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# MONITORING OF LIVING MODIFIED ORGANISMS RELEASED INTO THE ENVIRONMENT

*Version of 2 April 2012*

## INTRODUCTION

In accordance with the terms of reference for the AHTEG, this document provides guidance on monitoring of living modified organisms released in the environment,[1] and builds on and complements the Roadmap for Risk Assessment of Living Modified Organisms (LMOs).

In 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.[2] Monitoring may help detect changes related to adverse effects, in a timely manner, before the consequences are realized, and may inform on 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).

Monitoring-related provisions are found in both the Protocol and its parent Convention on Biological Diversity. From the Protocol, paragraph 8(f) of Annex III, 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". Article 16 of the Protocol and, in particular, paragraphs 2 and 4 may be relevant with respect to the implementation of monitoring. From the Convention on Biological Diversity (CBD), recognizing the importance of in situ conservation, Parties to the Protocol may consider monitoring within the broader context of article 7, "Identification and Monitoring" (e.g., monitoring of protected areas or keystone species).[3]

[1] Decision BS-IV/11 of the Conference of the Parties serving as the meeting of the Parties to the Protocol (http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=11690).

[2] See Article 1 of the Protocol.

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

## OBJECTIVE AND SCOPE

This document describes science-based and practical guidance for monitoring adverse effects of LMOs released into the environment 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 included in this guidance.

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.

## MONITORING AND ITS PURPOSES

For the purposes of this document, monitoring is categorized as "case-specific monitoring", or "general monitoring".

Case-specific monitoring is performed to address uncertainty in the level of risk for effects anticipated in the risk assessment. General monitoring may be undertaken to account for effects that were not anticipated in the risk assessment.

Case-specific monitoring 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 (e.g., to test specific risk scenarios) 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 regarding the level of risk, or to confirm that conclusions of the risk assessment are accurate once the environmental release has taken place. In some cases, effects may be identifiable but difficult to estimate or address in the framework of a risk assessment (e.g., they may include long-term, tri-trophic, or cumulative effects, as well as changes to management practices and effects on human health).

- *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.

General monitoring for unanticipated effects starts with general observations of changes in indicators and parameters, which are often defined within national protection goals, or related to the conservation and sustainable use of biological diversity, taking into account risks to human health. Should general monitoring detect changes that could be related to an adverse effect, a more specific hypothesis should be developed and tested to establish a causal relationship between the LMO(s) and the adverse effect, and be followed up by case-specific monitoring or further research. General monitoring may utilize programmes already established for the surveillance of broader protection goals wherever possible.

Annex I provides some examples of monitoring related to the each type and purpose of monitoring listed above.

## 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 a monitoring plan (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.[4]

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 relevant to address the uncertainty regarding the level of risk posed by the LMO under consideration.[5]

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 and assessment endpoints (which may include selection of indicators and parameters) may often be derived from the context and scoping phase of the risk assessment (See Roadmap, "Establishing the context and scope"). The scientific and technical details of the specific LMO, including detection methods, would in many cases be available from the information required for conducting the risk assessment as outlined in Annex III of the Protocol.[6]

The monitoring plan may be comprised of, where appropriate (i) case-specific monitoring for effects that were anticipated in the risk assessment but where there remains unresolved uncertainty as to their level of risk, including effects for associated risks that are difficult or impossible to estimate in a risk assessment, and (ii) general monitoring for unanticipated 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:

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

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

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

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

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

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

*Rationale:*

Monitoring for potential effects of an LMO involves the observation of changes to *indicators* (e.g., species, populations, soil, environmental processes, etc.) and/or *parameters* (i.e. a component to be measured in the observation of an indicator, such as species abundance or soil organic matter).

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.

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

[5] See Roadmap "Overarching issues in the risk assessment process", " Identification and consideration of uncertainty".

[6] See paragraph 9 of Annex III to the Protocol.

*Points to consider:*

(a) The potential of the indicators and parameters to signal changes relevant to 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) Quantitative and qualitative variability of the parameters to be measured;
(d) The usefulness of the candidate indicators and parameters to establish relevant baselines, including reference points;
(e) The importance of the candidate 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.

## 2. 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, 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 the 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 for the analysis of resulting data. Appropriate methods, observations, descriptive studies 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.

