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SCIENTIFIC OPINION

Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2, 3, 4]

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ABSTRACT

The European Commission asked the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) to update its 2006 scientific opinion on Post-Market Environmental Monitoring (PMEM) of Genetically Modified Plants (GMPs). For doing so, the EFSA GMO Panel made use of the experience gained from its assessment of applications on GMPs for cultivation and considered different sources of information such as the PMEM reports on cultivated GMPs, relevant scientific literature and stakeholders comments. This scientific opinion aims to clarify the objectives, tasks, tools and requirements for PMEM. Firsly, the present document explains the scientific rationale for PMEM, including the concept of developing management and monitoring strategies based on the overall conclusions and assumptions of the Environmental Risk Assessment. Secondly, it provides examples and guidance to applicants on how to develop and implement their plans for Case-Specific Monitoring (CSM), taking into account the case-by-case character of CSM. In addition, it provides guidance to applicants on the strategy, methodology and reporting of General Surveillance (GS). Different tools and approaches to implement a plan for GS are considered. The EFSA GMO Panel proposes a holistic and integrative approach for monitoring GMPs in the EU that considers GS within a framework of general environmental protection monitoring. Finally, the EFSA GMO Panel makes proposals to risk managers for the future conduct of PMEM in the EU and suggests that access to PMEM data could be facilitated by setting-up standardised and centralised reporting centres. This scientific opinion repeals the former 2006 scientific opinion of the EFSA GMO Panel on PMEM of GMPs.

KEY WORDS

Genetically Modified Plant (GMP), Environmental Risk Assessment (ERA), Post-Market Environmental Monitoring (PMEM), risk management strategies, Case-Specific Monitoring (CSM), General Surveillance (GS), protection goals, Directive 2001/18/EC.

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[4] Detlef Bartsch was member of the Working Group on the Update of the 2006 PMEM Scientific Opinion until 30 May 2011.

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SUMMARY

The Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked by the European Commission to update its 2006 scientific opinion on the Post-Market Environmental Monitoring (PMEM) of Genetically Modified Plants (GMPs).

The EFSA GMO Panel made use of the experience gained from its assessment of applications on GMPs for cultivation and considered different sources of information such as the PMEM reports on cultivated GMPs, relevant scientific literature and stakeholders comments.

The EFSA GMO Panel firstly focused on the scientific rationale for PMEM. This scientific opinion shows how the overall conclusions and assumptions of the Environmental Risk Assessment (ERA), including the remaining uncertainties, determine the requirements for PMEM.

In second instance, the EFSA GMO Panel developed guidance to applicants on how to establish and implement their plans for Case-Specific Monitoring (CSM) in order to generate robust, scientifically-sound and statistically relevant data to further inform the ERA. Guidance on the statistical design and, when needed, the choice of appropriate non-GM comparators for CSM is provided. In addition, subject to the case-by-case character of CSM, examples of objectives for CSM are given in this scientific opinion.

In third instance, the EFSA GMO Panel discussed the concept and principles of General Surveillance (GS). It was recognised that GS is not hypothesis driven as it targets unanticipated effects. A plan for GS should be designed to identify the aspects of the environment that need to be protected from harm. In this respect, the EFSA GMO Panel provides a non-exhaustive list of examples of protection goals, assessment endpoints and indicators as well as of possible approaches for GS. The EFSA GMO Panel refers to three main approaches for GS of GMPs, namely (1) by monitoring the GMP and its cultivation sites (e.g. using a questionnaire to farmer), (2) by utilising the data collected by existing monitoring networks active in biodiversity surveys at local/regional/national scale and (3) by compiling and analysis data from scientific literature. Whereas the EFSA GMO Panel highlights the advantages and limitations of these approaches for GS, it also provides detailed guidance on how to use and to improve them.

In the present opinion, the EFSA GMO Panel proposes a holistic and integrative approach for monitoring GM plants in the EU that considers GS within a framework of general environmental protection monitoring. In this context, the EFSA GMO Panel recognises that all parties (e.g. applicants, Member States) have to consider their roles in such an approach for environmental protection monitoring that embraces GS, both within countries and across the EU. In this wider context of monitoring GMPs as one component of the overall production system, the EFSA GMO Panel also suggests that standardised and centralised reporting centres for PMEM data be implemented. This would have the benefit of being able to harmonise and synchronise environmental monitoring, facilitate analysis and interpretation of PMEM reports.

Therefore, this scientific opinion repeals the former 2006 scientific opinion of the EFSA GMO Panel on PMEM of GMPs.

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BACKGROUND AS PROVIDED BY EFSA

According to Articles 13 and 20 of Directive 2001/18/EC (EC, 2001), each notification for placing on the market a genetically modified organism (GMO) shall contain a plan for monitoring in accordance with Annex VII of the Directive. Similarly, according to Articles 5.5(b) and 17.5(b) of Regulation (EC) No 1829/2003 (EC, 2003), each application for the placing on the market of a GMO or food/feed containing or consisting of that GMO shall be accompanied by a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC. Annex VII was supplemented by notes providing guidance on the objectives, general principles and design of the monitoring plan (EC, 2002).

From 2003 onwards, the European Food Safety Authority (EFSA) received notifications and applications for placing on the market of GMOs in the EU submitted respectively under the aforementioned Directive and Regulation. These notifications and applications contained a Post-Market Environmental Monitoring (PMEM) plan. The Panel on Genetically Modified Organisms of the EFSA (EFSA GMO Panel) is responsible for assessing the scientific quality of the PMEM plans.

Recognising the importance and complexity of developing PMEM plans, the EFSA GMO Panel then decided to develop specific guidance on PMEM in 2004. On 25 January 2006, after a two-year self-task mandate, the EFSA GMO Panel adopted a scientific opinion providing guidance to applicants on how to develop PMEM plans (EFSA, 2006).

Upon request of the European Commission, the EFSA GMO Panel recently updated its former Guidance Document (GD) on the Environmental Risk Assessment (ERA) of GM plants (EFSA, 2010a). The 2010 GD on the ERA of GM plants has been prepared by expanding and completing most sections of the previous GD in accordance with current legislation, experience gained by the EFSA GMO Panel and its respective Working Groups during the evaluation of the ERA of past applications, the outcome of a self-tasking activity on non-target organisms[5], the outcome of the sub-working group on statistical considerations for the safety evaluation of GMOs[6] and guidance on stacked events[7].

Following the update of the GD on the ERA of GM plants, the EFSA GMO Panel considered needed to review its 2006 scientific opinion on PMEM in light of the experience gained and comments from stakeholders. On its own initiative, in the course of April 2010, EFSA offered to the European Commission its technical support with respect to PMEM activities, reiterating its willingness to update, where appropriate, the aforementioned opinion. On 27 October 2010, the European Commission asked EFSA to update the 2006 scientific opinion on PMEM of GM plants by July 2011.

In accordance with the terms of reference, a draft updated opinion was delivered to the European Commission in April 2011. In addition, the draft opinion was submitted for comments by the public during an appropriate consultation period (18 April – 22 May 2011). Finally, EFSA invited representatives from Member States to further discuss the comments they had submitted through the public consultation, at the second meeting[8] of the EFSA Scientific Network for Risk Assessment of GMOs (Parma, 9 & 10 June 2011). Consequently, EFSA assessed all relevant comments from interested parties which were further considered by the PMEM WG and EFSA GMO Panel. EFSA published a Technical Report[9] on the outcome of the public consultation on the draft scientific opinion.

[5] http://www.efsa.europa.eu/en/efsajournal/pub/1877.htm
[6] http://www.efsa.europa.eu/en/efsajournal/pub/1250.htm
[7] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902599859.htm
[8] http://www.efsa.europa.eu/en/gmo/gmonetworks.htm
[9] http://www.efsa.europa.eu/en/panels/gmo.htm

The present document provides a detailed scientific opinion by the EFSA GMO Panel on the updated requirements for PMEM plans of GM plants and the scientific rationale for these plans, in line with the 2010 Guidance Document on the ERA of GM plants (EFSA, 2010a). This scientific opinion repeals the 2006 scientific opinion of the EFSA GMO Panel on the PMEM of GMPs (EFSA, 2006). The conclusions and recommendations of this scientific opinion will form the basis for an update of the approaches and methods for CSM and GS as outlined in chapter 4 of the 2010 EFSA Guidance Document on the Environmental Risk Assessment (ERA) of GMPs (EFSA, 2010a).

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

On 27 October 2010, the EFSA GMO Panel received a mandate from the European Commission to update its 2006 scientific opinion on the PMEM of GM plants. The European Commission asked to receive a draft opinion adopted by the EFSA GMO Panel no later than April 2011 in order to start discussion with Member States. Following a public consultation, the final opinion, revised in the light of received public comments, should be provided to the European Commission at a second stage, by July 2011.

ASSESSMENT

1. INTRODUCTION

In response to the mandate from the European Commission, EFSA immediately established a dedicated Working Group (PMEM WG) on the update of the 2006 scientific opinion providing guidance on PMEM of GM Plants (GMPs).

The PMEM WG activities firstly focused on the scientific rationale for PMEM and the chapter dedicated to Case-Specific Monitoring (CSM) as it lacked detailed recommendations for monitoring strategy, methodology and analysis. Secondly the PMEM WG updated and supplemented, where needed, the sections related to the concept and principles of General Surveillance (GS).

The present scientific opinion aims to clarify the objectives, tasks, tools, responsibilities and requirements for PMEM at both, the national and European scale. In addition, this document provides further guidance to applicants on the design of PMEM plans and their implementation (e.g. data analysis and interpretation) and makes proposals to risk managers for the future conduct and coordination of PMEM in the EU.

In preparing this document, the EFSA GMO Panel and its PMEM WG made use of the experience gained from their assessment of applications on GMPs for cultivation, the PMEM reports on cultivated GMPs, relevant scientific literature and from public comments from past EFSA consultations[10]. They also considered their ongoing assessment of the annual 2009 PMEM report on the cultivation of GM maize MON810 under a separate mandate from the European Commision. The preliminary conclusions from this assessment were also taken into consideration, when finalising the present scientific opinion.

2. LEGISLATIVE BACKGROUND

An objective of Directive 2001/18/EC (EC, 2001) and other environmentally-related legislation (see Table 1 of EFSA, 2010a) is to protect the environment, including natural resources and ecosystem services (biodiversity[11] and agro-ecological functions e.g. pollination, soil functions, production systems). The EFSA GMO Panel recognises that all human activities can have environmental impacts and the potential to affect ecological functions and processes, so that there is a general need to consider the impacts of any new product, development or process on environmental protection goals. In this respect, Directive 2004/35/EC (EC, 2004) on environmental liability with regard to the prevention and remedying of environmental damage defined environmental damage as a measurable adverse change in a natural resource or measurable impairment of a natural resource service which may occur directly or indirectly.

