex III and taking into account recognized risk assessment techniques"[7], before the decision is taken. The aim of the risk assesment is "to identify and evaluate the potential adverse effects of LMOs"[8], taking into consideration that "adverse effects may be direct or indirect, immediate or delayed."[9] The "Roadmap for Risk Assessment" provides elaborated guidance on overarching issues, context and scoping the risk assessment process, and specific considerations in the conduct of a risk assessment. With respect to monitoring, data generated from any of the steps in the pre-release assessment can be useful in the formulation of hypotheses on possible adverse effects that may be addressed post-release through monitoring.

At the completion of the risk assessment, a conclusion on risk level is made and the relevant recommendations are identified, taking into consideration uncertatinites in the risk assessment, which should be explicitly described[10]. The risk assessment may be limited in predictive capacity in some instances, particularly where variability and uncertainty is high. Such uncertainties may be related to the nature of the information provided (e.g. the scale or duration of release, the species used, the exposure model considered, the experimental model chosen). Identified uncertainties in such cases may be addressed through the implementation of risk management and monitoring measures. Hence, the risk assessment has strong interlinkages in the development of a Monitoring Plan, to confirm that the conclusions drawn from the the risk assessment (both tested assertions and untested assumptions) of acceptable risk are indeed accurate, and provide a means for detecting changes in the environment related to the use of the LMO over time.

In sum, the design and requirements accounted for in the risk assessment will largely impact the design and scope of the monitoring plan, underlining the importance of a comprehesive risk appraisal framework based on testable scenarios.

(See Annex I "LMO Monitoring in the context of the Protocol".)

See background documents [NB: To be developed].

3. Monitoring measures may address *unanticipated* adverse effects – mainly indirect, delayed, long-term, interactive and cumulative effects, or those that could not have been inferred within a single risk assessment

As LMOs are living organisms, their adverse effects may not be limited in time and space. They may occur in various parts of the ecosystem – land, water or air. Adverse effects may

Comment [O12]: What about the convention and subsequently the protocol

7 Article 15 (1)

8 Annex III (1)

9 Roadmap for Risk Assessment, Step 1 Rationale

10 Roadmap for Risk Assessment, "Overarching Issues"

occur, that have not been identified in the risk assessment, or which have been identified but which are difficult to predict or assess. Prediciton and assessment might be difficult with regard to the likelihood of exposure, the consequences of an effect or because of their complexity. Furthermore, cumulative or interacting effects may involve interactions among other varieties (both modified and unmodified in the receiving environment), which could not have been anticipated during the approval procedure and not addressed in a singular risk assessment. This underscores the value of establishing relevant baseline(s) for a given indicator or parameter as a starting point for identifying changes in the environment that may be linked to the release of an LMO. Therefore, monitoring plans should also be developed focusing on identifying causal interrelationships and should include general observations of relevant environmental parameters in relation to protection goals.

Consequently, a comprehensive for monitoring strategy is based on identifying causal interrelationships should include both, a general observations of relevant environmental parameters or indicators in relation to protection goals (with *unanticipated* effects) as well as more focused observation (*anticipated* effects) taking into account the LMO and the products. That is, addressing these other possible adverse effects not covered in the risk assessment also requires a recognition and provision in a Monitoring Plan.

See background documents [NB: To be developed].

4. Monitoring may be called for as a Risk Management measure

Article 16 reinforces this provision for risk management measures to "regulate, manage and control risks identified in the risk assessment"[11], where "measures based on risk assessment shall be posed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import."[12]. Under these provisions, a number of measures may be employed, including monitoring, to effectively address uncertain adverse effects with appropriate action. Further, monitoring can also provide valuable assurance that measures employed as a means of risk management actually achieve the declared protection goals, or in a worst case scenario, or as an early detection system, which may require modifications to the risk management measures, contigency measures or emergency plans outlined in the Protocol. However, monitoring itself should not be considered a means for risk mitigation under decisionmaking.

(See Annex I "LMO Monitoring in the context of the Protocol".)

See background documents [NB: To be developed].

5. Monitoring is a useful means of generating further scientific information

Results from monitoring may also provide an informational feedback that informs further risk assessment, risk management, or decisionmaking on the use of a specific LMO. Therefore monitoring has the potential to provide essential information on the level of risk, risk management needs, efficacy of risk management measures and for further refinements to risk assessments or decisions that may be necessary to meet the stated objectives of the Protocol.

(See Annex I "LMO Monitoring in the context of the Protocol".)

See background documents [NB: To be developed].