The best available science should always be used for monitoring. In some cases, the harmonization of methods, data formats, and analytical approaches facilitates the comparison of results from monitoring in different environments. When the use of existing surveillance networks is to be considered, the monitoring plan should specify the criteria for their selection and utilisation.

*Points to consider:*

(a) Relevance of the monitoring methodology to generate the necessary 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 surveillance 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;[7]
(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;

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

(h) The use of descriptive studies or questionnaires, taking into account their replicability and verifiability;
(i) Findings from ongoing and/or other monitoring activities, if relevant;
(j) Relevant local, regional and international monitoring practices.

**b) Establishing baselines, including reference points**

*Rationale:*

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.

*Points of consider:*

(a) The scientific quality of methods used for generating baseline data;
(b) The appropriate spatial scale of the baseline to be established;
(c) Effects of temporal and spatial variation (i.e. human induced or natural variation in the physical environment);
(d) The scale of potential spread of the LMO.

**c) Establishing the duration of monitoring**

*Rationale:*

The duration of the monitoring, including the frequency in which observations or measurements need to be made, 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, or unanticipated effects), type of LMO (e.g., short or long life cycles,[8] 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 on-going monitoring activities.

*Points to consider:*

(a) The duration necessary for changes in a parameter to likely become apparent;
(b) Characteristics of the indicators to be measured (e.g., persistence, life-cycle and generation time of species when 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 monitoring;
(e) Potential for environmental changes, both biotic and abiotic.

[8] See article 16(4) of the Protocol.

**3. 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 indicators that are species, their biological or ecological characteristics and life cycles;
(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 indicators that are 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.

**4. 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 allow verification to the quality and relevancy of data derived from monitoring to ensure the 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 plan 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.[9]

## CHALLENGES IN THE IMPLEMENTATION OF A MONITORING PLAN

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, both human and financial, helps to ensure the maintenance and completion of the proposed monitoring plan. Amendments to the plan may be required in some cases to ensure it meets the expected outcomes.

Changes or effects observed through monitoring may be a consequence of complex interactions of various biological and non-biological factors within the environment. When changes have been identified, further monitoring information, or follow-up studies may be important to determine whether the observed effects and an LMO have a causal link.

Examples of challenges that may be encountered during the implementation of monitoring may include (i) lack of capacity for the establishment of robust observation, detection or identification methodologies, (ii) difficulty in establishing 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.

[9] See article 21 of the Protocol.

***Annex I***
***Monitoring types and purposes***

| Types of monitoring and their purposes | Examples of monitoring activities |
|---|---|
| **Case-specific monitoring (for effects that were anticipated in the risk assessment but remain unresolved as to their level of risk)** | |
| • Monitoring during experimental, short-term and/or small-scale environmental releases | • Persistence of DNA or transgenic products in the soil<br>• Horizontal gene transfer<br>• *In situ* gene expression levels<br>• Exposure pathways |
| • Monitoring during long-term and/or large-scale environmental releases | • Vertical gene flow from the LMO to wild or weedy relatives<br>• Effect on non-target flora and fauna in the likely potential receiving environment<br>• Effect of altered management practices associated with the LMO<br>• Pest resistance development (e.g., herbicide tolerant or pesticide-producing LM crops)<br>• Screens for toxic or immunogenic effects |
| • Monitoring to evaluate the efficacy of specific risk management strategies | • Effects on biogeochemical cycles (e.g., changes in soil decomposition rates)<br>• Efficacy of refugia to delay resistance development of pesticide-producing LMOs<br>• Recording weed populations in herbicide-tolerant crop fields or adjacent areas |
| **General monitoring (for effects that were not anticipated in the risk assessment)** | |
| • Conservation of biological diversity | • Abundance and population changes in indicator species<br>• Developmental and fitness changes (direct and indirect) in indicator species<br>• Changes in management practices that could lead to adverse effects<br>• Persistence, dispersal or accumulation of the LMO or its products |
| • Protection of human health | • Changes due to long-term exposure to the LMO or its products |
| • Maintenance of plant health | • Changes in incidence of agricultural pathogens or disease, pests and/or weeds |
| • Protection of soil quality | • Survey of soil health indicators |

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