Directive 2001/18/EC (EC, 2001) introduces an obligation for notifiers to implement monitoring plans in order to trace and identify any direct or indirect, immediate, delayed or unanticipated effects on human health or the environment of GMOs as or in products after they have been placed on the market. Monitoring plans should be designed according to Annex VII of the aforementioned Directive. According to Annex VII, the objectives of (an environmental) monitoring plan are (1) Case-Specific Monitoring (CSM) to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the ERA are correct, and (2) General Surveillance (GS) to identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the ERA.

[10] http://www.efsa.europa.eu/en/efsajournal/pub/1880.htm
[11] See also the EU biodiversity strategy to 2020 here: http://ec.europa.eu/environment/nature/biodiversity/comm2006/2020.htm

In line with the regulatory framework, Annex VII to Directive 2001/18/EC was supplemented by the Council Decision 2002/811/EC establishing notes providing detailed guidance on the objectives, general principles and design of the monitoring plan referred to in that Annex (EC, 2002).

According to EC (2002), monitoring can be defined as the systematic measurement of variables and processes over time and assumes that there are specific reasons to collect such data, for example, to ensure that certain standards or conditions are being met or to examine potential changes with respect to certain baselines. Effective monitoring and general surveillance require that appropriate methodology has been developed and is available prior to the commencement of monitoring programmes. Monitoring should not be regarded as research *per se* but as a means to evaluate or verify results and assumptions arising from previous research and evaluation of potential risk.

In addition, and in line with EC (2002), CSM should, when included in the PMEM plan, focus on potential adverse effects arising from the placing on the market of a GMO that have been identified in the conclusions and assumptions of the ERA. However, whilst it is possible to predict that certain adverse effects may occur, on the basis of risk assessment and available scientific information, it is considerably more difficult to plan for potential effects or variables that cannot be foreseen or predicted. It may, however, be possible through appropriate planning of monitoring and surveillance plans to facilitate early detection of such effects. The design of the monitoring plan shall, therefore incorporate GS for unanticipated adverse effects.

According to Articles 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 (EC, 2003), the applications for placing on the market GMOs or food/feed containing or consisting of GMOs shall also include a monitoring plan for environmental effects conforming with Annex VII of Directive 2001/18/EC. Since Regulation (EC) No 1829/2003 explicitly refers to Annex VII of Directive 2001/18/EC, the environmental monitoring plan should be designed in accordance with the Council Decision 2002/811/EC (EC, 2002) supplementing Annex VII (i.e. strategy, methodology, analysis, reporting). The structure and content of a PMEM plan are laid down in the Commission Decision establishing standard reporting formats for presenting the monitoring results of GMOs as or in products (EC, 2009a).

In addition, Article 20(1) of Directive 2001/18/EC states that: '*Following the placing on the market of a GMO as or in a product, the notifier shall ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent*'. Thus the final monitoring plan and implementation of the monitoring will be determined by risk managers in association with applicants.

3. Interplay between Environmental Risk Assessment, Risk Management and Post-Market Environmental Monitoring

The ERA aims, on a case-by-case basis, to identify and evaluate potential adverse effects of the GMP, either direct and indirect, immediate or delayed or cumulative over time and space, on human health and the environment arising from its placing on the market.

As outlined in the EFSA Guidance Document on the ERA of GMPs (EFSA, 2010a), the ERA generally comprises six sequential steps (see Figure 2 of EFSA, 2010a): (Step 1) problem formulation to identify the critical issues associated with the GMP and its cultivation; (Step 2) hazard assessment that examines potential hazards and their magnitude; (Step 3) exposure assessment that covers levels and likelihood of exposure; and (Step 4) risk characterisation in which the magnitude of consequences and the likelihood of occurrence are integrated and areas of uncertainty are identified (see chapter 2.3.3.8 of EFSA, 2010a).

When risks or uncertainties are identified at Step 4 of the ERA, applicants should propose and describe the risk management strategies (Step 5) that will be associated with the cultivation and release of the GMP taking into account the range of scenarios (including worst-case scenarios) studied in the ERA (see Figure

1). The risk management strategies proposed should be proportionate to the results of the different scenarios studied, to the specific protection goals in the receiving environments and to the levels of uncertainty and risk identified in the ERA. Applicants should assess to what extent the proposed risk management strategies will reduce risks. In addition, applicants should identify any uncertainty associated with the efficacy and implementation of risk management strategies and their potential implications.

Finally, according to Step 6 of the ERA (see chapter 2.2.6 of EFSA, 2010a), an evaluation of the overall risk of the GMPs should be made, taking into account the results of the risk characterisation (Step 4), the proposed risk management strategies (Step 5) and the associated levels of uncertainty. The overall risk evaluation & conclusions determine the requirements for any additional risk management strategies and for PMEM of GMPs.

Overall, the results of the ERA of a GMP will be subject to varying levels of uncertainty associated with factors such as the availability of data to inform the ERA, the range of EU receiving environments where the GMPs are likely to be cultivated, the diversity of production and management systems across EU regions as well as the efficacy of any mitigation measures used to reduce levels of risk and uncertainty. As far as it is possible, the overall conclusions of the ERA should (i) specify under which conditions (e.g. receiving environments, management systems) the risks/uncertainties identified are most likely to occur and (ii) clearly identify the factors/processes which might affect the conclusions of the ERA in order to make it explicit the domain of validity of the conclusions of the ERA.

Thus the overall conclusions of the ERA provide the basis for PMEM plans, which focus on risks to human health and the environment (including domestic animal health) identified in the ERA and can be used to provide data on uncertainties identified in the ERA. When risks and/or significant levels of critical uncertainty[12] linked to the GMP and its management have been identified in the ERA, then CSM should be carried out after placing on the market, in order to further inform the ERA. Monitoring of potential adverse cumulative long-term effects identified in the ERA should also be considered initially within CSM. Thus the role of CSM in PMEM plans is to check the assumptions made during the ERA and to ensure that the ERA conclusions are valid as regards the authorised use of the GMP.

As for unanticipated effects, the EFSA GMO Panel recognises that all human activities can have environmental impacts and the potential to affect ecological functions and processes, so that there is a general need to consider impacts of the cultivation of GMPs within this context. In addition, the EFSA GMO Panel recognises that risk assessments are based on current knowledge and experience of a GMP and our current understanding of natural and managed environments. The knowledge on the environmental consequences of commercial scale releases of GMPs in different European receiving environments may be limited, and even when the ERA gives no indication of potential adverse effects, these can never be entirely dismissed. In addition, it can be difficult to predict all the potential future applications and systems under which the GMP may be grown and also to predict how different receiving environments may also change independently of the GMP. Thus large-scale and long-term cultivation of a GMP could result in some effects which were not predictable at the time of the ERA or consent.

Directive 2001/18/EC (EC, 2001) introduces the requirement for PMEM of GMOs for dealing with these residual uncertainties about environmental risk and harm. The objectives of GS are to detect unanticipated adverse effects to human health and the environment, to determine the harm to protection goals and to determine the causality between the detected unanticipated adverse effects and the cultivation of GMPs (see chapter 2). Protection goals and environmental damage are considered in more detail in the section on GS (see chapter 4.2.1).

[12] Critical uncertainty: uncertainty that, once resolved, may result in a conclusion that an effect is likely to cause environmental harm.

The introduction and extensive cultivation of some GM crops in certain countries (e.g. soybean in Brazil and Argentina) show that they may change crop management practices (e.g. tillage and use of pesticides (Altieri & Liebman, 1990; NAS, 2010)). Thus GMPs cultivation can have novel impacts, either positive or negative, on agricultural systems and environments which were not always considered in the original ERAs (van den Brink et al., 2010). As more GMPs are likely to be cultivated in Europe, it is anticipated that they will have different impacts and that more changes will occur in the cultivation practices of farmers. Thus the EFSA GMO Panel considers that the release and cultivation of GMPs in the EU may have unanticipated effects on the environment, including biodiversity, sustainable production and ecosystem services and functions. Some of these effects may be harmful while others are beneficial. However these are not likely to occur in isolation and will probably be a component of the overall trends and developments occurring in European agriculture in response to market, climatic and political/economic forces.

In addition, the experience in North and South America shows that in future it is likely that many different GM crops will be grown within a farm or a region. They will be grown in rotation in the same fields as well as in adjacent fields so that there will be both spatial and temporal interactions between GM crops as well as with non-GM crops. This means that any future GS monitoring system for environmental impacts of GMPs should not just be focussed on individual events but should also be concerned with the impacts on receiving environments of these GMPs, their interactions and their cultivation and management. Thus an additional focus of PMEM should be the impacts on the protection goals associated with production systems containing GMPs in comparison with systems that do not (see Table 1 in EFSA, 2010a).

Monitoring networks are already operating in Member States either at official or voluntary levels to monitor effects of human activities and processes on a range of environmental parameters, including biodiversity, water and air quality (see Appendix 1 to the report[13] of the Monitoring Working Group set up by the European Commision on the Environmental monitoring of GMOs & General Surveillance). In addition, many Member States have monitoring networks in place to monitor agricultural practices and their environmental impacts. These monitoring networks should be considered when setting-up PMEM plans.

