SCIENTIFIC OPINION

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

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

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NOTE TO THE PUBLIC:

The EFSA GMO Panel was asked by the European Commission to update its opinion providing guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified (GM) plants submitted within the framework of Regulation (EC) No 1829/2003 on GM food and feed or under Directive 2001/18/EC on the deliberate release environment of genetically modified organisms (GMOs). Following the recent update of the EFSA Guidance Document on the Environmental Risk Assessment (ERA) of GM plants, this draft scientific opinion shows how the conclusions of risk assessments determine the requirements for PMEM and it provides guidance for the development of PMEM plans. This draft opinion provides the scientific rationale for the different types of monitoring as well as draft guidelines and recommendations to applicants and to risk managers on monitoring strategy, methodology and reporting. Against this background, the EFSA GMO Panel welcomes comments from all stakeholders on the following aspects of this draft opinion:

(1) The concept of developing management and monitoring strategies based on the overall conclusions and assumptions of the ERA (including any uncertainties),

(2) The draft general guidelines proposed for Case-Specific Monitoring (CSM) by the applicants considering the case-by-case character of CSM,

(3) The draft guidelines and recommendations to applicants and risk managers on General Surveillance (GS). The EFSA GMO Panel proposes a more holistic and integrative approach to monitoring in the EU that considers GS within a framework of general environmental protection monitoring. Therefore, 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.

Comments from all stakeholders are also welcome on Panel's suggestion to set up standardised and centralised reporting centres for monitoring data.

The present draft opinion will be amended in the light of the comments received from the public consultation. This draft opinion is also likely to be supplemented with more detailed guidance following the final conclusions by the EFSA GMO Panel of its (ongoing) assessment of the annual 2009 PMEM report on maize MON810.

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[1] On request from European Commission, Question No EFSA-Q-2010-01253, adopted on DD month 2011.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on the Update of the 2006 PMEM Scientific Opinion for the preparation of this draft opinion and EFSA staff members for the support provided to this scientific opinion.

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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) receives notifications and applications for commercialisation of GMOs in the EU submitted respectively under the aforementioned Directive and Regulation and including a Post-Market Environmental Monitoring (PMEM) plan. EFSA and in particular its GMO Panel is responsible for assessing the scientific quality of the PMEM plans.

Therefore, recognising the importance and complexity of developing PMEM plans, the EFSA GMO Panel decided to develop specific guidance on general surveillance of unanticipated adverse effects of GM plants. 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). The guidance outlined in the 2006 scientific opinion on PMEM (EFSA, 2006) had been inserted into the overall Guidance of the EFSA GMO Panel for the Risk Assessment of GM Plants and Derived Food and Feed, adopted on 24 September 2004.

Upon request of the European Commission, the EFSA GMO Panel recently updated its 2004 Guidance Document (GD) on the Environmental Risk Assessment (ERA) of GM plants (EFSA, 2010). The updated GD on the ERA of GM plants has been prepared by expanding and completing most sections of the previous GD in accordance with i.e. current legislation, experience gained during the evaluation of the ERA of past applications, the outcome of a self-tasking activity on non-target organisms[4], the outcome of the sub-working group on statistics ERA guidance, additional guidance on stacked events[5].

Consequently, for sake of consistency, the EFSA GMO Panel felt that there was a need to review its 2006 scientific opinion on PMEM in light of the experience gained, comments from stakeholders and on the updated GD on the ERA of GM plants. 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 afore mentioned opinion. Consequently, on 27 October 2010, the European Commission asked EFSA to update the 2006 scientific opinion on PMEM of GM plants by July 2011.