11 Article 17 (1)

12 Ibid. (2)

Comment [O13]: Also taking into account consumer habits, patterns and practices

Comment [O14]: Also may lead to reviewing the decision on LMOs

6. The development of an LMO Monitoring Strategy can help ensure that monitoring activities and their outcomes are efficient and effective

The development of a Monitoring Strategy serves two main purposes. First, it sets the provisions for a detailed Monitoring Plan, which includes a description of the monitoring activities to be implemented with the approval of environmental release of the LMO. Second, a Monitoroing Strategy also deals with the reporting, review and use of the outcomes of the Monitoring Plan, in order to ensure the results meet the stated objectives. The design of a flexible and dynamic Monitoring Plan is essential in this regard so that the results obtained from the monitoring activities are efficient and effective in their use.

See background documents [NB: To be developed].

7. Monitoring frameworks should take into account possible limitations in technical and scientific capacities in the Party of import to carry out monitoring activities, and the possible need for capacity building

Where sufficient capacities are lacking, Article 22 outlines the provisions for capacity building for purposes of effective implementation of the provisions in the Protocol, including risk assessment and risk management. In some cases, the Competent Authority of a Party may lack the resources necessary to support or carry out specified provisions of the Monitoring Strategy (particularly those which utilize existing evironmental monitoring programs). In such cases, and following the principles layed out in Article 22 on Capacity Building, the Party of import may seek "that Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, for the purpose of effective implementation of this Protocol…".Further, relating to Article 15 on Risk Assessment, where "The cost of risk assessment shall be borne by the notifier if the Party of import requires it" taking into account the provision for monitoring and risk management under the risk assessment methodology specfied in Annex III (8f), resources for carrying out risk-related provisions of the Protocol from the Applicant may be required by the Party of Import .

8. The ability to establish a possible causal relationship between an LMO and an adverse effect is dependent on the ability to detect and identify the living modified organism or its products in the environment

Annex III 9(f) states that methods for detection and identification, "and their specificity, sensitivity, and reliability" must be specificed by the Applicant. Establishing a causal link between an LMO agent may requir~~i~~e the determinaton of the presence of the LMO or its products, including abundance. The description of the detection methodology should therefore consider the possible need for monitoring, including the possible long-term effects that LMOs, where its presence (abundance), persistance or accumulation may be difficult to track in the environment through time (particularly due to anticipated and unanticipated biological, ecological, or anthropogenic factors).

See background documents [NB: To be developed].

9. The Party of import may require the exporter to carry out the implementation and coordination of monitoring activities

While each Party is responsible that risk management measures are carried out, the Applicant may be asked by the Party of import to implement, coordinate, and provide the resources for the specified Monitoring Plan, as a pre-condition of environmental release (including the reporting and analysis of the derived information). Consistent with Article 15 (Risk Assessment), the responsibility for, and costs associated with the identification and evaluation

Comment [O15]: It is not just capacity building. Several articles of the convention are relevant here, they include very useful concepts and should be included:
Article 12. Research and Training
Article 16. Access to and Transfer of Technology
Article 17. Exchange of Information
Article 18. Technical and Scientific Cooperation

of adverse effects through the implementation and/or coordination of a Monitoring Plan may be borne by the Applicant requesting consent for environmental release, if required by the Party of import. Where appropriate, Competent Authorities should be integrally involved in the establishement and functioning of monitoring activities, particularly where long-term monitoring needs are called for, or existing environmental monitoring programs are utilized.

See background documents [NB: To be developed].

CONCEPTS FOR THE DESIGN OF A PRM-LT LMO MONITORING STRATEGY AND THE REPORTING AND USE OF RESULTS

The Protocol provides the Party of import the right to carry out monitoring in order to address uncertainties arising the risk assessment[13] or any measures to "regulate, manage, and control risks identified in the risk assessment provisions"[14] and "imposed to the extent necessary to prevent adverse effects of the LMO"[15]. Further, the Precautionary Approach sets the provision for appropriate actions in the face of "lack of full scientific certainty" regarding adverse effects, including lack of knowledge. The call for the submission of a Monitoring Strategy may be a voluntary, or a requirement if mandated by a Party of import's biosafety legislation.

Comment [O16]: It is an obligation under 7.b and 7.c article of the convention and subsequently a protocol obligation. Al monitoring is a way to detect unintential transboundary movement and to take appropriate responces to enable parties to fulfill their obligations under the protocol article 17. Unintentional transboundary movements and emergency measures

Comment [O17]: As well as methods ar plans for emergency responses if applicable

Submission of the Monitoring Strategy

Rationale:

When a Monitoring Strategy is called for, the Applicant should "describe in detail the monitoring strategy, methodology, analysis, reporting and review"[16] to be implemented. This description should follow from any monitoring requirements that were identified from the Competent Authority of the Party conducting the risk assessment. Monitoring plans should be developed on a case by case basis, taking into account the specifics of the LMO, the products, the intended use and the receiving environment in relation to the LMO. Furthermore existing technical and scientific capacity of existing domestic monitoring programs should be taken into account.

