**Monitoring of LMOs released into the environment**

**BACKGROUND**

The Cartagena Protocol on Biosafety and its parent treaty, the Convention of Biological Diversity, contain a number of provisions related to the monitoring of LMOs released into the environment.

Monitoring related provisions in the Protocol are laid out in paragraphs 8(e)[[1]](#footnote-2) and (f)[[2]](#footnote-3) of annex III on “Risk Assessment” and in article 16 on “Risk Management”[[3]](#footnote-4). Article 15 on “Risk Assessment” refers to Annex III and contains language on “observation”, and thereby indirectly to monitoring. Additional provisions that may be relevant to the monitoring of LMOs are elaborated in the Protocol’s parent treaty, the Convention of Biological Diversity (CBD) articles 7 on “Identification and Monitoring”[[4]](#footnote-5) and 8(g) on “In-situ Conservation”[[5]](#footnote-6).

**OBJECTIVE AND SCOPE**

This guidance document was developed with the general aim of providing assistance to the Parties to the Protocol and other Governments if and when, on a case-by-case basis and in accordance with their own biosafety frameworks, they decide to implement strategies to monitor LMOs. The specific objective is to provide countries with practical, comprehensive, science-based guidance to implement a monitoring strategy as needed. It is intended to be a “living document” that will be updated and improved as appropriate and when mandated by the Parties to the Cartagena Protocol on Biosafety.

This guidance applies to all types of LMOs, their intended uses and scales of intentional release into the environment in line with the provisions and objective of the Protocol. Unintentional introductions of LMOs into the environment and unintentional/illegal transboundary movements are outside of the scope of this guidance.

This guidance focuses on the monitoring of adverse effects that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health. Adverse effects may be direct or indirect, short or long-term, immediate or delayed, and occur at various ecological levels and biological processes, or at different stages in an organism’s life cycle or food chain.

Monitoring of LMOs for direct use as food or feed, or for processing are not covered in this document and would require different and/or additional approaches and guidance. Policy issues related to monitoring, e.g. when and what types of monitoring should be enacted, or who bears the responsibility for its implementation and associated costs are not addressed in this document.

**INTRODUCTION**

In the context of this guidance, the monitoring of LMOs refers to measures of systematic collection and analysis of data undertaken following the intentional release of an LMO into the environment.

**Purposes of monitoring**

Monitoring may serve several purposes within the risk assessment and decision-making processes (for an overview see Annex I, below). For example, monitoring can be used to generate data for risk assessments, particularly for short-term and small-scale releases (i.e. field trials). When conducted in such a step-wise manner and in parallel to a risk assessment, monitoring in a more controlled setting with a smaller number of variables can provide data on the potential adverse effect at a smaller scale as compared to the consequences should an adverse effect occur after a large-scale introduction into the environment. The results of such monitoring may increase the scientific strength of the risk assessment, help avoid the need for later risk management measures at a large-scale release, or contribute to much more targeted, cost-effective monitoring strategies. This approach may be further valuable for regulatory agencies with little or no practical experience with monitoring.

Monitoring of LMOs may also be used in conjunction with large-scale environmental releases and after a risk assessment process has been completed, in order to confirm the conclusions of the risk assessment and to address uncertainties that may still remain. Such uncertainties can be, for example, related to long-term effects of LMOs and which could not be addressed during the time period when the risk assessment was conducted. Monitoring may also address issues that were not anticipated during the risk assessment or that arise from information that came to light after the risk assessment process had been completed. Further, monitoring may be used to tackle unforeseen adverse effects on the protection goals of a country and serve as an early warning mechanism to limit the consequences of the adverse effect.

Monitoring may also be useful to evaluate the implementation and effectiveness of risk management strategies (e.g. to avoid the development of resistance in target organisms or to limit potential gene transfer to non-LMOs). In this way, monitoring may help identify, in a timely manner, the occurrence of events that could lead to adverse effects and for the implementation of appropriate response measures to these events.

In the decision-making procedures[[6]](#footnote-7), the outcomes of monitoring may lead to a review and change previous decisions regarding import of LMO if monitoring finds events that may influence the outcome of the risk assessment.

Annex 1 provides a diagram to contextualize the various uses of monitoring.

**TYPES OF MONITORING**

Monitoring can be grouped into two main types of activities: “Case-specific monitoring” and “General surveillance”.