EFSA therefore established a dedicated Working Group (PMEM WG) on the update of the 2006 scientific opinion providing guidance on PMEM. The PMEM WG activities firstly focused on the the scientific rationale for PMEM and the chapter dedicated to Case-Specific Monitoring 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. The EFSA GMO Panel and its PMEM WG made use of the experience gained from the cultivation of GMOs, the PMEM reports on cultivated GMPs,

[4] ESA-Q-2008-089
[5] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902599859.htm

relevant scientific literature, and from public comments from past EFSA consultations. In addition, the EFSA GMO Panel is currently conducting an assessment of the annual 2009 PMEM report on the cultivation of maize MON810 under a separate mandate from the European Commision. At the present time, the early results from this assessment were also taken into consideration. However, this assessment is ongoing and its final conclusions will be fully considered at a later stage, when finalising the present scientific opinion.

The present document provides a detailed draft opinion by the EFSA GMO Panel on the updated requirements for PMEM plans for GM plants and the scientific rationale for these plans, in line with the 2010 Guidance Document on the ERA of GM plants (EFSA, 2010).

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION AND EFSA

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 the public comments, should be provided to the European Commission at a second stage, by July 2011.

98 # ASSESSMENT

99 ## I. INTRODUCTION

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101 In 2006, the EFSA GMO Panel adopted a scientific opinion providing specific guidance to
102 applicants for developing Post-Market Environmental Monitoring (PMEM) plans (EFSA, 2006)
103 according to Regulation (EC) No 1829/2003 on GM food and feed (EC, 2003) or Directive
104 2001/18/EC on the deliberate release into the environment of GMOs (EC, 2001). The present
105 draft opinion of the EFSA GMO Panel proposes options for the post-market management and
106 monitoring of GM plants (GMPs) and provides updated guidance on establishing PMEM plans
107 according to Annex VII of Directive 2001/18/EC.

108 Following consultation and refinement, this draft opinion will be used as the basis for developing
109 detailed guidance which will replace the 2006 scientific opinion of the EFSA GMO Panel on the
110 PMEM of GMPs. The conclusions and recommendations of the final opinion will form the basis
111 for an update of the approaches and methods for case-specific monitoring and general
112 surveillance as outlined in chapter 4 of the 2010 EFSA Guidance Document on the
113 Environmental Risk Assessment (ERA) of GMPs (EFSA, 2010).

114 In preparing this document, the EFSA GMO Panel considered various references from scientific
115 literature, conference reports as well as several sources of information such as PMEM reports on
116 cultivated GMPs, comments by Member States on the PMEM plans submitted in the applications
117 and public comments from the consultation on the 2010 EFSA Guidance Document on the ERA
118 of GMPs (EFSA, 2010).

119 In this draft opinion, the EFSA GMO Panel focuses on the scientific rationale and approaches for
120 the post-market management and monitoring of GMPs. This draft opinion also aims to clarify the
121 objectives, tasks, tools, responsibilities and requirements for PMEM at both, the national and
122 European scale. In addition, this document provides further guidance to applicants on the design
123 of PMEM plans and their implementation (e.g. data analysis and interpretation) and makes
124 proposals to risk managers for the future conduct and coordination of PMEM in the EU.

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126 ## II. LEGISLATIVE BACKGROUND

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128 An objective of Directive 2001/18/EC (EC, 2001) and related legislation (see Table 1 of EFSA,
129 2010) is to protect the environment, including natural resources and ecosystem services
130 (biodiversity and agro-ecological functions e.g. water, soil, production systems). The EFSA GMO
131 Panel recognises that all human activities can have environmental impacts and the potential to
132 affect ecological functions and processes, so that there is a general need to consider the impacts
133 of any new product, development or process on environmental protection goals. In this respect,
134 Directive 2004/35/EC (EC, 2004) on environmental liability with regard to the prevention and
135 remedying of environmental damage defined environmental damage as a measurable adverse
136 change in a natural resource or measurable impairment of a natural resource service which may
137 occur directly or indirectly.

138 Directive 2001/18/EC (EC, 2001) introduces an obligation for notifiers to implement monitoring
139 plans in order to trace and identify any direct or indirect, immediate, delayed or unforeseen

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 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.

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 and research.