Comment [O18]: As well as methods ar plans for emergency responses if applicable

Comment [O19]: And potential

Comment [O20]: Likely potential

See background documents [NB: To be developed].

Description of the Monitoring Strategy

Rationale:

First, the two **types of monitoring** that should be included in the overall monitoring plan—*Case-specific monitoring (CSM)* and *General Surviellance (GS)* –are described below. These two plans form the basis of the proposed monitoring strategy. Next, the three components that should be addressed in the **design of the CSM and GS plans** are outlined: 1) the selection of effects/indicators, 2) the selection of methods, and 3) the selection of monitoring site and regions are discussed along with points to consider. Finally, **the reporting, review and use of data/results generated from monitoring activities** components are discussed and concludes with recommendations to help ensure the results are efficient, effective, and useful as an early

Comment [O21]: And frequency of monitoring

[13] See Annex III (8f)

[14] See Article 16 (1)

[15] See Article 16 (2)

[16] EFSA (2006) Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed. The EFSA Journal 99: 1-94.

indicator, informing further assessment and decisionmaking in the context of any protection goals, including those of the Protocol.

To facilitate the use of these guidelines, A "reference guide for a PRM-LTE Monitoring Strategy" is included as Annex 3.

See background documents [NB: To be developed].

Types of monitoring: Case-Specific Monitoring (CSM) and General Surviellance (GS)

Rationale:

Two types of monitoring activities should be proposed and detailed in the overall Monitoring Plan within the Monitoring Strategy:

- A *Case specific Monitoring (CSM) Plan,* to test whether any adverse effect identified in the risk assessment actually occur, once released into the environment. That is, CSM serves to confirm the outcomes made in the risk assessment that led to a decision of acceptable risk are indeed accurate after environmental release. It is often focused on specific hypothesis derived from specific potential adverse effects identified in the Risk Assessment. As a result, the CSM Plan has close links with the steps of the Risk Assessment performed in the evaluation of the identfied hazards in relation to specific protection goals and assessment endpoints. However, the evaluation of the risks of LMOs often faces considerable limitations (e.g. the scale or duration of release, the species used, exposure model considered, the experimental model chosen). In such cases, risks assessed as extremely unlikely or negligible, particularly where the likelihood cannot be specified due to outstanding uncertainties, including lack of information, may also be evaluated in the CSM Plan, if required by the Competant Authority of the Party of import. The description of uncertainties arising in the risk assessment, as recommended in the Roadmap, provides an important source of information to inform which identified effects may require CSM (see "Overarching issues in the Risk Assessment process" section of the Roadmap).

- A *General Surveillance (GS) Plan,* that aims at identifying and surveying the occurrence of *unanticipated* adverse effects not identified in the risk assessment, or adverse effects that *could not have been anticipated* due to the complexity of the receiving environment. This also would include interactive or cumulative effects (e.g. effect of large scale release, or interactions among other varieties both modified and unmodified in the receiving environment) which could not have been addressed in a singular risk assessment. As such, the establishment of relevant baseline serves as a reference point for observing change in a environmental variable (indicator, parameter) over time (i.e. before LMO cultivation) or in space (i.e. locations without LMO cultivation). The baseline estimation should utilize robust scientific methods, and be senstive to spatial heterogenity of a site and thus performed on the appropriate spatial scale.

  GS is of particular importance where there is uncertainty about the level of effects, or the existence of effects that may occur over the long-term, including in cases related to the persistence, accumulation or interactions between the LMO and the receiving environment, or cumulative effects from multiple LMOs in the same receiving environment. Hence it should be expected that GS will need to be conducted over a larger area and longer timeframe than the CSM Plan.

Comment [O22]: Also monitoring shou help in the selection of appropriate contingency measures as well as reponce measures including restoration in case of damage

Comment [O23]: Including Identify components of biological diversity important for its conservation and sustainable use having regard to the indicative list of categories set down in Annex I of the convention and paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use

Comment [O24]: Likely potential

As the identification and predictability of effects may vary from case to case, what should be considered appropriate for CSM and which for GS must be kept flexible in order to ensure a comprehensive Monitoring Plan. In some instances, similar parameters or indicators may need to be monitored in both CSM and GS simultaneously.

In conclusion, both the CSM and GS monitoring plans, taken together, together can be thought of as a reality-check plan, that considers both known and unknown uncertainties and effects of LMOs, and involves the generation of observational and experimental data that can serve as an early indication system, inform further assessment, decisionmaking, or risk management meaurements.

Comment [O25]: Or review of decision

See background documents [NB: To be developed].