*Case-Specific Monitoring (CSM)* is the type of monitoring to be undertaken, when necessary, in order to address questions and uncertainties related to specific risks associated with the introduction of an LMO into the environment.

The implementation of a CSM may be of value to provide observational data about the effects of the LMO on components of the ecosystem and environment (see step 5 of the Roadmap). This is generally undertaken in order to generate data for a risk assessment in the case of small-scale releases into the environment, which are often accompanied by management strategies to limit the exposure of the environment to the LMO, or to confirm that the conclusions of the risk assessment were accurate once the LMO has been introduced into the environment, particularly as a large-scale release.

CSM therefore reflects the considerations in the earlier steps of the the risk assessment, as it is based on the potential adverse effects identified in step 1, the considerations on likelihood and consequences in steps 2 and 3, and the considerations on uncertainty with regard to the overall risk of the LMO (step 4). In that way, the identification and description of uncertainties arising in the risk assessment (see “Identification and consideration of uncertainty” in the Roadmap) provides important elements to determine, in step 5 of the risk assessment, what aspects, if any, are in need of a CSM strategy. Additionally, CSM may be deemed necessary through the decision-making process to assess the effectiveness of any specific risk management practices that are to be enacted along with the approved use of the LMO.

Additionally, some effects that may not have been or could not been addressed in an environmental assessment of risks (e.g. long-term impacts, indirect food-web interactions, effects on human health from LMO handling) may be subject to CSM.

*General Surveillance (GS)* encompasses monitoring as observations for adverse effects that were not identified or anticipated in the risk scenarios evaluated in the risk assessment. GS, in contrast to CSM, thus tries to address more general questions from 'unknown' risks that could lead to adverse effects to biological diversity, taking into account risks to human health.

The objectives of GS are primarily derived from the protection goals identified in environmental and biosafety legislation or policies of each country. It is important to note that the GS strategy is undertaken independent of specific LMOs that are being used, or that have been used in the past. GS may be useful, for instance, in the monitoring of long-term, cumulative ~~and combinatorial~~ effects, particularly those arising from the use of multiple LMOs or when the interaction between LMOs or other organisms could not have been predicted. In some cases, there may be effects that may not have been or could not been addressed in and environmental assessment of risks (e.g. long-term impacts, indirect food-web interactions, effects on human health from LMO handling) could be addressed using GS.

Should GS detect changes that could lead to an adverse and potentially be correlated with the use of LMOs, a more specific hypothesis can be formulated to establish a causal relationship between the LMO(s) and the adverse effect, and be followed by CSM monitoring studies or risk assessment research to address the specific risk questions.

**DEVELOPMENT OF A MONITORING STRATEGY**

If a recommendation or requirement is made during or at the end of the risk assessment or decision process for the implementation of monitoring activities in the event that the LMO is introduced into the environment, this recommendation should be substantiated with a description of a science-based, effective monitoring strategy. This monitoring strategy can utilize, as appropriate, a designed plan for either one or both of the two types of monitoring (i.e. CSM and GS), and may include provisions to ensure the scientific quality and efficacy of the monitoring activities, and for reporting of monitoring data. When both types of monitoring activities are to be undertaken, the monitoring strategy should clearly outline a separate plan for each.

Regardless of the type of monitoring, i.e. CSM and GS, the design of the plan(s) within the monitoring strategy should outline the overall aims of the activities, and address a number of technical issues that supports the objectives of the Protocol, national protection goals, and contributes to informational needs under risk assessment, risk management, and/or decision-making. Further, the description of a monitoring strategy should be transparent and presented in sufficient detail to ensure scientific quality and relevance of the data obtained[[7]](#footnote-8).

**Designing a monitoring plan**

When designing (or evaluating) a monitoring plan, for either CMS or for GS, the following may be considered:

1. Identification and prioritization of protection goals, potential adverse effects and the choice of indicators and parameters for monitoring (“what to monitor?”);
2. Identification and description of appropriate monitoring methods and establishment of baselines (“how to monitor?”);
3. Duration and scale of the monitoring activities (“how long to monitor?”);
4. Monitoring sites and regions (“where to monitor?”);
5. Use of existing monitoring networks;
6. The reporting of results from monitoring;
7. Feasibility and challenges of the proposed monitoring plan.