[13] http://ec.europa.eu/food/food/biotechnology/index_en.htm

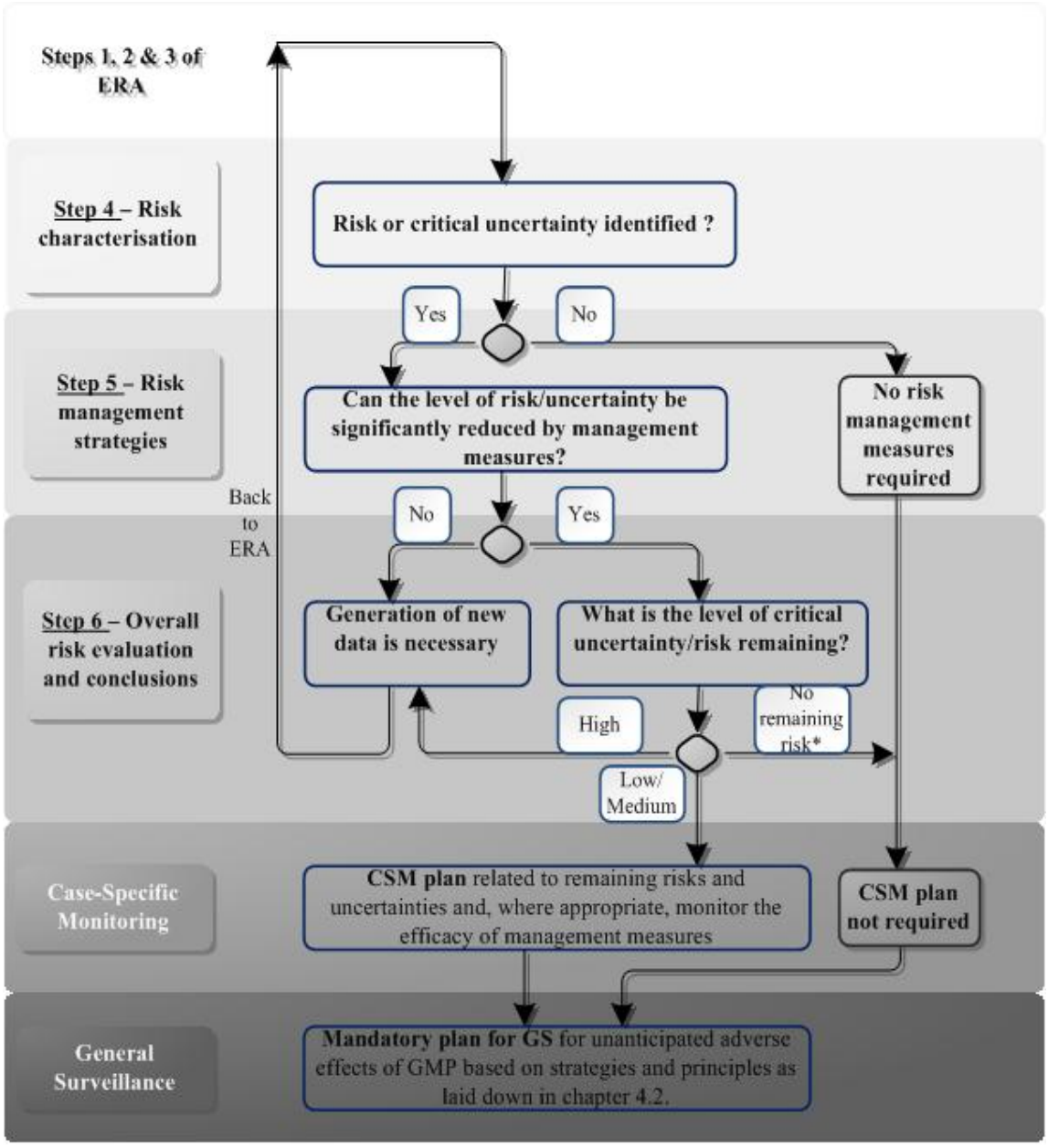

Figure 1: Chart showing links from the Risk Characterisation of the ERA (Step 4), the Risk Management Strategies (Step 5), the Overall Risk Evaluation and Conclusions including critical uncertainty (Step 6), and Case-Specific Monitoring (CSM) and/or General Surveillance (GS).

4. GUIDANCE ON POST-MARKET ENVIRONMENTAL MONITORING

According to chapters 2 and 3, when risks and/or significant levels of critical uncertainty[10] linked to the GMP and its management have been identified in the ERA, then CSM should be carried out after placing on the market, in order to further inform the ERA. The present scientific opinion provides various options for CSM implementation which depend on the outcomes of the ERA.

By contrast, GS is conducted in order to take account of general or unspecified uncertainties and any unanticipated adverse effects associated with the release and management of a GMP. Thus a GS plan is mandatory for each application, which includes the release of viable GMP material in the EU, in order to detect the occurrence of adverse effects that were not anticipated or specifically identified during the ERA (see chapter 2). Key objectives of GS should also refer to protection goals (see Table 1 in EFSA, 2010a; EFSA, 2010b) and ecosystem services and functions such as species/ecosystem biodiversity, soil functionality, sustainability of agro-ecosystems, pollination, plant health, human and animal health.

4.1. Case-Specific Monitoring (CSM)

4.1.1. Strategy for Case-Specific Monitoring

When risks or important gaps in scientific information or significant levels of critical uncertainty linked to the GMP and its management have been identified in the ERA, then CSM should be carried out after placing on the market, in order to confirm assumptions made in the ERA and to further inform the ERA.

CSM is hypothesis-driven and should be targeted at the assessment endpoints and protection goals identified in the ERA conclusions as being at risk or where levels of critical uncertainty were identified in relation to potential risks associated with the GMP. Monitoring of potentially adverse cumulative long-term or large-scale effects (see chapter 2.3.4 of EFSA, 2010a) and the resolution of areas of critical uncertainty, identified in the ERA (see chapter 2.3.3.8 of EFSA, 2010a), are important objectives of monitoring (EC, 2002), which should be considered initially within CSM. When there is critical uncertainty concerning the impacts of time and scale and/or the acceptability of environmental risks of GMPs compared to non-GM plants, then CSM is indicated. An example may be where the exposure and sensitivity of a range of insect species to a Cry toxin has not been fully determined but is predicted from studies of some key species (see Perry et al., 2010). Applicants shall clearly explain their rationale for not adopting CSM where risks and critical uncertainty have been identified in the ERA. An example may be where applicants develop risk management strategies that reduce risks to levels where no environmental harm is occurring (see Figure 1).

The CSM of GMP may have different objectives and these can determine the type of monitoring that is conducted (see Box 1).

As stated above, one objective may be to reduce the level of uncertainty on key processes identified in the ERA. An example would be the Cry protein sensitivity of some protected/rare non-target (NT) species occurring in certain localities and being potentially at risk which may not have been tested in the ERA. In those cases, additional monitoring studies could be done in certain regions to determine which species are exposed and their sensitivity to the Cry protein.

Another objective of CSM would be to record actual exposure levels of certain biota considered to be potentially at risk if exposure levels were above a certain threshold.

The most direct method of CSM is to monitor directly the impacts on assessment endpoints identified as being at risk in the ERA conclusions. For example, in case of a NT lepidopteran species whose host plants might be dusted with Bt pollen nearby GM crop fields, effects on populations of exposed biota would be

monitored. An alternative approach would be to monitor the host plants of non-target herbivores potentially at risk in the area of the GMP. In addition, ecosystem services (e.g. natural pest regulating mechanisms) and their indicators could be monitored.

Finally, if risk management strategies have been put in place due to identified risks or critical uncertainty (e.g. gaps in the scientific information), their efficacy could be monitored in order to determine the reduction in exposure. In such cases, the monitoring results can be used to modify the risk management strategies, so that they are proportional to the remaining levels of risk.

Examples of these Options (O) and Approaches (A) are given below in Box 1.

Box 1: Examples of Objectives (O) and Approaches (A) for CSM

(O) Reducing the level of uncertainty on key processes identified in the ERA

(A) Example:

- by providing additional data on the sensitivity of Non-Target (NT) species to Cry proteins.

(O) Measuring *in vivo* exposure levels

(A) Examples:

- presence of NT Lepidoptera young larvae & Bt maize pollen deposition on host plants during pollen shed,
- presence of NT insect host plants in GM Insect-Resistant crop fields.

(O) Monitoring directly the impacts on assessment endpoints identified as being at risk in the ERA conclusions

(A) Examples:

- monitoring populations of selected exposed NTOs and weed species,
- monitoring recovery from adverse effects in a time frame deemed necessary to reach acceptable baseline conditions as defined in Annex I of Directive 2004/35/EC.

(O) Monitoring impacts on organisms/processes related to the assessment endpoints identified in the ERA

(A) Example: food web and prey/predator effects, such as presence of selected NTOs at different trophic levels.

(O) Recording impacts on functional or production systems related to sustainability, IPM, etc

(A) Examples: Measuring the effectiveness of pollination, natural pest regulating mechanisms.

(O) Assessing the efficacy of risk management strategies arising from conclusions of the ERA in order to estimate the uncertainty associated with risk management strategies

(A) Examples:

- checking the efficacy of the 'high dose/refuge' strategy by surveying the change in susceptibility of target pest(s) to GM Insect-Resistant plants: this involves both field sampling and laboratory testing,
- recording weed populations in HT crops and rotations.

After identification of the objectives and the approaches (see examples in Box 1), the next step in establishing a CSM plan is to identify the hypothesis to be tested and parameters that need to be measured in order to achieve these objectives. Parameters to be measured must be valid and fit-for-purpose and applicants should consider the range of information published on monitoring parameters and indicators (e.g. Hilbeck et. al., 2008; Aviron et al., 2009; Graef, 2009; Fengyi et al., 2009; Higgins et al.; 2009; Zhu, 2009; Beckie et al., 2010; Engels et al., 2010).

4.1.2. Methodology for Case-Specific Monitoring

The design of the CSM needs to consider the practicality and feasibility of observing, and recording data of sufficient quality to provide a valid assessment. Where practical CSM should be directed at the focal species or the assessment endpoints of concern in receiving environments where effects are most likely to be detected, i.e. where there are high levels of exposure of both the assessment endpoint and the GMP. However in some cases this may not be practical as the subject to be monitored occurs at low or eratic levels or is heavily influenced by other factors so that quality data cannot be collected. In these cases, consideration should be given to indirect methods that can be used to assess impacts on assessment endpoints or protection goals. These include recording changes in biota associated with the focal biota or

assessment endpoints, changes to species in food webs affected by the GMP and its management, or changes to ecosystem functions associated directly or indirectly with the GMP and associated biota (EFSA, 2010a). For example, if there is monitoring of the ecosystem function 'predation', the options include: (1) directly monitoring the predator population, (2) monitoring the main food prey of the predator or (3) monitoring pest management on farms growing the GMP to see if there are effects on Integrated Pest Management (IPM) and hence the sustainability of the farming systems.

Whilst the planning and execution of CSM is under the applicant's responsibility, it may be appropriate for the applicant to involve public scientific institutions to contribute to the planning, conduct and/or analysis of the CSM.

Applicants shall clearly identify and describe the methodology to monitor the selected parameters, including techniques for sampling and analysis. Standard methodology, such as those provided for by internationally agreed European CEN Standards and OECD-methods for monitoring organisms in the environment, should be followed where appropriate and reference to the source of the methodology provided (see chapter 9[14] of Züghart et al., 2011). In addition, methods used for CSM should be scientifically sound and valid under the conditions in which they are to be applied. Therefore, consideration should be given to the characteristics of the methods, such as selectivity, specificity, reproducibility and any limitations such as detection limits, the availability of appropriate controls, and proportionality to risk.

Depending on the objectives of CSM, studies should be conducted at field, farm or landscape level with the GMP grown under commercial conditions in order to determine effects at these scales of cultivation. CSM plans should be scientifically designed but are not obliged to adopt the protocols usually associated with replicated trials within a field experimental setting, unless this is specifically identified as required by the ERA conclusions. However, whatever scientific approach is adopted, CSM shall be designed in order to test specific hypotheses of possible adverse effects derived from the ERA conclusions and, where appropriate, to evaluate risk management strategies associated with the cultivation of the GMP (see chapter 2.2.5 of EFSA, 2010a). It is essential that these hypotheses be stated explicitly at the design stage of the CSM study and that applicants demonstrate that the design has the appropriate methodology and statistical power to test the hypothesis.

Applicants should establish effective quality assurance (e.g. GXP standards) and auditing schemes for the design, conduct and reporting of CSM (see also chapter 2.3.1 of EFSA, 2010a).