The Description of the proposed CSM and GS Monitoring Plan

Rationale:

The Competent Authority of the Party of import should specify the need for monitoring that should be addressed in the Monitoring Plan developed by the Applicant.

The Applicant should elaborate on the criteria and rationale leading to:

1. The identification and prioritization of hazards and scenarios for monitoring, including determination of the relevant indicators and parameters,
2. The identification and selection of monitoring methods, and
3. The selection of monitoring sites and regions.
4. The establishment of relevant baselines

Comment [O26]: And frequency of monitoring

The points to consider within each of these three aspects, detailed below, may be used as a basis to evaluate the proposed CSM and GS monitoring plans.

1. The identification and prioritization of adverse effects and the choice of indicators and paramaters for monitoring.

Rationale:

For CSM, of effects (hazards) should be principally derived from specific hypothesies derived from the outcomes of the risk assessment (see Step 1-5 of the Roadmap). This helps to ensure its conduct includes the relevant sample and effect sizes, in light of protection needs. Determining the relevant indicators (e.g. species, groups of species, environmental processes, etc) and parameters (i.e. component to be measured in the observation of an indicator) for CSM must therefore be performed by Competent Authority on a case by case basis. The central point is that their selection should be based on their potential to signal LMO-related changes, or reveal particular protection concerns using robust scientific approaches, methodologies and data sets.

For GS, which may identify adverse effeccts not covered in the CSM plan, the GS Plan may utilize additional sources of information (e.g. hazard identification or biosafety research) and

or inference of possible effects from analytical approaches such as modeling or geo-spatial extrapolation analysis, cause-effect scenario analysis, or information from ecological data. Further, it should be considered that those in the user-chain most closely associated with the actual use of the LMO (e.g. farmer, land manager) may be the first to observe relevant changes. Therefore, the use of observations, descriptive studies, or questionnaires from those in the user-chain should be included where possible in the collection data for unanticipated effects as supplementary information, if appropriate.

A GS Plan cannot be expected to evaluate effects arising in each sphere of the ecosystem (i.e. water, soil and air) and at every scale of interactions within them (i.e. species/populations, communities, habitats, ecosystems, etc). Their selection and prioritization should be based on their potential to signal LMO-related changes, or reveal particular protection concerns (e.g. decline of a protected species) using robust methodologies and data sets. The protection goals and assessment endpoints within each Party's domestic legislation can inform which indicators may be of priority. From this, relevant indicators (e.g. species, groups of species, environmental processes, etc) and parameters (i.e. component to be measured in the observation of an indicator) may be established.

There may be additional relevant adverse effects, particularly long term effects that may be identified on the basis of hazard identification research, but not evaluated in the risk assessment (e.g. food-web interactions, effects on animal or human health). These types of effects may be addressed in either the CSM or GS Plan.

Points to consider regarding *criteria* that may be used to decide which indicators and parameters that may be suitable to address the protection goals in both the CSM and GS plans may include, *inter alia*:

(a) The potential of the indicator or parameter to signal possible LMO-induced changes;

(b) The breadth of distribution and abundance of an indicator;

(c) The importance of the indicator or parameter to key ecological processes and functions;

(d) The potential of the indicator or parameter to reveal protection concerns;

(e) The level of difficulty involved in the sampling or identification of the indicator;

(f) The ability to establish relevant baselines with the indicator.

In addition, criteria for deciding which of the potential adverse effects should be included in the GS Plan, and which indicators and parameter that may be suitable to address the protection goals:

(g) Adverse effects identified in the RA but not included in the CSM plan;

(h) An appraisal of pathways and scenarios by which an LMO may have an impact within or beyond the receiving environment (may interface with similarities in the CSM Plan);

(i) Adverse effects identified via modeling possible effects from analytical approaches such as modeling or geo-spatial extrapolation analyeses, cause-effect scenario analysis, or information from ecological data;

(j) An evaluation of protection goals (particularly biodiversity protection) within a selection of indicators within the appropriate ecosystem spheres (land/soil, water) in the relevant environment.

Please refer to Annex II, "Catagories of potential effects of LMOs ecosystems" [NB: This Annex is to be developed by members of the SWG and Open-ended Group.]

See background documents [NB: To be developed].

2. The identification and selection of monitoring methods for the identified adverse effects, their indicators and relevant parameters

Rationale:

The choice of monitoring methods is dependent on the specific case to be evaluated, ranging from short term to long term and from small to large scale observations. Further, the detection of small but potentially important effect sizes (i.e. chronic effects) may be difficult within the monitoring plan, thusly devloping appropriate study designs, including the statistic methods applied, will have to take this into account.