Because this guidance focuses on the development of a monitoring plan in the context of risk assessment and risk management, it will emphasize in the following on the design of a case-specific monitoring plan. Nevertheless, considerations described for CSM below, may also apply to GS, as appropriate.

**1. Identification and prioritization of protection goals, potential adverse effects and the choice of indicators and parameters for monitoring (“what to monitor?”)**

*Rationale:*

The identification of potential adverse effects, indicators and parameters to be monitored will vary from case to case, depending on the LMO and the characteristics of the receiving environment. These will be contingent upon specific risk questions and scenarios that were established during the risk assessment (see steps 1-5 of the Roadmap) and on the protection goals and biosafety legislation or policies of each country.

The indicators (e.g. species, populations, groups of species, environmental processes, etc.) and parameters (i.e. a component to be measured in the observation of an indicator) chosen are ideally those that can ~~best~~ reliably detect changes that could lead to the potential adverse effects identified during the steps of the risk assessment and at sensitivities to avoid an adverse effect at the scale of the release.

*Points to consider in the identification of potential adverse effects or protection goals:*

1. Likelihood and consequences of a potential adverse effect identified in step 1 of the risk assessment (see Roadmap) to occur;
2. The relevant protection goals (e.g. protection of biodiversity, ecological function and ecosystem services) within the appropriate ecosystem spheres (e.g. land/soil, water) ~~exist in the relevant environment~~;
3. Uncertainties that were identified during the risk assessment process, in particular those related to specific risk hypotheses or scenarios as well as those that may affect the protection goals.

*Points to consider regarding the identification and selection of relevant indicators and parameters:*

1. The potential of the indicator or parameter to signal possible LMO-induced changes;
2. ~~The breadth of distribution and abundance of an~~ That the indicator’s potential ~~and its~~ level of exposure to the LMO is sufficient to ensure a change in the measured parameter if the LMO caused an adverse effect;
3. The importance of the indicator or parameter to key ecological processes and functions or to the identified protection goals;
4. The potential of the indicator or parameter to reveal changes that could be an indicative of adverse effects;
5. The level of difficulty involved in the sampling or identification of the indicator;
6. The ability to establish relevant baselines with the indicator.
7. The relation of the indicator or parameter to identified protection goals
8. Suitability of indicators or parameters monitored from local observation networks.

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

**2. Identification and description of appropriate monitoring methods and establishment of baselines (“how to monitor?”)**

*Rationale:*

The choice of monitoring methods is largely dependent on the identification of potential adverse effects or protection goals, as well as indicators and parameters decided upon in the preceding step.

The description of the monitoring methodology should include the steps of collecting and analysing data. This involves, for example, methods for (i) sampling of biotic (e.g. of LMOs and/or indicator species) and abiotic (e.g. water, soil) components of the receiving environment, (ii) gathering information (e.g. questionnaires, accessing data from existing networks), (iii) generating data (e.g. analytical methods), and (iv) data analysis (e.g. statistical methods, procedures, and statistical significance requirements).

In describing appropriate methods, it should be considered that for agronomic and land-management issues, those with the greatest potential exposure to ~~most closely associated with the use of~~ the LMO (e.g. farmer, land manager) may be the first to observe relevant changes. Observations, descriptive studies, or questionnaires from those in the user-chain, may be included in the collection data for unanticipated effects as supplementary information, if appropriate. For ecological issues, or effects occurring outside of the intended area of introduction, specialized knowledge may be required that would not be available from LMO users.

The establishment of relevant baselines is a key element for detecting changes and inferring whether there is a causal link to one or more LMOs. The baseline should be described in the monitoring methodology in order to provide an accurate representation of the environment prior to its exposure to the LMO(s). In practice, the baseline is a record of the parameters’ measurements ~~measurement of the relevant~~ indicators prior to the introduction of the LMO(s) in the likely potential receiving environment. While the data needed to establish a baseline may be readily available from previous studies, it may also need to be generated before the introduction of the LMO, or in parallel, based on suitably similar ~~receiving~~ environments that have not been exposed to the LMO(s).