4.1.2.1. Statistical design & analysis

For each CSM study, all the relevant scientific questions that the study is designed to address shall be listed explicitly at the design stage of the study and, in addition, each of these questions shall be re-stated in formal terms, in the form of the null hypothesis that is to be tested to answer the question. Clear and explicit statements shall be made concerning the minimum levels of data acceptable for each variable being assessed, below which results would lack credibility (EFSA, 2010a). A minimum effect size shall be specified that the study is designed to detect. In addition, where appropriate, a statistical power analysis shall be done to estimate the power of the study to detect this effect, based on the stated effect size and assuming a 5% type I error rate. The power analysis shall use only information verifiable as available prior to the study; under no circumstances shall data from the study itself be used. For situations where many species are sampled, a power analysis should be done only for focal species (for further details, see chapter 3.4.1.2. of EFSA, 2010a) expected to be the most abundant.

[14] Chapter 9 entitled 'Standardisation of methods for monitoring effects of GMOs in the environment' refers to series of guidelines developed by the Association of German Engineers (VDI, 2006 and 2009).

4.1.2.2. Choice of comparators

Some aspects of CSM, particular those that relate to exposure, involve estimation of parameters rather than a comparative approach, and for these the choice of comparators is not relevant (see chapter 4.1.2.3).

However, a common problem in PMEM studies arises when the paramount aim is to assess environmental impacts by comparing the effects of GM and non-GM cropping at a large scale. Here, the choice of comparator(s) will in most cases require acknowledgement that the effect of cropping is likely to be manifest within systems and at a relatively large scale. Different fields might be compared which may be remote from one another.

Appropriate comparators should be selected that fulfil the requirements of replication, control of variability and the use of blocking factors, such as e.g. field/farm size, previous management (see chapter 2.3.3. of EFSA, 2010a). For CSM, sampling units will be larger than the plots typically used in agricultural or variety trials, otherwise the effects studied are not representative. However, as noted by Perry (1997), adequate replication within such restrictions requires considerable land resources, especially as between-field heterogeneity is likely to be far greater than that usually encountered between plots in conventional field experiments (see Aviron et al., 2009). This is costly, and may be inconvenient, causing problems in management that are not encountered in small-plot experiments. Furthermore, it is necessary to ensure that variability between units is well controlled (Perry, 1997). Problems may be compounded when non-standard response variables, such as 'sustainability' are involved, for which there may be little experience in analysis. Such difficulties may be further compounded if the degree of required isolation of the GM field from non-GM fields might be a confounding factor, as when, for example, the non-GM fields are a potential source of pests or natural enemies. Often, proposed solutions involve the pairing of farms and/or fields with different treatments (e.g. Gibson et al., 2007 and see hereunder[15]), but care is required to ensure that factors, such as e.g. field/farm size, previous management, altitude, soil characteristics, are properly matched. Often it is difficult to find sufficient candidates to ensure a good match because of the multiplicity and complexity of the interacting factors involved.

Therefore, applicants should describe the chosen comparators and explain why they are preferred, their attributes and their weaknesses. The range of variability expected from the comparators and the main factors influencing them (e.g. cultivation practices) should be described. Some aspects of CSM, particular those that relate to exposure, involve estimation of parameters rather than a comparative approach, and for these the choice of comparators is not deemed relevant.

4.1.2.3. Spatial scale of Case-Specific Monitoring

Since CSM is hypothesis-driven, it is important that it is carried out at sites where there is the greatest likelihood of measurable impacts occurring. Therefore, applicants should consider where the potential environmental stress associated with the GMP is likely to be greatest in relation to levels of exposure in the receiving environments, e.g. different geographical regions and other specific site influences. Applicants should select monitoring sites considering where there is significant and repeated growing of the GMP, large-scale cultivation of the GMP, the occurrence of target species and/or potentially at risk biota, and the sensitivity of particular receiving climatic/eco-regions. In some specific cases, CSM will require sampling of biota at varying levels of exposure (e.g. sampling of target pests to survey possible change in susceptibility to GM Insect-Resistant plants). In these cases, samples should also be collected from areas of lowest possible exposure in order to record baseline data.

[15] http://www.fao.org/fileadmin/templates/agphome/documents/Biodiversity-pollination/Pollination_Protocols/PollinationDeficitsProtocol.ppt

The methods selected, the choice of monitoring sites, the extent or number of monitoring sites and the parameters to be monitored will be determined on a case-by-case basis and shall be clearly explained by the applicant in its CSM plan.

4.1.2.4. Temporal scale of Case-Specific Monitoring

CSM should be carried out over a sufficient time period to test the hypothesis. Also the time period should be of sufficient length to detect potential delayed adverse effects which have been identified in the ERA. The EFSA GMO Panel refers to chapter 2.3.4 of its Guidance Document on the ERA of GMPs (EFSA, 2010a) stating that '*The consideration of long-term effects in the ERA should address effects that might arise up to a minimum of 10 years after the start of cultivation for annual plants, i.e. corresponding to the time frame of the consent authorisation (EC, 2001; EFSA, 2008), but possibly longer for perennial species, and should in all cases cover the time period over which progeny of the GM plant might persist and appear as volunteers or ferals. Thus, the analysis should be conducted case-by-case and applicants should fully justify their approach*'.

The EFSA GMO Panel considers that a similar approach should be taken for CSM and that the life cycle and production cycle of the GMP should also be taken into consideration, particularly in relation to long lived and slowly generating perennial species. In addition, the growth, reproduction cycles and lifespan of biota, identified as being at potential risk in the ERA conclusions, should also be considered when designing the CSM plan.

Consideration should also be given to the interplay between the estimated level of risk (e.g. toxicity of GMP pollen; see EFSA, 2010a; EFSA, 2009; Perry et al., 2010) and the duration of the environmental exposure (e.g. Hofmann et al., 2010). Therefore, applicants should describe the likely time scale for effects to be detected in their monitoring plan and explain why they consider their plan is of sufficient length to detect these effects.

4.1.3. Analysis of data from Case-Specific Monitoring

Applicants should provide the raw data and analysis of the CSM results to Member States and the European Commission at the agreed time intervals (see chapter 4.3 for further details). Applicants should describe the methods used to analyse the data and a clear rationale for the statistical methods chosen. They should establish effective quality assurance (e.g. GXP standards) and auditing schemes for the analysis and archiving of data.

They should discuss the biological significance of any impacts observed, discuss to what extent the results confirm or not the assumptions made during the original ERA and conclude on the implications of their results for confirming the conclusions of their original ERA. If CSM of the GMP provides new information which could have consequences for the risks of the GMP on the environment and human health, then the conclusions of the ERA need to be re-addressed in order to (1) determine whether the initial risk characterisation has changed; and (2) determine whether it is necessary to change risk management strategies (including lifting some of them) as well as (3) to determine whether changes to the monitoring procedures are needed. Therefore the CSM plan should also indicate how it will be reviewed in order to consider results and experiences gained from the previous year(s) of CSM.

4.2. General Surveillance (GS)

Directive 2001/18/EC (EC, 2001) introduces the requirement for General Surveillance (GS) dealing with any residual uncertainty about environmental risks associated with a GMO. The objectives of GS are to detect unanticipated adverse effects, to determine the harm to protection goals and to determine the causality between the detected unanticipated adverse effects and the cultivation of GMPs.

In this chapter, the EFSA GMO Panel discusses the scientific strategy, objectives, approaches and methods that should be adopted by applicants in formulating GS plans within their applications. These should include the possibility of integration with other production systems and/or appropriate environmental monitoring networks operating in Member States, as well as with the monitoring plans for other GMPs released in the EU.

GS is mandatory for viable GMP releases into the environment. However, while it is considered the role of applicants to develop PMEM and GS plans, it is also clear that EU Member States have certain responsibilities for broader environmental protection monitoring, which could be used by applicants in GS. Thus GS planning and implementation will also involve Member States and this is discussed in chapter 4.2.2.

4.2.1. Strategy for General Surveillance

4.2.1.1. Approach and principle

According to Directive 2001/18/EC (see chapter 2) and as described in chapter 3, the objective of GS is to detect any unanticipated adverse effects on protected and valued entities of the environment that may be due to the cultivation of the GMP, including biodiversity and ecosystem services and functions (see Table 1 in EFSA, 2010a; EFSA, 2010b).

Directive 2004/35/EC, on environmental liability with regard to the prevention and remedying of environmental damage (EC, 2004), defines environmental damage as a *measurable* adverse change in a natural resource or *measurable* impairment of a natural resource service which may occur directly or indirectly. Other similar definitions are supplied e.g. by the Convention of Biological Diversity[16] and these have implications for GS of GMPs (Bartsch et al., 2008). Thus the EFSA GMO Panel is of the opinion that GS needs to consider environmental harm in relation to protection goals and these definitions of environmental damage.

The major challenges in designing GS plans are:

- to detect a change (= an alteration that results in values that fall outside the normal range, given the variation due to changes in management practices, receiving environments and associated biota in the EU). This requires that comparisons and/or baselines are assessed so that deviations from current or normal values can be detected. This is discussed in chapter 4.2.1.4 on the importance of baselines,

- to determine whether the change is causing an adverse effect (e.g. causing irreversible damage to a protection goal) and,

- to determine whether the adverse effect is associated with the release or cultivation of the GMP.

Environmental damage can be determined by considering effects on certain relevant subjects of protection associated with environmental protection goals (Bartz et al., 2010). The subject of protection is considered to be damaged if the adverse effect is considered biologically significant. The identification of a biologically *significant* adverse effect should consider its intensity (e.g. extent of loss), the value of the impaired subject of protection (e.g. high value of the populations of a species protected by law) and the reversibility of, or recovery from, the damage.

A range of existing monitoring networks can supply baseline data (Pascher et al., 2011) and provides the ability to compare data from a range of different sources and to indicate whether an effect is unusual and

[16] http://www.cbd.int/doc/meetings/lr/eglr-01/information/eglr-01-inf-03-en.pdf

potentially adverse. In order to determine whether an effect is harmful and linked to a GMP, a specific study to evaluate the harm and determine the cause would then be required.

4.2.1.2. Selection of protection goals, assessment endpoints and indicators

In line with chapter 2.2.1 (on problem formulation) of EFSA (2010a), a crucial step in designing a GS plan is to identify the aspects of the environment that need to be protected from harm and to define the assessment endpoints and measurable indicators to be considered for monitoring. Defining assessment endpoints is necessary to focus GS on assessable/measurable aspects of the environment – a natural resource (e.g. natural enemies) or natural resource service (e.g. biological control functions of pest populations performed by natural enemies) that could be adversely affected by the GMP and that require protection from harm. Defining the assessment endpoints should be done considering the receiving environments where the GMP will be cultivated and the EU standards implemented by Member States. The selected assessment endpoints need to be examined to determine how these endpoints can be monitored and whether they are already being surveyed by existing environmental monitoring networks. General environmental monitoring networks in EU Member States are an expression of the need to observe assessment endpoints systematically in order to detect or measure impacts on protection goals. The indicators for environmental monitoring should be selected in accordance with the relevant protection goals, the crop/trait combination and the receiving environments (BEETLE report, 2009).