The selection of appropriate methods should take into account *inter alia*, the following considertaions:

For CSM and GS:

(a) The nature of the adverse effect to be monitored, whether short or long term, delayed or indirect;

(b) The proposed methods for establishing relevant baselines, including their scientifc quality;

(c) The scientific robustness of the analytical method/sampling plan;

(d) The degree to which the method will meet the objectives of the proposed Plan;

(e) The availability of standardized detection and analytical methods;

(f) The effect size required for the possible detection of change in each indicator;

(g) The appropriateness of the proposed duration and scales of monitoring, taking into account spatial heterogenity between sites, for achieving relevant protection goals.

Specifically for GS: As GS methods may involve more extensively the use of existing monitoring programs, additional considerations may be taken into account, *inter alia*:

(h) The degree to which the use of methods of existing monitoring data or programs are suitable for the GS Plan;

(i) The adaptability of any existing methods within the monitoring program to make the observation relevant to the goals of the GS Plan;

(j) Where relevant data or analytical means or programs are not available, the development of further surveillance tools to fulfill the goals of the GS Plan;

(k) The appropriatness of any descriptive studies or questionnaires as supplementary information to the proposed scientific monitoring plan.

See background documents [NB: To be developed].

Monitoring duration

Rationale:

The monitoring period necessary for each proposed parameter and methodology required in order to achieve relevant scientific information may vary, taking into consideration:

For both CSM and GS:

(l) That "adverse effects may be direct or indirect, immediate or delayed."[17];

(m) The variability of the monitored parameter through time;

(n) Unanticipated effects may be difficult to predict;

(o) Effects may become detectible only after a longer period of observation.

See background documents [NB: To be developed].

Use of standardized methods

Rationale:

The description of the monitoring methodology should be clearly outlined by the Applicant. An important feature of the proposed methodology is the degree to which the methodological approach can be comparable of data across regions. For this reason, the use of standardized detection and analytical methods is highly preferable and should be implemented where appropriate. The use of standardized methods further ensures the use of scientifically defined criteria for data quality, including transparency, reproducibility, and verifiability of monitoring results (reference to VDI standards).

See background documents [NB: To be developed].

Where appropriate, monitoring activities should make use of existing montioring programs

Comment [O27]: This point and the following point on harmonisation could be merged into single point

Rationale:

Parties should identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity ,including the release of LMOs, and monitor their effects through sampling and other techniques. The monitoring plan should specify "the processes and criteria that will be used

17 Roadmap for Risk assessment, Step 1 Rationale

for selecting and evaluationg existing monitoring systems for supply data"[18]. The suitability of such programs should be evaluated beforehand.

The suitability of existing monitoring programs to achieve the goals of the monitoring plans should take into account, *inter alia:*

(a) Adapability of existing monitoring to LMO monitoring indicators or parameters;

(b) The robustness of data generated for the monitoring objectives;

(c) The number and relevance of monitored indicators for LMO monitoring;

(d) Representativeness of sites in number or distribution in relation to the intended receiving environment of the LMO release;

(e) The frequency of observation and methods employed;

(f) The long-term continuity of the monitoring sites;

(g) The willingess of monitoring institutions to collect, report and disseminate data derived from monitoring activities;

(h) Further access to data before or beyond the timeframe of observation;

(i) Expertise and resources (capacity) available to carry out the monitoring activity.

Harmonization with existing monitoring methods and programs

Rationale:

The monitoring plan to be performed by the applicant will in all likelihood need to be coordinated with existing monitoring programs, e.g. conservation, agricultural and are environmental monitoring schemes. Harmonization of methods, data formats, and analytical approaches will facilitate the adaptability of monitoring methods performed by these programs towards the needed approaches within the LMO monitoring plan[19].

See background documents [NB: To be developed].

3. The selection of monitoring sites and regions

Rationale:

The salient feature in the selection of monitoring sites and region is the representativeness of the proposed locations in relation to the receiving environments where the LMO is intended for release, taking into consideration:

(a) Exposure of the LMO to the environment may be anticipated (e.g. in the case of transboundary movement as import and processing);

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18 EFSA (2006) Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed. The EFSA Journal 99: 1-94.

19 See EC Council decision 2002/811/EC

(b) The biological and ecological behavior of the monitored parameter in the receiving environment for consistend detection and observation;

(c) The introduced trait(s) which may effect impact fitness or dissemination of an LMO;

(d) Monitoring in protected areas and centres of crop origin and genetic diversity or ecologically sensistive regions with specific protection goals, including the use of buffer areas in order to detect invasions or other unexpected effects;

(e) The availability of existing monitoring networks operating within representative regions / availability of sites already monitored within cultivated agroenvironmental programs;

(f) Number of monitoring sites and regions sufficient to support statisitcal analysis of results based on good scientific practice;

(g) Monitorng should take place in exposed areas, preferably cultivated fields and their environment;

(h) The selection of monitorng sites / the design should be flexible, and adapted to the specific LMOs, its environment and the annually changing cultivated fields;

(i) For long term effects and cumulative effects, sites are needed which remain over years;

(j) Reference areas without LMOs have to be available;

(k) Areas with favourable environmental conditions for facilitating spread or survival of GMOs.