*Points to consider regarding the monitoring methodology:*

1. The nature of the adverse effect to be monitored (e.g. whether short or long term, delayed or indirect, etc.);
2. The availability of appropriate methods;
3. Methods for establishing relevant baselines and monitoring changes to them;
4. The scientific rigor of the approach (sampling, analytical and statistical methods)[[8]](#footnote-9);
5. The availability of standardized methods;
6. The degree to which the methods will meet the objectives of the proposed strategy;
7. Descriptive studies or questionnaires as supplementary information to the proposed scientific monitoring strategy;
8. The adaptability of any existing already established programmes for the surveillance of broader protection goals and/or the potential to establish new modules within them.

*Points of consider for the establishment of baselines:*

1. The use of scientifically rigorous methods in constructing the baseline;
2. The spatial scale over which to establish the baseline;
3. Effects of spatial heterogeneity on the representativeness of the baseline in each of the compared scenarios (LMO vs. non-LMO);
4. The breadth of potential spread related to the type of LMO.

**3. Duration and scale of the monitoring** **activities (“how long to monitor?”)**

*Rationale:*

The duration and scale of the monitoring will depend on the type of adverse effects that are to be monitored (e.g. direct or indirect, immediate of delayed, short- or long-term, etc.), type of LMO (e.g. short or long life cycles), or time length of proposed environmental release. The duration and scale of the monitoring may further vary for each proposed parameter and/or methodology in order to achieve scientific information relevant to inform on adverse effects at the chosen scale or durations (e.g. long-term or scale-dependent effects).

Monitoring activities that require long periods of observation in order for changes to become apparent on one hand provide benefits for understanding potential long-term effects, yet may pose a number of practical challenges (see “Evaluating the feasibility and challenges of the proposed monitoring strategy” below).

*Points to consider:*

1. Different types of adverse effects (i.e. direct or indirect, immediate or delayed, combinatorial, etc.);[[9]](#footnote-10)
2. Life-cycle and generation time of selected indicators / parameters
3. Life-cycle and generation time of the LMO as well as its intended use;
4. The variability of the monitored parameters through time;
5. Unanticipated changes that may be difficult to predict or detect;
6. Effects may become detectible only after a longer period of observation.

**4. Monitoring sites and regions (“where to monitor?”)**

*Rationale:*

Monitoring sites and regions should be selected on a case-by-case basis depending on 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(s) may be introduced.

Relevant information regarding the sites and regions to be monitored include, for example, specific locations, their size and relevant characteristics of the sites may be included in the monitoring strategy.

*Points to consider:*

1. The type of LMO as well as indicators or parameters to be monitored, and their particular biological or ecological attributes and life cycles
2. The intended use of the LMO;
3. Availability of reference sites and regions without the LMOs for a comparisons over the monitoring period, where applicable;
4. Dissemination and establishment of the LMO(s) in the likely potential receiving environment;
5. Pathways through which the environment is likely to be exposed to the LMO(s);
6. The biological and ecological behaviour of the indicators in the receiving environment for consistent detection and observation;
7. Protected areas and centres of origin and genetic diversity or ecologically sensitive regions with specific protection goals, including the use of buffer areas in order to detect unintended presence or unexpected effects, where applicable;
8. The availability of existing monitoring networks operating within representative regions, and their number;
9. Number of monitoring sites and regions sufficient to support rigorous statistical analysis.

**5. Use of existing monitoring networks**

*Rationale:*

The monitoring plan should specify the criteria for choosing any existing monitoring systems and programs to be used for supplying monitoring data. The suitability of such networks should be evaluated beforehand with respect to their potential to achieve the goals of the monitoring plan*.* In the case that existing monitoring networks are found to not be suitable or adaptable to the goals of the monitoring plan, the implementation of other monitoring approaches will therefore be necessary.

*Points to consider:*

1. The adaptability of existing monitoring schemes to LMO monitoring of selected indicators or parameters;
2. The potential for additional monitoring modules;
3. The robustness of data generated possible to meet the monitoring objectives;
4. The number and relevance of existing indicators for LMO monitoring;
5. Representativeness of sites in number or distribution in relation to the intended receiving environment of the LMO release;
6. The frequency of observation and methods employed;
7. The long-term continuity of the monitoring sites;
8. The capacity of the managing institution to collect, report and disseminate data derived from monitoring activities;
9. Access to data before or beyond the timeframe of observation;
10. Expertise and resources available to carry out the relevant monitoring activities.

