**Monitoring of LMOs released into the environment**

*Version of 22 February 2012*

**INTRODUCTION**

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

In this document, 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.[[1]](#footnote-1)

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”. 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”.[[2]](#footnote-2) Article 16 of the Protocol and, in particular, paragraph 2 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 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.

**MONITORING AND ITS PURPOSES**

Monitoring can be done in a case-specific mannerto address questions and uncertainties related to the 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.

**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.[[3]](#footnote-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 commensurate with the uncertainty regarding the level of risk posed by the LMO under consideration.[[4]](#footnote-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, 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.[[5]](#footnote-6)

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, 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 to monitor?”);
2. Choice of indicators and parameters for monitoring (“what to monitor?”);
3. Monitoring methods, (“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 to monitor?”)**

*Rationale:*

The monitoring plan may differ according to the uncertainties regarding the level of risk of an LMO. The monitoring plan should be described in such a way that it will contribute to achieving its expected outcomes.

*Points to consider:*

1. Uncertainties regarding the level of risk of the LMO;
2. Identified causal pathways from the LMO to potential adverse effects in relation to the risk hypothesis;
3. Uncertainties related to the duration and scale of the release;
4. 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),

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

*Points to consider:*

1. The potential of the indicators and parameters to signal potential adverse effects, in particular, before the consequences are realized;
2. Characteristics of the indicators, as well as the distribution and abundance of those indicators that are species and, their level of exposure to the LMO;
3. Variability of the parameters to be measured;
4. ;
5. The importance of the indicators and parameters to relevant key ecological processes and functions or to the identified protection goals;
6. 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.

*Points to consider:*

1. Relevance of the monitoring methodology to generate information to address uncertainty related to the level of risk;
2. The nature of the effect to be monitored (e.g. whether short- or long-term, delayed or indirect, cumulative, etc.);
3. The specification of the ranges or degrees of changes in a parameter or indicator to signal an adverse effect;
4. The scientific quality of the sampling, analytical and statistical methods to be employed;[[6]](#footnote-7)
5. The availability of relevant standardized methods, and whether and how these could be taken into account;
6. Whether methods are adequate to meet the objectives of the proposed monitoring plan;
7. The use of descriptive studies or questionnaires, taking into account their replicability and verifiability;
8. Findings of the ongoing and/or other monitoring activities, if relevant;

**b) Availability of baselines, including reference points**

Relevant baselines, including reference points, if available, may be useful 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, if a baseline is used, it 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:*

1. The scientific quality of methods used for generating baseline data;
2. The appropriate spatial scale of the baseline;
3. Effects of temporal and spatial variation (i.e. human induced or natural variation);
4. 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.

*Points to consider:*

1. The duration necessary for changes in a parameter being monitored to likely become apparent;
2. Whether variability in the monitored parameters over time could affect the results of the monitoring;
3. Potential for environmental changes.

**4. Choice of monitoring sites (“where to monitor?”)**

*Rationale:*

Monitoring sites are selected on a case-by-case basis.

*Points to consider:*

1. Dissemination and establishment of the LMO in the likely potential receiving environment;
2. The type of LMO as well as indicators and parameters to be monitored and, in case of indicators species, their biological or ecological characteristics and life cycles;
3. Appraisal of suitable, relevant reference sites where the LMO is not present for a comparison over the duration of the monitoring, if applicable;
4. Pathways through which the environment is likely to be exposed to the LMO(s);
5. The distribution patterns, including seasonal distribution (e.g. migration), of the selected indicator species in the receiving environment for consistent detection and observation;
6. 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;
7. The appropriate number of monitoring sites sufficient to support meaningful statistical analysis;
8. The continued availability of the monitoring sites throughout the duration of monitoring;
9. 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:*

1. Reporting requirements set out by the competent authority(ies) or in national biosafety regulations, if available;
2. The completeness of the report, including transparency in presentation of methods, data and analytical tools used to draw conclusions;
3. Accessibility to raw data accrued during the monitoring activities, taking into account information that may be confidential.[[7]](#footnote-9)

**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.

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 2***

**Examples of monitoring in relation to reducing uncertainty.**

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| --- | --- | --- |
| **Objective:** Reduction of levels of significant uncertainty of potential effects identified in the RA | **Indicator(s)/Parameter(s)** | **Example(s) of monitoring** |
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*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.]

1. See Article 1 of the Protocol. [↑](#footnote-ref-1)
2. COP-MOP decision BS-IV/11 (<http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=11690>). [↑](#footnote-ref-2)
3. See Roadmap “Overarching issues”, “Quality and relevance of information”. [↑](#footnote-ref-4)
4. See Roadmap “Overarching issues”, “ Identification and consideration of uncertainty”. [↑](#footnote-ref-5)
5. See Annex III pagraph 9 (a thru h) [↑](#footnote-ref-6)
6. See also considerations on “Quality and relevance of information” in the Roadmap. [↑](#footnote-ref-7)
7. See article 21 of the Protocol. [↑](#footnote-ref-9)