In addition, and in line with EC (2002), CSM should, when included in the monitoring plan, focus on potential effects arising from the placing on the market of a GMO that have been highlighted as a result of the conclusions and assumptions of the ERA. However, whilst it is possible to predict that certain 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 optimise the chances for early detection of such effects. The design of the monitoring plan shall, therefore incorporate GS for unanticipated or unforeseen 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 structure and contents of this 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).

In the particular case of pesticides associated with GMPs e.g. GM Herbicide Tolerant (GMHT) plants, other legislative texts than those strictly limited to the placing on the market of GMOs should also be taken into account. Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market (EC, 2009b), and repealing Directive 91/414/EEC (EC, 1991), and Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides (EC, 2009a) should be considered in the frame of managing and monitoring of GMPs, especially GMHT plants (for further details, see Appendix I).

III. 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 and animal health and the environment arising from its placing on the market.

As outlined in the EFSA Guidance Document on the ERA of GMPs (EFSA, 2010), the ERA generally comprises several sequential steps (see Figure 2 of EFSA, 2010): (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. Where the consequences of commercialisation and large scale/long-term exposure to the GMP have to be considered in an ERA, then applicants are recommended to consider a range of representative scenarios (including worst-case scenarios) to cover these areas of uncertainty (see chapter 2.3.3.8 of EFSA, 2010).

When risks or uncertainties are identified at Step 4 of the ERA, applicants should propose and describe in detail, risk management and mitigation measures 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. The risk management and mitigation measures 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 to lower levels. In addition, applicants should identify any uncertainty associated with the efficacy, application and implementation of risk management and mitigation measures and their potential implications.

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

Thus the ERA conclusions provide the basis for PMEM plans, which focus on detecting any adverse effects on human health and the environment identified in the ERA and can be used to provide data on uncertainties identified in the ERA. Therefore, the role of PMEM is to check the assumptions made during the ERA, to ensure that the deployment of the GM plant 'falls within the domain of validity of the ERA conclusions' and to detect any unanticipated adverse effects.

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 GMO and our current understanding of natural and managed environments. The knowledge on the environmental consequences of commercial scale release 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 is often 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 effects which were not predictable at the time of the ERA or consent.

Directive 2001/18/EC (EC, 2001) identifies this limitation of risk assessments and introduces the requirement for General Surveillance (GS) of GMOs as measure for dealing with these residual uncertainties about environmental risk and harm. The EFSA GMO Panel is of the opinion that an important function of GS is to detect unanticipated environmental effects, to determine the harm to environmental protection goals and to determine any associations with the cultivation of GMPs (see chapter II). Protection goals and environmental damage are considered in more detail in the section on GS (see chapter B.1).

Experience with the introduction of GMPs in certain countries is that they may result in more extensive cultivation of certain crops (e.g. soya in Romania, Brazil, Argentina) and they may change crop management practices (e.g. tillage and use of pesticides (Altieri & Liebman, 1990; NAS, 2010)). Thus they can have novel impacts, either positive or negative, on agricultural systems and environments at scales which were not always considered in the original ERAs. As more GMPs are 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 a general hypothesis can be applied to the release and cultivation of GMPs in the EU that the cultivation of GMPs may have unanticipated effects on protected and valued entities of 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 general surveillance 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 environmental protection goals associated with production systems containing GM plants in comparison with systems that do not.

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 terrestrial 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 should be considered when setting-up monitoring plans.

IV. Guidance on Post-Market Environmental Monitoring

According to chapters II and III, when potential adverse effects or significant levels of critical uncertainty[6] 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. This draft opinion provides various options for CSM implementation which depend on the outcomes of the ERA, i.e. potential adverse effects and levels of uncertainty.

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 must be part of each application which includes the release of viable GMP material in the EU, in order to monitor for effects that were not anticipated or specifically identified during the ERA (see chapter II).

As outlined in EFSA (2010), key objectives of monitoring should also refer to protection goals and ecosystem services and functions such as species/ecosystem biodiversity, soil functionality, sustainable agriculture, pollination, plant health, human and animal health. Indicators should be selected which can indicate impacts on these factors and these indicators should be measurable, appropriate, adequate in terms of statistical power, and comparable with existing baseline data (see chapter IV.B.1.b and d).