**6. Reporting of results from monitoring**

*Rationale:*

The reporting of results serves various purposes. It is the primary means to provide feedback on the efficiency and efficacy of the monitoring activities in relation to the objectives set out in the monitoring strategy, to indicate the need for changes to the monitoring plan and/or other risk management strategies (or for follow-up studies or risk assessments), and to inform authorities of adverse effects.

The reporting of results under the monitoring strategy may include a description of how the results of the monitoring activities are to be communicated. A reporting plan may include, for instance, (i) the expected frequency of report submissions, (ii) specifications for the description of the activities undertaken, (iii) requirements for and description of a scientifically rigorous analysis of the results, including whether and if so what changes were observed and (iv) conclusions (on the basis of accrued data, interpretations and experience) and/or recommendations. From this, the regulatory authority should be able to provide a clear interpretation of the results and to decide on the regulatory action to be taken as a result. Since monitoring is both a scientific and regulatory undertaking, the report should clearly describe how the scientific result relates to the original regulatory need for monitoring.

*Points to consider:*

1. The completeness of the report, including ~~the traceability~~ transparency in presentation of data used to draw ~~of~~ conclusions;
2. Requirements regarding reporting of results from monitoring activities that are set out by the competent authority (ies) or in national biosafety regulations, if available;
3. The LMO, including its potential adverse effects and overall risk, the intended use and the likely potential receiving environment as well as any other element that could affect the periodicity of reporting;
4. The choice of methods, duration and scale, as well as sites and regions of the proposed monitoring activities;
5. How to report changes (e.g. to indicators) observed during the monitoring that could lead to an adverse effect and any possible mitigation measure;
6. Any potential challenge associated with the monitoring which could affect its implementation (see below);
7. The magnitude of change that constitutes a followup action or decision;
8. The accessibility to raw data accrued during the monitoring activities.

**7. Feasibility and challenges of the proposed monitoring strategy**

*Rationale:*

In the development or assessment of a proposed monitoring strategy, it may become apparent that resource limitations or technical and analytical challenges may affect effective implementation. Therefore, an analysis of the capacities and resources required to ensure the maintenance and completion of the proposed monitoring strategy may be necessary. Amendments to the strategy may be required in some cases to ensure the monitoring strategy is efficient and effective.

*Points to consider:*

1. Possible methodological challenges for the observations in the monitoring plan to provide statistically meaningful data;
2. Accessibility to representative monitoring sites of all likely potential receiving environments;
3. Challenges in observing adverse effects in the selected parameters/indicators;
4. Challenges for establishing cause-effect relationships (causalities) between the LMO(s) and observed changes in the indicator(s) or parameter(s);
5. Difficulties in interpreting monitoring results and relating them to further specific investigations;
6. Costs and capacities for implementation;
7. Capacity to adapt monitoring activities in the face of unanticipated practicalities or results.

***Annex 1***

**Monitoring strategies in relation to risk assessment, decision-making and implementation   
of risk management under the Protocol**