Table 1: **Examples** of protection goals for GS of GMPs & examples of assessment endpoints, their indicators[17] and measurement endpoints, including **examples** of tools* for GS

***FQ=** farmer questionnaire**, EN=** existing monitoring network**, SR =** monitoring and review of ongoing research & development and scientific literature

PROTECTION GOALS	ASSESSMENT ENDPOINTS & INDICATORS	MEASUREMENT ENDPOINTS	TOOLS FOR GS*
Conservation of biodiversity: **Flora**	Wild species, protected species, weeds, seedbanks	- Change in populations, establishment and persistence - Hybrids with wild species - Survival ability of seeds, germination - Botanical diversity	**FQ**: E.g. Dominant weeds & volunteers in crops and weed infestation levels; herbicide usage/efficacy/control failures. **EN**: E.g. botanical surveys in different environments (including farmland); herbicide sales/usage & weed resistance data; pollen records; seed certification. **SR**: data on efficacy of different herbicide management systems and of target effects.
Conservation of biodiversity: **Fauna**	Vertebrates (e.g. mammals, birds) and invertebrates (e.g. arthropods) populations e.g.: non-target arthropods from functional groups (e.g. herbivores, detritivores & saprophytes, pollinators, parasitoides, predators), with focus on beneficial organisms and protected species	- Abundance, population change - Growth, development - Change in host range - Decrease of natural pest regulation mechanisms (i.e. monitor [novel] pest infestations)	**FQ**: Failures in natural pest regulating mechanisms (or increases of pesticide use): indirect indication of predator/parasite functions losses in crops. **EN** E.g. Surveys on farmland biodiversity (e.g. bees, butterflies, pests (like aphids)); National monitoring programmes (i) for birds with focus on protection areas under EC (1979), and (ii) for farmland birds with focus on protection areas- under the EAFRD (European Agricultural Fund for Rural Development). **SR**: Data on GMP interactions with NTOs.

[17] 'Indicator' is a sign or signal that relays a complex message, potentially from numerous sources, in a simplified and useful manner. An ecological indicator is defined here as a measure, an index of measures, or a model that characterizes an ecosystem or one of its critical components. An indicator may reflect biological, chemical or physical attributes of ecological condition. The primary uses of an indicator are to characterize current status and to track or predict significant change. With a foundation of diagnostic research, an ecological indicator may also be used to identify major ecosystem stress (EPA, 2000).

Soil quality/ functionality	Soil biota (e.g. soil microorganisms, invertebrates), fertility, texture, respiration, biomass decomposition, nutrients dynamics, erosion, organic matter	- Populations change (e.g. earthworms, springtails) - Change in soil microorganism communities (e.g. rhizobia) - Analysis of organic compounds - Fertiliser usage - Nutrient analysis	**FQ**: E.g. Crop growth, yield and health; soil pesticide, sterilant usage; soil analysis, fertilizer usage ; tillage, crop residue incorporation ; erosion, cracking, panning, water logging, sub-soiling, drainage; dominant weed species. **EN**: E.g. Fertiliser and soil nutient usage; national networks on soil quality; crop productivity and losses due to water capacity; botanical surveys (see flora above); surveys on soil pest and disease and on soil pesticide usage. **SR**: Interactions of GMPs with soil flora and fauna and consequences for soil functioning and crop production.
Water	Physical (density, silt load) and chemical (pollutants, pH, nutrients levels, algal content) characteristics; oxygen content	- Pollutants: pesticides, silt load - Anoxia - Turbidity	**FQ**: Crop performance in relation to water availability and usage **EN**: National monitoring programmes under EC, 2000 (e.g. river quality elements (e.g. biological elements, nitrates)) E.g. Fishing records, fish disease surveys, watercourse management info (e.g. weed clearance), water extraction by agriculture, farm waste and effluent management. **SR**: Interactions of GMPs and products with aquatic biota and/or water usage.
Sustainability of agro-ecosystems, including plant health	Fauna (e.g. pollinator populations) and flora indicators of functionality as above, at the field and landscape level Crop management factors such as rotation, varieties, pesticide and fertiliser usage, mechanical operations: sowing/ploughing/harvesting and the timing; crop performance and productivity data Plant diseases and pests	- Pollinator Abundance (colony survival and/or development); foraging behaviour; levels of pollination; change in honey production. - IPM indicators: e.g. predation levels, pests, diseases, weed incidence, pesticides and fertilisers usage	**FQ**: All parameters related to crop production (growth/yield/quality), performance (pests, diseases, weeds), inputs (seeds, pesticides, fertilisers). **EN**: E.g. - Surveys on e.g. varieties, pesticide and fertilizer usage, pests and diseases, weeds, bees, crop production and performance; - Data collection by national plant protection services on e.g. pesticide usage, pest monitoring; - National/Regional beekeeping organisations. **SR**: Interactions of GMPs (& associated agricultural practices) and products with other biota, inputs, outputs.
Human & domestic animal health (excluding food & feed consumption)	Pathogenicity, toxicity, allergenicity	- Animal performance - Human & animal health	**FQ**: E.g. Experiences with performance of exposed livestock; health of exposed farmers/workers. **EN**: E.g. National veterinary inspection services; feed producer surveys. **SR**: E.g. Interactions of GMPs and products with farm animals and humans.

4.2.1.3. Main tools for General Surveillance

GS should consist of both monitoring focused on the cultivation sites and immediate area surrounding the GMP (e.g. field of cultivation), and also utilise existing environmental studies and monitoring of appropriate indicators at scales ranging from specific research studies, several farms, landscape and regional scales. Monitoring at smaller scales may indicate potential effects at larger spatial scales and these effects can be measured by monitoring at the larger scales.

It is the task of the applicant to identify the appropriate tools in the GS plan (e.g. existing monitoring networks, farmer questionnaires, monitoring and review of ongoing research & development, and scientific literature) to cover the indicators and measurement endpoints defined for the protection goals (see chapter 4.2.1.2). Applicants should consider the range of assessment endpoints that the identified tools for GS will cover and whether they are likely to detect unanticipated effects as well as their cost-effectiveness and proportionality. A non-exhaustive list of examples of protection goals and their assessment endpoints is given in Table 1. In addition, the approaches that can be used within GS to collect data related to the assessment endpoints for a typical GMP are also listed in Table 1.

A thorough statistical analysis of the information collected by GS may not be possible in some cases, due to the nature of the data collected for GS (e.g. data gathered by third parties) and the use of qualitative as well as quantitative data. In addition, GS methodology may not be sensitive enough to subsequently determine whether a detected effect is associated with the GMP and its cultivation. However, scientific methodology shall be applied, wherever possible, in order to collect empirical data and establish certain baselines. This especially refers to defining sample sizes, sampling and recording methods, in order to produce statistically valid data for detecting any unanticipated adverse effects.

When a biologically relevant effect is observed, further information is needed to identify the cause of the effect and the level of harm (see chapter 4.2.1.1). The detection of an unanticipated adverse effect would therefore trigger the need for a specific in-depth study, using full experimental and statistical techniques in order to determine causality and the environmental consequences. Such a study would need control data to allow comparison with effects of non-GMPs.

Thus GS of GMP can be conducted following three main approaches:

(1) Monitoring the GMP and its cultivation sites

The GMP and its cultivation sites, the immediate area surrounding these cultivation sites and the GMP management are monitored for impacts on the environment in comparison with a non-GMP. For GM crops, this is usually done through farmer questionnaires in order to obtain first hand information from those cultivating the GM crop at a farm/field scale. In the case of other GMPs (e.g. trees, ornamentals), questionnaires relating to their production systems will be required. The design of questionnaires is discussed in chapter 4.2.2.1.

The objective of the questionnaires is to ask those directly involved in GMP production (e.g. farmers) to describe the management of the GMPs and to identify any differences in management, plant growth and development, productivity and interactions with other biota in the receiving environment of the GMP. Some of the questions link directly to assessment endpoints (see Table 1) or give indirect indications of effects on assessment endpoints.

Other forms of monitoring focusing on the GMP and its cultivation sites may also be considered by applicants. These could include:

- intensive monitoring of certain assessment endpoints in regions where there is concern about particular environmental protection goals,

- monitoring of environmental indicators where there is a requirement to assess the sustainability of a GMP and its management systems. In the EU, there are already some

initiatives to survey and record a range of environmental parameters under different cropping conditions (e.g. flora surveillance in France[18] from 2002).

(2) Existing monitoring networks

The second approach of GS seeks to obtain data on the impact of GMP cultivation in the landscape from a range of existing monitoring networks which observe changes in biota and production practices from farm up to regional level. This recognises that GS for adverse effects of GMPs at complex regional and/or national levels is beyond the scope of monitoring the GMP and its cultivation sites and consequently the applicant's direct capability. Utilising existing monitoring networks established by land use and environmental organisations was identified as a method for increasing the scope of GS (EC, 2002) (e.g. Gathmann, 2008; Sanvido et al., 2008a,b). The data for this can come from some existing monitoring networks operating in Member States. This monitoring is generally available in two forms:

i) Environmental monitoring

Many national and voluntary organisations monitor animal and plant species and other aspects of the environment (e.g. water quality). In addition, these monitoring networks can provide baseline data from the time before cultivation of the GMPs and comparative data from areas where GMPs are not cultivated. The use of regional, national and international environmental monitoring networks is discussed in chapter 4.2.2.2.

ii) Land use and production related monitoring

A number of Member States have systems in place to monitor e.g. land use, cropping patterns, forestation. In addition, many Member States have monitoring systems in place to advise or assist farmers: e.g. pest, weed and disease monitoring and monitoring of crop and new variety performance in different regions, monitoring of regional/national use of pesticides or fertilisers. All these systems provide information that can indicate changes to production systems in areas where GMPs are being cultivated, that might result in, or be associated with, environmental impacts.

(3) Monitoring and review of ongoing research & development and scientific literature

The third approach of GS monitoring is to review all new scientific, technical and other information relating to the GMP, including information on GMPs with similar traits or characteristics, which has emerged during the reporting period. This will include reviewing of results from ongoing research and development studies (e.g. variety registration trials) and all publications including peer-reviewed journal articles, conference proceedings, review papers and any additional studies or other sources of information relevant to the cultivation of the crop/trait combination. Applicants should describe the criteria for selecting and evaluating the scientific reliability of the publications in the PMEM plan. The publications should be considered and analysed in the context of the PMEM results and the PMEM plan. These publications should be listed, summarised and details provided as per the Appendix of the Commission Decision 2009/770/EC (EC, 2009a).

In addition, at the time of commercialisation, applicants will have developed plans for the introduction, marketing, management and stewardship of the GMP. Applicants should describe how the relevant parts of their stewardship programme will be incorporated into the PMEM plan as they will contain some elements that can complement the PMEM plan.