Information on the specific locations of GMOs release is therefore critical for the selection of receiving environments for monitoring. This underscores the need that information on specific locations of LMO cultivation or release should be registered in a public LMO register provided for by the Competent Authority that includes at minimum relevant information for carrying out montioring activities (specific location, LMO type(s) released, release dates, management practices, or variations from intended use that may affect the usefulness of the site for generating relevant, good quality monitoring data).

See background documents [NB: To be developed].

4. The establishment of relevant baselines

Rationale:

Determining a causal link between an adverse effect and one or more LMOs requires the re~~l~~v~~e~~l~~e~~vant baseline be established for comparison. In such a way, effects can be compared in receiving environments prior to the introduction of the LMO, or in parallell with a similar receiving enviornment that does not contain the LMO. Points of consideration for the establishement of baselines include, *inter alia:*

(a) The use of scientifically robust methods in constructing the baseline;

(b) The spatial scale over which to establish the baseline;

Comment [O28]: The idea that those established baselines are not static and should take into account any other human induced variation and natural variation shoul be reflected here

(c) Effects of spatial heterogeneity on the representativeness of the baseline in each of the compared scenarios (LMO vs. Non-LMO).

See background documents [NB: To be developed].

DESCRIPTION OF THE REPORTING, REVIEW, DISSEMINATION AND USE OF MONITORING RESULTS

Rationale:

Along with the Monitoring Plan, the Applicant should describe how monitoring results will be reported, reviewed and utilized. A clear description of these aspects serves two purposes. First, it ensures that the results of monitoring undergo an evaluation of its efficiency, efficacy and utility towards meeting the stated objectives in the monitoring plan. Second, it can help make sure that results can be timely and useful to support further assessment, decisionmaking, or changes to risk management.

The Applicant should submit regular monitoring reports to the Party Competent Authority in accordance with the monitoring plans, including who should review and evaluate the relevance, effectiveness, efficiency, and scientific quality of the overall Monitoring Strategy as it was carried out. This ensure that the the monitoring activites as they were implemented meet critieria and requirements specificed and approved by the Competant Authority of the importing Party.

These reports should include a scientifically rigorous analysis of the results and conclusions to be drawn, taking into account site-specific conditions. In establishing the data quality criteria, those outlined under the "Ovarching issues" set forth in the Roadmap should be followed. The report should further highlight where results indicate which aspects of the monitoring plan are needed for continued monitoring, or adaptation of the monitoring, or further assessment, risk management or review of decisions, as provided for in the Protocol and the "Roadmap for Risk Assessment". If cumulative effects are observed, this may involve the reassessment of several LMOs. Raw data should be provided if requested by the Parties.

The proposal should be revised as needed, and approve the Monitoring Strategy as a part of a conditional acceptance for environmental release of the LMO in question. In the case where followup studies are needed, how they should be designed and who should be responsible for their implementation should be decided by the Competent Authority, in accordance with the monitoring provisions adopted by the Party of import.

The dissemination of monitoring reports is important for broad use (including public awareness and participation) and review of the data, its interpretation, and conclusons drawn from the monitoring activities. Reporting should also be disseminated, as determined in the monitoring plan, via LMO registers establishd by the Competent Authority and other public databases (e.g. the Biosafety Clearing House).

Points to consider in the plans for reporting, review, dissemination and use of LMO monitoring results include, *inter alia:*

(a) The Monitoring Plans are sufficiently flexible and adpative to take in new information or changes in monitoring needs, in order to ensures that Monitoring Plans remain efficient, effective, and useful through time. Such adaptations may be necessary in cases, for example:

i Where practicial problems are encountered during the implementation of the monitoring plan (e.g. inaccessability of monitoring sites);

ii Actual experience that demonstrates the infeasibility of utilizing exisiting monitoring programs or methodologies as envisioned in the monitoring plan after the LMO has been approved for environmental release;

iii Unanticipated affects are encountered in the existing LMO monitoring, that may require adaptation of the monitoring activities (e.g. changes in or inclusion of new parameters or indicators);

iv Results from the monitoring indicate that the needs to be updated or reassessed, and consequently changes the specific hypotheses to be tested in the Monitoring Plan;

v Where more suitable results can be achieved in relation to the monitoring objectives;