A. CASE-SPECIFIC MONITORING (CSM)

1. Case-Specific Monitoring strategy

CSM should be targeted at the assessment endpoints and environmental protection goals identified in the ERA as being at risk or where significant levels of uncertainty were identified (see chapter 3 of EFSA, 2010). Monitoring of potentially adverse cumulative long-term or large scale effects (see chapter 2.3.4 of EFSA, 2010) and the resolution of areas of critical uncertainty[6], identified in the ERA (see chapter 2.3.3.8 of EFSA, 2010), are important objectives of monitoring (EC, 2002), which could 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 GM compared to non-GM plants, then CSM may be indicated.

The scientific approach should be designed in order to test specific hypotheses of possible adverse effects derived from the ERA and – where appropriate - to the evaluation of risk management and mitigation measures associated with the cultivation of the GMP (see chapter 2.2.5 of EFSA, 2010). It is essential that these hypotheses be stated explicitly at the design stage of the monitoring study and that applicants demonstrate that the design has the appropriate methodology and statistical power to test the hypothesis.

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

306 The CSM of GMP may have different Objectives (O) and Approaches (A), as given below:
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(O) Reducing the level of uncertainty on key processes identified in the ERA

(A) Example:

- by confirming the sensitivity range of Non-Target (NT) species to CRY proteins;

(O) Measuring *in vivo* exposure levels

(A) Examples:

- exposure of NT Lepidoptera to Bt maize pollen,
- presence of weed species in Herbicide-Tolerant (HT) crop fields;

(O) Monitoring directly the impacts on assessment endpoints identified in the ERA

(A) Examples:

- by monitoring populations of selected exposed NTOs and weed species,
- by 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 subjects 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: pollination, pest control.

(O) Recording the implementation of risk management strategies

(A) Examples:

- by setting up of non-Bt refuge as part of the High dose/Refuge strategy implemented to delay resistance development of target pests to Bt toxin expressed by GM Insect-Resistant plants (EFSA, 2009b),
- by setting up border rows of non-lepidoptera resistant maize around GM Bt maize fields to limit the exposure of NT *Lepidoptera* to maize expressing e.g. CRY1Ab protein (EFSA, 2009b),
- by selecting herbicide programmes used on HT plants to achieve weed diversity targets.

(O) Assessing the efficacy of risk management strategies arising from conclusions of the ERA

(A) Examples:

- checking the efficacy of the High dose/Refuge strategy by surveying the change in susceptibility of target pests to GM Insect-Resistant plants,
- recording weed populations in HT crops and rotations.

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

2. Case-Specific Monitoring methodology

The design of the monitoring 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. Thus if there is monitoring e.g. of a beneficial predator, 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 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 agreed work.

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. In addition, methods used for monitoring 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 cost-effectiveness.

a) 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. 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 those species of prime importance and those expected to be the most abundant.

b) 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.

However, a common problem in GM monitoring 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.

Appropriate comparators should be selected that fulfil the requirements of replication, control of variability and the use of blocking factors, such as field/farm size, previous management, etc. For CSM, experimental units will often be larger than the plots typically used in agricultural or variety trials, otherwise the effects studied are not representative. Indeed, often different fields or farms must be compared and, in addition, these may be remote from one another. This is especially true when studying highly-mobile natural enemies such as parasitoids or coccinellids. 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. This is costly, and may be inconvenient, causing problems in management that are not encountered in traditional 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[7]), but care is required to ensure that factors such as field/farm size, previous management, altitude, soil type, soil moisture, etc 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.

c) Spatial scale of CSM

The scale of the monitoring should consider the scale of commercialisation and be increased as the area and range of the GMP expands, and the plant is grown in more regions. The design of the CSM plan 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. Thus applicants should select sites considering where there is significant and repeated growing of the GMP, the extent of the cultivation of the GMP, the occurrence of targeted species and/or potentially at risk biota, and the sensitivity of particular receiving climatic/eco-regions. It is important that monitoring is carried out at sites where there is the greatest likelihood of measurable impacts occurring but should also consist of the systematic recording of relevant parameters at representative locations. The methods selected, the duration of the monitoring, the extent or number of areas and the

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

parameters to be monitored will be determined on a case-by-case basis and shall be clearly explained by the applicant in the CSM plan.

d) Temporal scale of CSM

CSM should be carried out over a time period of sufficient length to detect not only immediate effects but also potential delayed 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, 2010) 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 to PMEM and that the life cycle and production cycle of the GM plant should also be taken into consideration particularly in relation to long lived and slowly generating perennial species.