[18] http://www.fredonra.com/filiere-agricole/grandes-cultures/%C2%AB-biovigilance-flore-%C2%BB-un-reseau-de-surveillance-des-adventices/

4.2.1.4. Importance of baselines

A range of indicators can be selected in order to determine impacts on protection goals (see Table 1 for examples of protection goals and indicators). However, the scale of effects can only be assessed if comparable baselines are available for the selected indicators. Therefore, it is preferable to compare these indicators both before and after the introduction of the GMP and/or in areas where the GMP is not being grown.

There is a need for GS plans to compare impacts of GMPs and their cultivation with those of conventional plants as a baseline. The baseline is generally the comparable conventional production system which is the alternative to the GM system and is being replaced by the GM system. Direct comparison with current non-GM plant reference areas should be used if available, but reference can also be made to historical baseline data or previous knowledge and experience of the ”observer” (e.g. farmers, inspectors, existing networks like wildlife surveyors) in relation to the situation prior to the introduction of the GMP.

4.2.1.5. Data quality, management and statistical analyses

The design of the GS plan will influence the quality and usefulness of resulting data, hence efforts should be made to ensure that data from monitoring can be statistically analysed (Wilhelm et al., 2003, 2004a,b, 2009; Graef et al., 2008). According to chapter 4.2.1.3., a scientific methodology shall be applied, wherever possible, in order to collect empirical data and establish certain baselines. This especially refers to defining sample sizes, sampling and recording methods, in order to produce statistically valid data for detecting any unanticipated adverse effects.

Meta-analyses (e.g. Marvier et al., 2007) of different datasets might be useful. If relationships between datasets can be identified, it will contribute to the credibility of GS.

The GS plan should

- take account of the scale of commercialisation as well as the historical baseline knowledge in different areas to be monitored,
- take account of the multi-level structures in European agricultural production and agricultural practices,
- consider the geographical areas to be studied and which existing environmental monitoring programmes could be useful for inclusion,
- consider national cultivation registers of GM plants (including co-existence measures),
- describe the approaches used for data collection, management and examination within GS (e.g. data from existing monitoring networks and farmer questionnaires),
- define the type and size of effects when monitoring the GMP and its cultivation sites (e.g. farmer questionnaire),
- describe how harm to protection goals will be assessed including details of the statistical approaches,
- include a comprehensive description of the techniques to be used for data analysis and statistical analysis, including the requirements for statistical significance, where appropriate,
- provide a detailed description of the operational handling of data from different sources into a ‘general surveillance database’,

- describe the approach to categorise the data (e.g. influencing factor, monitoring character) and the method for pooling the results and matching them with data on GM cultivation in time and space.

Applicants should demonstrate the independence of their GS plans by implementing effective quality assurance and auditing, and should ensure that raw data and analyses of monitoring data are provided to Member States and the European Commission.

4.2.2. Methodology for General Surveillance

4.2.2.1. Monitoring the GMP and its cultivation sites

Questionnaires, directed at farms or production systems where GMPs are grown and utilised, are considered a useful method for collecting first hand data on the performance and impacts of a GMP and its cultivation and for comparing it with conventional plants (ACRE, 2004; Wilhelm, 2004a,b; Sanvido, 2005; Schmidt et al., 2008). Where applicable, this can include information on the health of humans and domestic animals exposed to the GMP. In recent years, applicants have developed questionnaires, directed at farms where GM crops are grown, and an example of a farmer questionnaire is publicly available[19]. In the case of other GMPs (e.g. trees, ornamentals) questionnaires relevant to their production systems will be required. This section focuses on monitoring approaches for GM crop production using farmer questionnaires, but the general principles are applicable to questionnaires that could be applied to other GMPs and their production systems.

It is recognised that the information supplied by farmers will be limited to observations they can make within their areas of experience, related mostly to the areas on their farms cultivated with the GM and non-GM crop and their historical experience. Observations on impacts on biota will be limited mostly to biota directly interacting with the crop and its management. However, this information may give indications of other environmental effects which can then be examined to determine the scale of an effect and its possible impact(s).

Applicants may consider additional forms of monitoring focusing on the GMP and its cultivation sites in regions where there are high levels of environmental concern or where the introduction of new production systems requires achievement of certain levels of sustainability (see chapter 4.2.1.3 (1)).

When developing and implementing their GS plans, including farmer questionnaires, applicants should consider the following points:

(1) Design of the Farmer Questionnaire

Farmer questionnaires should be designed to determine whether the farmer/manager/worker has noticed any differences between the GM crop and its management and that of similar non-GM crops growing on the farm, nearby or previously.

These differences should include consideration of all aspects of the cultivation and management of the crops and interactions with other biota and crops. Special emphasis should be given to the statistical design of the questionnaire and the survey methods used (e.g. by setting a minimum percentage or number of questionnaires required in each cultivation region for proper analysis). Issues on health of humans and domestic animals (e.g. due to exposure and handling of GM plants or feeding to livestock) should also be integrated into farmer questionnaires as appropriate.

Farmer questionnaires should

- be designed to ensure the appropriate statistical validity and representativeness of the collected data, including the proportion of fields growing the GMP in a region and a minimum

[19] http://ec.europa.eu/food/food/biotechnology/docs/2009_Farmer_Questionnaire.pdf

percentage or number of questionnaires required to achieve statistical power in the data collected,

- be designed to generate data on the agronomic management of the GMP as well as data on impacts on farming systems and the farm environment,

- use a field or group of fields growing the GMP as the basic unit for monitoring. The precise fields should be identified, so that their locations can be subsequently retrieved from registers of GMP sites,

- clearly identify the comparator (e.g. variety, location) and whether it is being grown adjacent to the GMP, on the same farm or in another location. If no comparators are being grown spatially or temporally close to the GMP, then the rationale for selecting another comparator (e.g historical data) should be fully described,

- where appropriate, observe the field/fields in subsequent years for any unusual residual effects,

- provide information on other GM events being grown at the same sites and farms,

- be adapted, where needed, to each GMP monitoring on a case by case basis by considering additional data requirements relevant for each species/event, its management and its receiving environments,

- be user friendly but also information rich,

- be constructed to encourage independent and objective responses from farmers, land managers and others involved with the GMP or its products,

- be audited to ensure the independence and integrity of all monitoring data.

It should be noted that the farmer questionnaire, submitted in the 2009 PMEM report on the cultivation of GM maize MON810 and publicly available[20], is currently being evaluated by the EFSA GMO Panel under a separate mandate[21] from the European Commission. The early results from this evaluation have been considered and absorbed in the present scientific opinion which describes general considerations in designing and operating farmer questionnaires. The forthcoming scientific opinion of the EFSA GMO Panel on the 2009 PMEM report on GM maize MON810 will provide further detailed guidance on some aspects of PMEM.

(2) Indicators and Parameters to be measured in the Farmer Questionnaire

The parameters to be recorded will depend on the GMP, the event, the regions in which it is grown, the management requirements, and, where applicable, the post-harvest handling, storage, processing and any exposure by livestock and humans. Monitoring for health effects associated with exposure of operators handling the GMP and its products should be considered in conjunction with general health and safety measures in the plant production unit or farm. Farmer questionnaires should include questions on unanticipated effects on human health observed in exposed operators (see chapter 4.2.2.1). In addition, information on livestock productivity and domestic animal health can be collected from farms where GMPs are cultivated and processed into feed on these farms in order to monitor for unanticipated effects.

[20] http://ec.europa.eu/food/food/biotechnology/docs/2009_Farmer_Questionnaire.pdf
[21] http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO

The information collected should typically include:

Background data, for example

- A specific identifier related to the location of the monitoring site and comparator site,
- Surrounding landscape, type of field margins, proximity to conservation areas,
- All data associated with the cultivation and management of the GM field including recent history and previous cropping,
- Data on the soil type, structure quality, nutrient status, fertilization (organic and inorganic), irrigation.

Data informing on possible change in behaviour and performance of GMP, for example:

- Information on any other GMPs currently or previously grown on the same sites or farm, and number of years of cultivation of GMP,
- Soil cultivation, tillage from the removal of the previous crop to seed sowing,
- Crop husbandry including sowing/planting date, all post sowing/planting managements, crop emergence, growth (vigour, height); pest, disease and weed management; flowering, standing ability, harvesting date and methods, yield,
- Post-harvest management and subsequent cropping of the site,
- Post-harvest storage, handling, processing, feeding (if appropriate).

Data informing on possible ecological/environmental impacts of GMP on the protection goals and measurement endpoints in receiving environments (see Table 1), for example :

- Weed and pest populations,
- Observations of other flora and fauna such as insects, birds and mammals,
- Pollination and presence of pollinators,
- Health of humans and performance of livestock.

Implementation of specific management requirements, such as:

- Implementation of risk management measures (e.g. *refugia*, isolation distances, weed and pest management),
- Coexistence segregation measures,
- Stewardship recommendations (e.g. good agricultural practices),
- Specific management due to regional environmental requirements.

(3) Data collection in the Farmer Questionnaires

Focussed questionnaires and interviews are generally accepted by farmers. Professional interviewers may be an additional help and applicants may use interviewers to collect data from farmers**.** However they should be trained to be neutral in their approach and to encourage thoughtful and critical responses from farmers. Interviewers should have no direct interest in agricultural production or GMPs and impartial in their approach. According to EC (2002), the responsibility for each step in the monitoring plan should be clearly assigned by the applicant. Where third parties are employed or contracted to conduct monitoring studies, the nature of their involvement should be detailed. In addition, the regular records of on-farm inputs to production systems (e.g. pesticide and fertiliser applications), are likely to be of added value when filling in the questionnaires. Applicants should describe how the farmer surveys will be audited to ensure independence and impartiality of the approach and results.

Questionnaires adapted to agronomists or other stakeholders working on the farms growing the GMPs may also be useful sources of information.

The questions should be posed as seeking specific information, e.g. on previous and current cropping and management. In addition, when a comparative response is required, questions should be composed that compare GM and non-GMPs, e.g. was parameter X greater, same or less than in the non-GM comparator area. Furthermore, farmers should be encouraged to comment on any observations they have made and provide additional information on issues outside the range of questions in the questionnaire. This will allow additional exploratory analysis of the reasons for observed changes.

Farmer questionnaires should be distributed, completed and collated annually via an arranged reporting system (e.g. farmer questionnaire forms or online systems).

(4) Statistical design and analysis of the Farmer Questionnaires

Applicants should describe the effect sizes and provide a scientific justification for the selection of effect sizes that will be required to be detected for each of the parameters in the farmer questionnaire and the sampling frame and strategy, including the proportion of GMP sites to be sampled and the optimum sample sizes in different regions, in order to detect this effect. The specific location of the site sampled on each farm must be recorded so that it is apparent which sites have been sampled previously and those not. This will allow separate analysis of site specific data over time as well as location, so that local and regional effects can be determined, as well as cumulative effects.