(b) A detailed description of plans for reporting, dissemination and use of the monitoring information. The reporting plan should make clear how montoring information can be used to support further assessment and decisionmaking, and how relevant biosafety databases and repositiories, including the Biosaftey Clear House, will be utilized to disseminate the monitoring results;

(c) Assurances that the monitoring results are of sufficient quality, transparent, publically available, and accessibile in content and interpretation of results;

(d) Consent for the use of monitoring observations should be obtained from all involved actors beforhand, to ensure the outcomes from monitoring activities may be publically disseminated;

(e) In the event that adverse effects related to the use of the LMOs are identified, the Applicant should adequately describe in the monitoring report a plan for contingency and/or emergency measures, including notification and corrective action, in accordance with contigency measures provided for in Annex I and emergency measures in Article 17 (3c) and (4).

See background documents [NB: To be developed].

IMPLEMENTING THE MONITORING PLAN: CHALLENGES IN THE EFFECTIVE USE OF MONITORING INFORMATION

Rationale:

As discussed throughout this guidance, the two fundamental parts of the Monitoring Strategy—the design of the Monitoring Plan, and the means to report, review and make use of its results—are critical if the monitoring activities are going to be efficient and effective. Nonetheless, the practical implementation of monitoring faces some inherent challenges that must be considered in the Monitoring Strategy to meet these goals. While there are obstacles, they need not be if the Monitoring Strategy is effectively conceptualized.

The points to consider with regard to challenges in meeting these goals include, *inter alia:*

(a) *Methodological weaknesses in the Monitoring Plan to provide meaningful data.* Provisions should be specified in the Monitoring Plan to make sure studies are conducted within the scientific state of the art, or utilize standardize methods for comparability and verfiability of results. Monitoring sites must be carefully selected to be reprsentative of the intended receiving environment of the LMO:

(b) *Difficulties in observing adverse effects.* The observation of small but biologically meaninful effects, particularly occuring over longer time frames may be difficlut to detect using routine approaches, thus the study design must take this into account. In the case of GS, detecting the unexpected remains a distinct challenge. This can be addressed by targeting the protection of specific species or indicators for safeguarding, rather than targeting the investigation of a specfic hypothesis within the CSM Plan. Applying the provisions suggested in this guidance can be an effective means for dealing with them in the design of the monitoring strategy;

(c) *Interpreting monitoring results and needs for further monitoring.* In interpreting monitoring results, the decision and rationale for when further studies are needed, what environmental changes should be further investigated, and who should carry them out, must be clearly specified;

(d) *Establishing cause-effect relationships (causalities) with the LMO.* In the event that environmental changes are detected, determining whether they are harmful or not, and can be related to the release of the LMO under observation, is a crucial point. In such instances, more in-depth studies may be necessary to identify causal links.When a change or adverse effect identified in the Monitoring Plan is identified, it must be determined whether the LMO plays a role in causation or occurs above a pre-defined risk threshold. Possible response measures include the termination of consent for environmental release, or suspension of release followed by the implementation of appropriate risk management measures or further risk assessment studies. These challenges may be addressed by robust statistical methods for clearly establishing linkages, and/or may require further in-depth study in order to ascribe causality;

(e) *Techncial capacities existing in the Party of import.* As discussed, technical, scientific or other resource limitation may exist in the Party of import that would prevent them from effectively carrying out the provisions of the Protocol. Other Parties should cooperate in establishing such capacities, particularly linked to broader protection goals afforded under the CBD. The Party of import may call for assistance or resources in the development of such capacities, as needed, to carry out risk management measures, particularly if required by the national biosafety frameworks.

See background documents [NB: To be developed].

BIBLIOGRAPHIC REFERENCES

(*As needed)*

Annex 1

"LMO Monitoring in the context of the Protocol"

[This graphic still needs to be developed by the AHTEG SWG and Open-ended Group.]

Annex 2

Table of possible adverse effects/monitoring subjects/parameters in the ecosystem

[The table still needs to be developed by the AHTEG SWG and Open-ended Group from the LMO monitoring literature – effect on biodiversity, soil, water, air....]

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REFEERENCE GUIDE :

CONCEPTS FOR A MONITORING STRATEGY, INCLUDING THE DESIGN OF A MONITORING PLAN, AND REPORTING, REVIEW AND USE OF RESULTS

The series of questions presented below may be used as a guide to ensure that a comprehensive and effective Monitoring Strategy is implemented, if required by the importing Party, and may be a preconditon of approval for environmental release.