Consideration should also be given to the interplay between the estimated level of risk (e.g. toxicity of GM plant pollen; see EFSA, 2010; EFSA, 2009b; Perry et al., 2010) and the duration of the environmental exposure (e.g. Hofmann et al., 2010). A prolonged period of exposure may increase the likelihood of cumulative effects occurring. Consideration should also be given to extending the CSM plan beyond the period of the original period of consent if the potential for long-term adverse effects remains. This may be the case, for example, where the persistence of GMPs in the environment has the potential to be significant. (e.g. for the development of resistance in pest/pathogen species to pest and disease resistance gene products of GMPs) or for slow cycling perennial species (e.g. trees) which may only reproduce after several years.

The CSM plan should also indicate how the methodology will be reviewed in order that results and experiences gained from the monitoring can be considered in planning the subsequent monitoring approach and strategy.

3. Analysis of data from CSM

Applicants should provide the raw data and analysis of the CSM results to national Competent Authorities and the European Commission at the agreed time intervals (usually annually - see chapter IV.C). They should discuss the biological significance of any impacts observed 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 GM plant on the environment and human health, then the conclusions of the ERA may 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 requirements, including changes to the monitoring procedures.

B. GENERAL SURVEILLANCE (GS)

In this chapter, the EFSA GMO Panel discusses the rationale, 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 plant production and appropriate terrestrial monitoring networks operating in Member States, as well as with the monitoring plans for other GMPs released in the EU.

While it is considered the role of applicants to develop PMEM and GS plans, it is also clear that EU Member States have certain responsibilites of 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 IV.B.2.

1. General Surveillance strategy

a) Approach and principle

The objective of general surveillance is to identify the occurrence of unanticipated adverse effects of the GM plant or its use, on human health or the environment, that were not anticipated in the ERA (see chapter II). The EFSA GMO Panel is of the opinion that GS should also consider animal health and that GS of viable GMP material is always required.

An objective of Directive 2001/18/EC (EC, 2001) is to protect the environment including biodiversity and agro-ecological functions (e.g. water, soil, production systems) (see Table 1 of EFSA, 2010). Thus the EFSA GMO Panel is of the opinion that an important function of GS is to link monitoring to these environmental protection goals. Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage (EC, 2004) 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, and this has implications for general surveillance (Bartsch et al., 2008). Protection goals and the definition of environmental damage need to be considered for GS.

Thus a general hypothesis is applied that the release and cultivation of a GMP may have unanticipated adverse effects on protected and valued entities of the environment including biodiversity, sustainable production and ecosystem services and functions. Therefore the role of GS is to detect these unanticipated adverse effects as and when they occur, considering that plant production systems and the environment are also changing, and that there are a wide range of other potential stressors.

The major challenges in designing GS plans are:

- to observe an unusual effect (= 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 IV.B.1.d on the importance of baselines,

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

- to determine whether the adverse effect is associated with the GMP and/or its cultivation.

The use of a range of monitoring networks to supply data and the ability to compare data from a range of different sources will help to indicate whether an effect is unusual and 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.

Environmental damage can be determined by considering effects on certain relevant subjects of protection associated with environmental protection goals (Bartz et al. 2009). The subject of protection is considered to be damaged if it is *significantly* adversely affected. The identification of a *significant* adverse effect should consider both its intensity (e.g. extent of loss) and 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.