Applicants should:

- describe the number of farmers/growers involved, the areas covered, the reporting methods and the suitability of the data collected for appropriate statistical analysis,

- describe in detail the monitoring methods, the sampling methods, the questionnaire, the analysis of the data and the reporting methods,

- provide the raw data as well as all programmes, logs and output files related to the statistical analysis of the farmer questionnaires.

Farmer questionnaires should be analysed by the applicant and reports submitted at the agreed time intervals (see chapter 4.3) to Member States and the European Commission. The applicants should provide raw data to Member States and the European Commission.

(5) Duration of plan for GS

A released GMP, its products and its cultivation may have unanticipated environmental impacts during the life time of the GMP and also subsequently. GS plans should therefore consider the possibility of unanticipated adverse effects occurring from plant residues, shed seeds and changes to management occurring after the removal of the GMP. In addition, GMP products may be stored, transported and processed on farm, so that livestock and farmers may be exposed. The design of farmer questionnaires needs to consider the duration of the environmental exposure to the GMP and its management. This also requires consideration of the life cycle and production cycle of the GMP, when determining the duration of the GS plan (see chapter 2.3.4 of EFSA, 2010a). In addition, GMPs may be grown in sequence or in rotation with other GMPs. It is important that these levels and duration of exposure, and the interactions with other GMPs are also considered when designing and conducting monitoring.

(6) Management and stewardship of GMPs by applicants

In order to develop monitoring on the farm, production and processing level, it is important that applicants also develop the general good management and stewardship of the GMP. This includes:

- informing growers, seed suppliers, processors and other stakeholders about the GMP and its management,

- developing reporting systems so that all parties in the production and supply chain and those intending to import, process and produce GMPs, particularly farmers (or their agents and advisors) will be fully informed about the GMP, any specific management requirements, the importance of the monitoring programme and the importance of reporting of any unanticipated adverse effects during and after the cultivation of the GMP.

The results of the farmer questionnaires will allow the applicant to record the implementation of recommended management and stewardship of the GMP (e.g. good agricultural practices, hazard analyses, critical point compliance) as well as identifying unanticipated adverse effects.

General Surveillance of GM plants intended for Import & Processing

Applications concerning import & processing for food/feed uses (excluding cultivation) do not require scientific information on possible environmental effects associated with the cultivation of the GMP. The extent of GS for these GMPs will depend on the level of environmental exposure and the protection goals and indicators selected. Therefore the EFSA GMO Panel differentiates between GS plans as part of applications for import & processing, and applications for cultivation.

The import & processing of GM material for food & feed uses or for other uses can lead to environmental exposure, e.g. by accidental release into the environment of viable GM seeds, and through manure and faeces from animals fed GM feed. In the ERA of imported GM products containing viable propagating material, the applicant has to show that environmental release and exposure will be at levels or in a form that does not present a risk to other living organisms or the environment, taking into consideration that the scope of the application does not include the full environmental exposure associated with cultivation of the GMP.

Appropriate management systems should be in place to restrict environmental exposure if a risk is identified. Applicants should submit a PMEM plan addressing relevant exposure pathways and should report using the standard reporting format for applications for import & processing on a yearly basis (EC, 2009a). GS plans should include questionnaires to those involved in the handling and processing of the GMP and its products and be designed to monitor whether unanticipated levels of loss, spillage and establishment are occurring (e.g. Lee et al., 2009; Kawata et al., 2009; Nishizawa et al., 2009) and/or if there are any adverse environmental consequences.

4.2.2.2. Existing Monitoring Networks

(1) Approach & principles

Monitoring networks are operating in Member States either at official or voluntary levels to monitor effects of human activities and processes on a range of environmental parameters like biodiversity, water and air quality. In addition, many Member States have monitoring networks in place to monitor agricultural practices and their environmental impacts. These monitoring networks are recording changes in diversity of flora and fauna associated with certain agricultural practices. Directive 2009/128/EC (EC, 2009b) establishing a framework for Community action to achieve the sustainable use of pesticides and schemes such the Integrated Pest Management (IPM) programme also contain monitoring requirements as part of sustainable production systems. Such national programmes will include environmental and agricultural monitoring and, in addition to being potential sources of information relevant to GS, are also an example of how GMP monitoring could be integrated into more general monitoring of land use.

These existing monitoring networks include monitoring of many of the assessment endpoints related to the protection goals listed in Table 1.

In GS, existing monitoring networks should be used where available (e.g. routine farm recording systems) and any 'unusual' effect, not occurring in similar situations within conventional plant production, should be recorded. Therefore, applicants are encouraged to make use, when compatible, of existing monitoring networks such as established routine surveillance practices e.g. agricultural varieties, variety/seed registration, plant protection, plant health and soil surveys as well as ecological monitoring and general environmental monitoring (EC, 2002).

However, the design of the existing monitoring programs, the indicators (e.g. birds, plants, butterflies), the time, frequency, geographical location of monitoring sites, scale of data collection, sampling, analysis and reporting methods may not suit the monitoring of impacts of GMP because they have been designed for other purposes (Gathmann, 2008; Züghart et al., 2011). Moreover, the existing monitoring networks will differ from country to country but efforts are being made to coordinate some surveys (e.g. LifeWatch[22], Pan-European Common Bird Monitoring Scheme[23]). Thus applicants may not consider some existing networks to be sufficiently useful sources of information for monitoring. There may be a need to amend the monitoring objectives and/or methods of existing monitoring networks in order to collect relevant data or to be able to analyse the collected data (see also Sanvido, 2005; Sanvido et al., 2008a,b). Existing monitoring networks could be adapted to the needs of monitoring GMPs as a means to ensure comparability and to limit the expenditure of resources. Applicants should identify changes that could be made to existing monitoring networks to improve the quality or usefulness of the data collected. This would include existing environment observation systems in the field of agriculture, nature conservation, ecological long-term monitoring programmes and soil observation.

Inclusion of such programmes as part of the GS plan would firstly require that applicants gain an appropriate agreement with the persons or organisations, including national authorities, conducting such work. However, many aspects of the use of existing national monitoring networks are outside the management and control of individual applicants and thus it cannot be the task of applicants alone to use, modify or improve existing monitoring networks. Many of the existing monitoring networks will supply information relevant to many new developments and products occurring in agriculture and land use, including the future release and cultivation of many new GMPs, as discussed in the introduction. It would be valuable if Member States would consider developing their national and statutory environmental monitoring programmes and integrating them with commercial, voluntary and other programmes. This comprehensive network could then be used to monitor the environmental impacts of many land uses including GMPs and pesticides. Improvement or adaptation of existing national

[22] http://www.lifewatch.eu/ for e-science and technology infrastructure for biodiversity data and observatories.
[23] http://www.ebcc.info/index.php?ID=28

environmental monitoring programmes could help to measure whether certain protection goals are being affected and to define the likely causes of the effects. By their nature, networks involved in such existing monitoring programmes would become a national tool for environmental monitoring and thus beneficial to the Member States in determining and implementing a range of policies for land-use and environmental protection. Where such national monitoring networks are in place, applicants can identify relevant surveys in areas where GMPs will be grown and can contact each Member State in order to get access to more relevant data (see Gathmann and Bartsch, 2006).

(2) Guidance for selection and use of existing monitoring networks

Because existing monitoring networks can be of variable quality and consistency, it is important that the consistency and reliability of surveys utilised in GS is evaluated in order to ensure long-term coherence and reliability of data collection and data quality. In addition, as environmental surveys will differ between networks, methods for integrating data from different origins should be evaluated.

Knowing the limitations of existing monitoring networks, it is important to describe the processes and criteria that will be used for selecting and evaluating existing monitoring networks for supplying data related to the unanticipated adverse effects of GMPs in the GS.

Applicants, in consultation with Member States,should:

- consider the protection goals, the assessment endpoints and their indicators that could be monitored through existing monitoring programmes,

- identify the type of existing monitoring networks that would be appropriate to survey the protection goals considered to be at risk in the countries where the GMP will be grown (e.g. monitoring of agricultural cultivars and plant protection surveys),

- describe the generic approach and develop more detailed criteria to evaluate existing monitoring networks and how appropriate networks will be selected (considering the hereunder list of points),

- identify what changes need to be made to these monitoring networks and describe how these might be implemented, and identify gaps in information that could be filled by additional surveys,

- encourage these networks to adopt the proposed modifications and describe how data from these networks will be integrated and assessed.

In addition, when selecting the existing monitoring networks to be part of the GS plan, applicants should consider the following points for assessing the suitability of these existing networks to supply relevant GS data:

- the relevance of the protection goals and their indicators monitored through the existing monitoring networks,

- the type (e.g. raw data) and quality of the data recorded,

- the statistical power and the effect sizes detected by the monitoring networks, where appropriate,

- the ease of access to the data collected by the existing monitoring networks (e.g. availability of data via Internet, free access to data or access subject to a fee, protected data of ongoing research projects),

- the track record and past performance of the existing monitoring networks,

- the methodology used by the existing monitoring networks (e.g. sampling and statistical approach) including the

    - spatial scale of data collection (e.g. local, regional, national, zonal): the existing monitoring networks focusing on agricultural areas cultivated with GMPs or with conventional plants like maize, potato (for which GM are also available and grown) should be preferred;

    - temporal scale of data collection: appropriate frequency of data collection and reporting (e.g. short-term vs. long-term data sets, regularity of the data collection).

- other parameters such as the language of the reports, impartiality etc.

Furthermore, applicants should specifically

- describe arrangements with any third parties participating to their GS plan,

- describe how arrangements for collecting, collating and analysing data will be made,

- describe how formal agreements, procedures and communication will be established with the European Commission and Member States or other third parties depending on the time and geographical range of market introduction, although detailed arrangements may not have been agreed at the time of the application.

4.2.2.3. Monitoring & review of ongoing research & development and scientific literature

There is considerable research and development work ongoing around the world on the management, cultivation and impacts of GMPs. These studies include experimental research, developmental and advisory studies on crop cultivation, variety registration and variety performance trials. Applicants should show an awareness of these activities particularly on GMPs with similar traits or characteristics. The results of these studies should be reviewed and put into the context of the original ERA by relating each study to the respective area of risk to be addressed in the ERA (see chapter 3 of EFSA, 2010a); finally, the implications of the results should be considered.

All peer-reviewed publications including peer-reviewed journal articles, conference proceedings, review papers and any additional studies or other sources of information relevant to the cultivation of the crop/trait combination for which the report is being drafted, should be considered and analysed in the context of the monitoring results and the monitoring plan. The review should also include consideration of literature on related GMPs and similar events.