SUBMISSION AND EVALUATION OF THE PROPOSED MONITORING STRATEGY

The development of a *Monitoring Strategy* serves two main purposes. First, it sets the provision for an detailed *Monitoring Plan*, which includes a description of the monitoring activities to be implemented. Second, a Monitoring Strategy also includes the *plans for the reporting, review and use of the outcomes* of the Monitoring Plan, and that the results meet their stated objectives. The Competent Authority of the Party of import should evaluate that the proposed Monitoring Strategy meets the critieria and requirements set forth as necessary to meet the set protection goals, and revise the Plan as needed, as a conditional acceptance for environmental release of the LMO in question. Evaluation and of the monitoring plan, and regular review of its outcomes, helps ensure that the proposed monitoring activities are feasible, appropriate, efficient, effective, and useful in relation to the protection goals of the Party of import in particular and the objectives of the Protocol in general.

The considerations for criteria and requirements for a Monitoring Plan and review, reporting and use of results are outlined as a series of questions below, to aid the user with the evaluation and needs in the overall LMO Monitoring Strategy.

DESCRIPTION OF THE PROPOSED MONITORING PLAN

As directed by the Compenent Authority, the Applicant should describe in detail the proposed Monitoring Plan, including: 1.) the choice of effects, indicators and parameters to be monitored, 2.) the monitoring methodology and 3) selection of sites and regions for montoring, and 4) the establishment of relevant baselines.

Did the Applicant:

☐ **Include a description of a Case-Specific Monitoring Plan (CSM) and General Surviellance Plan (GS)?** *The CSM and GS Plans monitor for anticipated and unanticipated effects of an LMO where there are outstanding relevant uncertainties.*

And for each CSM and GS description:

☐ **Identify and prioritize the adverse effects, the choice of indicators and paramaters to be monitored?**

☐ Do the selected aspects to be monitored have the capacity to signal LMO-related changes, or reveal particular protection concerns?

☐ **Identify, select and describe relevant and appropriate monitoring methods for the observation of adverse effects, indicators and relevant parameters?**

☐ Are the criteria for the generation of good-quality data specified? *This ensures that data is of high scientific quality to support further assessment and decisionmaking.*

☐ Will the proposed methods utilize standardized methods for comparability of derived data? If not, how will the proposed plan deliver monitoring results that are comparable across sites, regions or even countries?*The use of standardized methods helps ensure consistency and comparability of results across sites, regions or even countries.*

☐ Are there existing monitoring programs or information that may be utilized or modified to carry out the monitoring strategy? *Where appropriate, the use of existing monitoring programs can ensure the efficiency and continuity of the monitoring activities.*

☐ Are the proposed duration and scales of monitoring, taking into account spatial heterogenity between sites appropriate for achieving relevant protection goals? *The chosen duration and scales of monitoring may impact the detection of effects or changes.*

☐ Are any proposed descriptive studies or use of questionnaires as supplementary information to the proposed scientific monitoring plan appropriate for achieving relevant protection goals? *Questionnaires may provide useful supplementary information if they are targeted to protection goals.*

☐ **Sufficiently describe the proposed monitoring sites and regions?**

☐ Are the proposed monitoring sites representative for the intended receiving environment? *The monitoring sites must be representative in order to achieve meaningful results.*

☐ **Adequately describe the means for establishing relevant baselines?**

☐ Utilize scientifically robust methods in constructing the baseline?

☐ Consider the spatial scale over which to establish the baseline?

☐ Consider the effects of spatial heterogeneity on the representativeness of the baseline in each of the compared scenarios (LMO vs. Non-LMO)?

DESCRIPTION OF THE REPORTING, REVIEW, AND USE OF MONITORING RESULTS

The Applicant should describe in the Monitoring Strategy how the results from the proposed Monitoring Plan will be reported, reviewed, and used in order to ensure its efficiency, efficacy and utility in meeting the set protection goals and objectives of the Protocol.

Did the Applicant:

☐ Ensure that the monitoring plans sufficiently flexible and adpative to take in new information or changes in monitoring needs? *This ensures that monitoring plans remain efficient, effective, as useful through time.*

☐ Describe the plans for reporting, dissemination and use of the monitoring information that ensures effective use of monitoring data? *The reporting plan should make clear how monitoring information can be used to support further assessment and decisionmaking, and how relevant biosafety databases and repositories, including the Biosaftey Clear House, will be utilized to disseminate the results.*

☐ Contain assurances that the results from monitoring are transparent, publically available, and accessibile in content and interpretation of results? *Consent for the use of monitoring observations should be obtained from all involved actors must beforhand, to ensure the outcomes from monitoring activities may publically disseminated.*

☐ Adequately describe a plan for contingency measures and emergency measures, including notification and corrective action in the event of identified causal adverse effects? *The description of contingency measures (as mandated in Articles 8, 10, 11 and 13) and emergency measures (Article 17) provides information what actions should take place to meet the objectives of the Protocol.*

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