**[To be developed by the SWG]**

***Annex 2***

**Examples of monitoring subjects/indicators and monitoring methods in relation to protection goals**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of monitoring**  **(CSM or GS)** | **Protection goal(s) / Objective** | **Subjects/Indicator(s)** | **Example(s) of monitoring methods** |
| CSM | Reduction of level on uncertainty of potential effects identified in the RA | Target organisms, Non-target organisms, environmental parameters, etc. | • Confirming host-range effects of target transgenic proteins, resistance development,  • Confirming exposure routes or levels |
| CSM | Impact on assessment endpoints or related indicators identified and evaluated in the RA | Target organisms, non-target organisms, environmental parameters, etc. | • Presence and population levels of key selected NTOs  • Food web and predator/prey interactions of key selected NTOs at different trophic levels |
| CSM | Confirmation of in vivo exposure levels | Non-target organisms, etc. | • Direct or indirect uptake/exposure of NTOs to transgenic pesticidal proteins  • Existence of weed species in herbicide tolerant (HT) fields  • Accumulation of transgenic products in the soil |
| CSM | Impact on production systems in relation to sustainability | Functional organisms, key environmental services, etc. | • Pollination impacts  • Pest control efficacy |
| CSM | Monitoring for scale-dependent effects | Wild and weedy relatives, HGT candidates | • Persistence of DNA or transgenic products in the soil  • Frequency of gene transfer potential |
| CSM | Efficacy of risk management strategies | Case-specific | • Efficacy of refugia strategies to delay resistance development of pesticide-producing crops by testing susceptibility of target pests  • Recording weed populations in HT crop fields or adjacent areas |
| GS | Conservation of terrestrial faunal biodiversity | Vertebrates (mammals, birds, etc.), invertebrates (arthropods, fungi) with a focus on beneficial/functional organisms or protected species | • Abundance and population changes  • Resistance development  • Effects of agrochemical usage associated with the LMO in indicator species  • Developmental and fitness changes (direct and indirect) in indicator species  • Host range or key behavioral changes in indicator species  • Dissemination changes for the LMO  • Changes in pest prevalence or pathology  • Landscape alterations |
| GS | Conservation of terrestrial floral biodiversity (including genetic diversity) and ecosystems | Primary producers (e.g. plants) with a focus on beneficial/functional organisms and important sources of genetic diversity, and protected species | • Outcrossing/hybridization with wild or weedy relatives  • Plant population dynamics and changes  • Effects of agrochemical usage associated with the LMO  • Fecundity and fitness effects  • Dispersal, establishment and persistence  • Landscape alterations |
| GS | Soil quality and functional processes | Soil microbes and invertebrates (e.g. bacteria, fungi, and arthropods) particularly those providing key soil ecological services (nutrient cycling and decomposition) | • Population changes  • Gene transfer frequencies  • Organic compound changes  • Effects of agrochemical usage associated with the LMO  • Soil fertility changes  • Changes to degradation processes  • Soil erosion and compaction changes |
| GS | Conservation of aquatic biodiversity (including genetic diversity) and ecosystems | Aquatic species (e.g. fish, arthropods, algae, plants, mammals) with a focus on beneficial/functional organisms and important sources of genetic diversity, and protected species | • Abundance and population changes  • Effects of agrochemical usage associated with the LMO  in indicator species  • Developmental and fitness changes (direct and indirect) in indicator species  • Host range or key behavioral changes in indicator species  • Dissemination changes for the LMO  • Changes in pest prevalence or pathology  • Habitat alterations  • Outcrossing/hybridization with wild or weedy relatives  • Fecundity and fitness effects  • Dispersal, establishment and persistence |
| GS | Air quality and air pollution prevention | Organic/inorganic pollutants, volatiles, greenhouse gas/C02 concentrations, pollen loads, etc. | • Particulates analysis  • Ozone and SO4 concentrations  • Pollen counts |
| GS | Water quality and water pollution prevention | Physical and chemical pollutants in water, etc. | • Nutrient levels  • Pollutants: pesticides, herbicides, etc.  • Emission of transgenic product to water  • Anoxia |
| GS | Plant health | Plant diseases, pests and weeds, etc. | • Incidence of disease, pests and weeds  • Pesticide usage |
| GS | Human health (e.g. LMO handlers) | Handlers of LMOs or their products (e.g. farmers, research technicians, mill workers, etc.) | • Exposure analysis  • Screens for toxic or immunogenic effects  • Epidemiological surveys |
| GS | Agroecological sustainability | Floral and faunal indicators of functionality (pollinator populations, beneficial plant communities), non-renewable input levels, etc. | •Abundance  • Foraging behaviors and pollination levels  • Soil indicators |
| GS | Socioeconomic aspects | Agricultural methods or production systems, etc. | • Changes in the spectrum/abundance of diseases, pests, or beneficial organisms  • Reduction in effectiveness of target trait or management practices  • Changes in cultivation practices |

*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. “a recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks”. [↑](#footnote-ref-2)
2. “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”. [↑](#footnote-ref-3)
3. “measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects”, and Parties shall “establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions”, and “endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use”. [↑](#footnote-ref-4)
4. See CBD article 7(a) to (d). [↑](#footnote-ref-5)
5. “establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health” [↑](#footnote-ref-6)
6. See Article 10, paragraph 6, Article 11, paragraph 8, and Article 12 paragraph 1 of the Protocol. [↑](#footnote-ref-7)
7. See Roadmap, ”Overarching issues” [↑](#footnote-ref-8)
8. see also considerations on “Quality and relevance of information” in the Roadmap [↑](#footnote-ref-9)
9. Roadmap for Risk assessment, Step 1 Rationale [↑](#footnote-ref-10)