These publications should be listed, summarised and details provided as per the Appendix of the Commission Decision 2009/770/EC (EC, 2009a). The literature review should identify all relevant publications which have emerged after submission of the original application during the reporting period. The EFSA GMO Panel recommends that applicants follow the EFSA Guidance Document[24] on systematic literature review methodology to select relevant papers likely to have an impact on the previous ERA of the GMP. Applicants should describe the criteria for selecting and evaluating the scientific reliability of the publications in the PMEM plan. Conference proceedings, review papers and additional studies carried out by the consent holder which have not been subject to peer review may be provided where they are deemed to be relevant.

Applicants shall report how the literature informs the ERA, whether this literature indicates any potential adverse environmental impacts associated with the GMP and its cultivation and whether

[24] http://www.efsa.europa.eu/en/efsajournal/pub/1637.htm

these findings alter the conclusions of the ERA, the requirements for risk management or the PMEM plans.

4.3. Reporting the results of PMEM

Overall approach

Following the placing on the market of a GMP, the applicant has a legal obligation to ensure that monitoring and reporting are carried out according to the conditions specified in the consent. The applicant is responsible for submitting the PMEM reports to the European Commission and Member States. The PMEM results of the deliberate release into the environment of GMOs should be presented in accordance with the standard reporting formats established by Commission Decision 2009/770/EC (EC, 2009a). Applicants should describe the methods, frequency and timing of reporting in their PMEM plan.

Where it is recognised that several different GMPs are being cultivated on the same farms or in the same regions, then applicants should make arrangements to cooperate in their PMEM so that the interactions between GMPs and their cultivation are considered in the PMEM plans and the PMEM reports. Where GM events stacked by hybridisation are being cultivated together with their lower stacks including single events, then applicants should share PMEM results and compile PMEM reports which consider the results of the PMEM of both the single and stacked events. The EFSA GMO Panel recommends that integrative systems allowing applicants to cooperate and share PMEM plans and PMEM results should be established. The current system of monitoring imports of certain GM products for food and feed processing is a good precedent for developing such a cooperative approach to monitoring the cultivation of GMPs.

The EFSA GMO Panel is of the opinion that the Member States also have an important role in establishing liaison with applicants in order to coordinate data collection and analyses from different monitoring programmes (see e.g. LifeWatch[25] and concept of 'Virtual Labs[26]'). Data from PMEM will be used by both Member States and the European Commission to take decisions on the level of cultivation of a GMP. In order to reach these decisions, the appropriate data and analyses need to be available for scrutiny at both national and EU level (e.g. Delos et al., 2007; Züghart et al., 2008; Reuter et al., 2010).

Against this background, the EFSA GMO Panel considers that it is important that there is a formalised and centralised reporting and analysis procedure for all monitoring of GMPs and for the data from existing monitoring networks that may be relevant to areas where GMPs will be or are being cultivated (Kleppin et al., 2011).

Guidance to applicants

Applicants are responsible for submitting the PMEM reports to the European Commission and Member States. The PMEM results of the deliberate release into the environment of GMOs should be presented in accordance with the standard reporting formats established by Commission Decision 2009/770/EC (EC, 2009a). Applicants should describe the methods, frequency and timing of reporting in their PMEM plan. In addition, applicants should provide raw data in order to allow different analyses and interrogation of the data and to allow scientific exchange and co-operation between applicants, Member States, the European Commission and EFSA. In addition, applicants should describe whether their PMEM reports will also contain cumulative analyses of data with previous years' results.

[25] http://www.lifewatch.eu/

[26] "Virtual Labs" are created for specific purposes, by bringing together Complex Data, Analytical Tools, and Expertise (from environmental sciences, ecology, informatics) to work jointly on building an integrated system for scientific analyses and decision support.

Applicants should submit their PMEM reports

- annually confirming that monitoring has been carried out according to the given consent together with a summary of major preliminary results that are important for a short-term feedback on the environmental risk assessment ('annual reports'), and

- periodically (e.g. every third year) covering longer periods in which observations and data collected are reported and analysed in detail and which therefore provide more comprehensive reports that are important for a longer term feedback on the environmental risk assessment ('comprehensive report').

The comprehensive PMEM report should include the results of any available relevant monitoring by third parties, including the farmers/growers, seed companies, independent surveyors, local, regional and national environmental surveyors. In addition, applicants should evaluate these results and incorporate full analysis and conclusions in the submitted PMEM report. If required, applicants should provide access to raw data gathered by third parties for stimulating scientific exchange and co-operation.

Those conducting PMEM should record any unusual effects and include them in reports. Unusual effects observed during PMEM should not be excludedat the time of recording because they do not appear to be adverse. Assessment of the frequency and scale of an effect is conducted when monitoring data are being analysed.

Recommendations to Member States

Reporting centres for PMEM data should be initially established in Member States cultivating GMPs and their functions would be as follows:

- incorporate the information of the national cultivation registers referred to in Article 31. 3 (b) of Directive 2001/18/EC (EC, 2001), with location references which can be correlated with GPS references and field references within each Member State,

- compiling monitoring reports and appropriate raw data from all CSM and farmer questionnaires,

- reports from all existing networks supplying data from areas where GMPs are cultivated or released with access to raw data if required,

- analysis of data from monitoring including analyses not conducted by applicants (e.g. analysis of regional data from several GMPs, analysis of data from different but similar events (e.g. Bt, HT plants), analysis of data from farms growing successive GMPs).

These reporting centres should also agree to share information and data with other reporting centres in other countries so that they can conduct analyses across wider regions.

The reporting centres could have a role in developing harmonised methodologies, protocols and procedures to ensure environmental monitoring datasets can be analysed at national and EU level for PMEM. They could also be involved in reanalysing data from monitoring reports as well as conducting new analyses (e.g. meta-analysis) in order to determine whether environmental impacts were occurring. They could also examine information from the existing networks in order to discover environmental impacts occurring at larger scales than farms or production systems. Since monitoring the environmental impacts of GMPs is only a component of what is required for environmental monitoring, it would make sense to extend the role of these reporting centres to be coordinators of all environmental monitoring, so that data on other major agricultural and land use stressors (e.g. pesticides, intensive agriculture) is also collated and analysed. This would have the benefit of being

able to harmonise and synchronise environmental monitoring, facilitate analysis and interpretation of monitoring reports, and provide a strong scientific basis for determining land use environmental policy.

In Directive 2009/128/EC (EC, 2009b), Member States are required to develop a framework for sustainable use of pesticides. According to this Directive, Member States are asked to adopt 'National Action Plans' to encourage the development and introduction of IPM, including measures to reduce risks for the environment and human health, and to communicate them to the European Commission by December 2012. Such national programmes will include environmental and agricultural monitoring and, in addition to being major sources of information relevant to GS, are also an example of how GMP monitoring could be integrated into more general monitoring of land use.

4.4. Review and adaptation

Monitoring plans should not be viewed as static. It is fundamental that the monitoring plan and associated methodology are reviewed at appropriate intervals and may need to be modified and adapted depending on the results of the monitoring information collected. The monitoring plan might also be adapted based on an assessment of the appropriateness and cost effectiveness of the monitoring plan. Monitoring results and experience may lead to adjustments of certain parts of the original monitoring plan, or may be important in the development of further research and in decision making. Implementation of the revised monitoring plan remains the responsibility of the applicant unless otherwise determined by the Competent Authority.

CONCLUSIONS AND RECOMMENDATIONS

In general, the EFSA GMO Panel recommends that the environmental monitoring plan should describe in detail the monitoring objectives, strategy, methodology, analysis, reporting and review as laid down in Council Decision 2002/811/EC (EC, 2002).

The conclusions and recommendations set in the chapters of the present opinion are summarised hereunder:

Case-Specific Monitoring (CSM)

The overall conclusions of the ERA, taking account of any risk management strategies and remaining uncertainty, trigger the need for CSM and form the basis for formulating CSM plans. CSM should be used to confirm the assumptions made in the ERA and provide information on specific risks and uncertainty identified in the ERA. CSM may have different objectives such as:

- reducing the level of uncertainty on key processes identified in the ERA,
- measuring *in vivo* exposure levels,
- monitoring directly the impacts on assessment endpoints identified in the ERA,
- monitoring impacts on organisms/processes related to the assessment endpoints identified in the ERA,
- recording impacts on functional or production systems related to sustainability, IPM, etc,
- assessing the efficacy of risk management strategies arising from conclusions of the ERA.

Applicants should fully explain the rationale for CSM decisions and describe CSM plans according to objectives, hypothesis to be tested, design and analysis.

General Surveillance (GS)

GS is mandatory for viable GMP releases into the environment in order to determine unanticipated adverse effects of the GMP and its management and use. The approach to GS should be to determine any adverse effects on the assessment endpoints of protection goals by studying effects on measurement endpoints and indicators. The applicants should therefore

- define the objectives of the GS in terms of the protection goals and indicators that are considered important in the different receiving environments (see Table 1),
- define the methods and approaches that will be used to conduct GS of regions where the GM plant is cultivated and expected to occur,
- describe the range of parameters and indicators that will be assessed in both farmer questionnaires and existing monitoring networks,
- refer to introduction, stewardship and exploitation plans for the GMP,
- make proposals for the time period, area covered, and the frequency of monitoring,
- describe the processes for collation of data, analysis, interpretation and reporting.

GS of GMPs can be conducted following three main approaches:

(1) *Questionnaires for the GMP producers and users*

The design and implementation of farmer questionnaires are discussed in more detail. Specific design is required according to the plant and trait and particular receiving environments with the focus on comparing the cultivation, agronomic characteristics and management with an appropriate non-GM comparator and acquiring information on any associated environmental effects.

(2) *Use of existing monitoring networks*

These networks operating in Member States are seen as potentially useful sources of information. Applicants should then consider the use of these monitoring networks in GS plans for GMPs. However, in reality, the data they collect is often not in a useable form. Therefore, applicants, in consultation with Member States, should identify changes that could be made to existing environmental monitoring networks to improve the quality or usefulness of the data collected. In addition, it is proposed that Member States coordinate the use of these networks so that they can be used to generally monitor the impacts of land use, including GMPs. It is also proposed that the integration of these monitoring networks includes the development of national reporting centres which can receive all monitoring reports and data from all the relevant monitoring networks, interrogate this information and disseminate intelligence. This would allow Member States to be more informed about changes to their environments and the possible role of GMPs in these changes.

(3) *Monitoring and review of ongoing research & development and scientific literature*

There are considerable research & development activities ongoing around the world on the management, cultivation and impacts of GMPs. Applicants should show an awareness of these activities particularly on GMPs with similar traits or characteristics as their particular event. The results of this research should be reviewed and the implications of the results considered. Applicants should describe the criteria for selecting and evaluating the scientific reliability of the publications in the PMEM plan.

Applicants shall present an analysis and conclusions of their PMEM annually and periodically (e.g. every third year). Applicants shall report how the PMEM results inform the original ERA, whether they indicate any potential adverse environmental impacts associated with the GMP and its cultivation and whether these findings alter the conclusions of the ERA, the requirements for risk management or the PMEM plans.

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