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 operators (see chapter IV.B.2.a). Information on livestock consumption and exposure to GMP products can be linked to information on productivity and animal health in order to monitor for unintended effects.

b) Selection of protection goals, assessment endpoints and indicators

In line with chapter 2.2.1 (on problem formulation) of EFSA (2010), 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 as subjects 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. 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. It is the task of the applicant to select, if available, appropriate tools in the GS plan (approach of data collection from e.g. existing surveillance networks, farmer questionnaires, monitoring and review of ongoing research & development, and scientific literature) that are suitable to cover the indicators and measurement endpoints defined for the protection goals (for examples see Table 1). The indicators for environmental monitoring should be selected in accordance with the relevant protection goal, the crop/trait combination and the receiving environments (BEETLE, 2009).

525 **Table 1:** Examples of protection goals, assessment endpoints & their indicators[8] and
526 measurement endpoints of use in General Surveillance

PROTECTION GOALS	EXAMPLES OF ASSESSMENT ENDPOINTS & INDICATORS	EXAMPLES OF MEASUREMENT ENDPOINTS
Conservation of biodiversity: **Fauna**	Vertebrates (birds, mammals, fishes) and invertebrates (soil organisms, arthropods) populations e.g.: non-target arthropods from functional groups (herbivores, detritivores & saprophytes, pollinators, parasitoides, predators, etc), with focus on beneficial organisms and protected species	- Abundance, population change - Growth, development - Resistance development - Change in host range - Decrease of natural pest regulation mechanisms (i.e. monitor [novel] pest infestations)
Conservation of biodiversity: **Flora**	Primary producers, seedbanks, wild species, weeds, protected species	- Outcrossing/breeding with wild relatives - Plant populations - Survival ability of seeds, germination - Change in dispersal, establishment and persistence - Balance of species
Soil quality/ functionality	Soil flora and fauna (e.g. invertebrates), fertility, texture, respiration, biomass decomposition, nutrients dynamics (erosion), organic matter	- Populations change (e.g. earthworms, springtails) - Balance of organic compounds - Fertiliser usage - Nutrients analysis
Air quality	Pollen and spore loads, volatiles, organic/inorganic pollutants, particulates, radiation levels, greenhouse gas/CO_2 concentrations	- Pollen counts - Ozone, SO_2 - Particulates analysis
Water quality	Physical (density, silt load) and chemical (pollutants, pH, nutrients levels) characteristics; oxygen content	- Balance of nutrients levels - Pollutants: pesticides, silt load - Anoxia
Agro-ecosystems sustainability	Fauna (e.g. pollinator populations) and flora indicators of functionality as above; non renewable input levels	- Abundance: colony survival and/or development - Foraging behaviour, Levels of pollination - Decrease/increase in honey production
Production systems	Crop management factors such as rotation, varieties, pesticide and fertiliser usage, mechanical operations: sowing/ploughing/harvesting and the timing; crop performance and productivity data; economic data on crop production	- IPM indicators: e.g. predation levels, pests, diseases, weeds incidence, pesticides and fertilisers usage
Plant Health	Plant diseases and pests, weeds	- Disease, pest, weed incidence - Botanical diversity - Pesticide usage
Human & animal health	Pathogenicity, toxicity, allergenicity, nutrition quality	- Animal health and productivity - Human health

[8] **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).

c) Main tools for General Surveillance

Scientific methodology should 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. However, a thorough statistical analysis of the information collected by GS may not be possible in all cases, due to the nature of GS 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. Therefore, the EFSA GMO Panel considers that GS is primarily a system for observing significant unanticipated effects and that, when an effect is observed, further information is needed to identify the cause of the effect and the level of harm (see chapter IV.B.1.a). The detection of an unanticipated effect would therefore trigger the need for a specific in-depth study, using full experimental and statistical techniques in order to determine causality and consequence. Such a study would need control data to allow comparisons with effects of non-GMO comparators.

GS should consist of both focused monitoring of the cultivation and immediate area surrounding the GMP (e.g. field of cultivation), and also utilise existing 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 impacts at larger spatial scales and these effects can be measured by monitoring at the larger scales. Ongoing or further research may be needed to interpret any changes detected at these scales in order to understand the consequences over larger spatial scales or over many generations.

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

(1) Monitoring focused on the cultivation of the GMP

GMP-focused monitoring systems where the GMP, its immediate environment and its management are monitored for impacts on the production system and the immediate environment. 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 IV.B.2.a.

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 production system and on-farm monitoring 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 sustainability indicators where there is a desire to assess the sustainability of GMP management systems.

When considering these alternative forms of monitoring, applicants should consider the range of assessment endpoints they will cover and whether they are likely to detect unanticipated effects.

(2) General monitoring networks

The second approach of GS seeks to obtain data on the impact of GMP cultivation in the landscape by obtaining data from a range of existing monitoring and surveillance networks which are observing changes in biota and production practices from the level of several producers (e.g. farms) to whole districts or regions. This recognises that surveillance for adverse impacts of GMPs at complex regional and/or national levels is beyond the scope of production system monitoring or the applicant's direct capability. Also, increasing complexity and interaction of GMPs use with other land management systems can be better studied in other ways. Utilising existing surveillance 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 and surveillance 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 environmental quality (e.g. water quality). This approach has the advantage of collecting information related to the combined effects of GMPs and their management in a region as well as information on single applications. 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 IV.B.2.b.

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 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 pesticide efficacy. Also other land use activities are monitored such as regional/national uses of pesticides or fertilisers. All these systems provide information that can be used to indicate system changes 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. 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 for which the report is being drafted, should be considered and analysed in the context of the monitoring results and the monitoring plan. These publications should be listed, summarised and details provided as per the Appendix of EC, 2009c. The literature review should identify all relevant publications which have emerged during the reporting period.

612 In addition, applicants will have developed plans for the introduction, marketing, management
613 and stewardship of the GMP. Applicants should describe these and incorporate relevant parts into
614 the monitoring plan as they will contain some elements that can complement the monitoring plan.

615 The range of environmental protection goals and their assessment endpoints are identified in
616 Table 1. The approaches that can be used to collect data related to the assessment endpoints for a
617 typical GMP are listed in Table 2.

618

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620
621 **Table 2:** Examples of tools for General surveillance according to different protection goals, assessment endpoints & indicators[9]
622
623 **FQ=** Farmer Questionnaire**, EN=** Existing monitoring Network**, SR =** Monitoring and review of ongoing research & development and scientific
624 literature
625

PROTECTION GOALS	EXAMPLES OF ASSESSMENT ENDPOINTS AND INDICATORS	EXAMPLE OF TOOLS FOR GENERAL SURVEILLANCE (FQ, EN, SR)
Conservation of biodiversity: **Fauna**	Vertebrates (birds, mammals, fishes) and invertebrates (soil organisms, arthropods) populations e.g.: non-target arthropods from functional groups (herbivores, detritivores & saprophytes, pollinators, parasitoides, predators, etc), with focus on beneficial organisms and protected species	**FQ**: Failures in biocontrol systems for pests and virus diseases (or increases of pesticide use): indirect indication of predator/parasite functions losses in crops. E.g. Pollination in insect-pollinated crops; failures in recycling in soils that could indicate harm to soil fauna; crop performance (indicator of crop and soil health); weed populations in crops. **EN** for bees, butterflies, pests (e.g. aphids), virus diseases E.g. - 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), - EIONET[10] & EuMon[11], - National/Regional beekeeping organisations. **EN**: E.g. Farm and agric surveys of pesticide and fertilizer usage; biocontrol failures/increased pest and virus disease pressure; general crop performance data. **SR**: Data on GMP interactions with NTOs.

[9] See table 1 for examples of measurement endpoints

[10] EIONET = European Environment Information and Observation Network of the EEA is the most developed and readily available information system for environmental data coordination at EU level. A network of National Focal Points that coordinate the collection of environmental information at national level to be reported to the EIONET. It will incorporate data from monitoring under the Habitats Directive, the Water Framework Directive and other EU reporting obligations.

[11] EuMon = EU-wide monitoring methods and systems of surveillance for species and habitats of Community interest. Databases fed with monitoring data from local, regional and national stakeholders (birds, mammals, fishes)

Conservation of biodiversity: **Flora**	Primary producers, seedbanks, wild species, weeds, protected species	**FQ**: E.g. Dominant weeds & volunteers in crops and weed infestation levels; herbicide usage/efficacy/control failures. **EN**: E.g. botanical surveys of weeds 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 off target effects.
Soil quality/ functionality	Soil flora and fauna (e.g. invertebrates), fertility, texture, respiration, biomass decomposition, nutrients dynamics (erosion), organic matter	**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.
Air quality	Pollen and spore loads, volatiles, organic/inorganic pollutants, particulates, radiation levels, greenhouse gas/CO_2 concentrations	**FQ**: E.g. Crop performance and health (as an indicator of air quality and purity); ozone and acid rain damage to crop plants. **EN**: Regional/National/international monitoring of air quality, pollen counts, particular matter, NO_x, CO_2 levels, greenhouse gas emissions, rainfall acidity, depletion of ozone layer, radiation Asthma surveys **SR**: Interaction of GMPs and products with factors relating to air quality, allergenicity of pollen, volatiles and dusts
Water quality	Physical (density, silt load) and chemical (pollutants, pH, nutrient levels) characteristics; oxygen content	**FQ**: Crop performance in relation to water availability and usage, E.g. Water extraction, irrigation, fertiliser usage and timing, effluent and wet waste management info. **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.

Agro-ecosystems sustainability	Fauna (e.g. pollinator populations) and flora indicators of functionality as above; non renewable input levels	**FQ**: All parameters related to crop production, performance, inputs, weeds, pests, diseases. E.g. Crop protection measures, agrochemical usage (pesticides, fertilizers), biocontrol measures, irrigation, cultivation, tillage, fuel consumption (e.g. red diesel). **EN**: - Surveys of biodiversity in farmland; - Surveys on weeds, pests and diseases; on pesticide and fertiliser usage; on water extraction/usage data; on bees; on crop production and performance; on greenhouse gas emission; farm pollutants; farm energy consumption. **SR**: Interactions of GMPs and products with other biota, inputs, outputs, management.
Production systems	Crop management factors such as rotation, varieties, pesticides and fertilisers usage, mechanical operations: sowing/ploughing/harvesting and the timing; Crop performance and productivity data; Economic data on crop production	**FQ**: All parameters related to crop production (growth/yield/quality), performance (pests, diseases), inputs (seeds, cultivation, weeds) E.g. Crop protection measures, agrochemical usage (pesticides, fertilizers), biocontrol measures, irrigation, cultivation, tillage, energy consumption, input costs and gross margin. **EN**: National data on seeds, varieties, pesticide and fertilizer usage, pests and diseases, cultivation, energy consumption, input costs, gross margins, crop production/yields, water extraction. E.g. Surveys on crop production and performance; on greenhouse gas emission; on farm pollutants; on farm energy consumption. **SR**: Interactions of GMPs and products with other biota, inputs, outputs, management.
Plant Health	Plant diseases and pests, weeds	**FQ**: Changes in pest, weed and disease levels E.g. Usage of pesticides and fertilisers, pollination in insect-pollinated crops, crop performance (indicator of crop and soil health), weed populations in farms **EN**: National plant protection services data E.g. Pesticide usage data; pest monitoring; virulence surveys. **SR**: interactions of GMPs, management and products with pests, diseases and weeds.
Human & animal health	Pathogenicity, toxicity, allergenicity, nutrition quality	**FQ**: E.g. Experiences with livestock feeding and with exposed livestock; health of exposed farmers /workers **EN**: E.g. National veterinary inspection services; feed producer surveys **SR**: Interactions of GMPs and products with farm animals and humans.

626

627 **d) Importance of baselines**

628 In principle, GS can observe whatever indicators are available in order to determine impacts on
629 protection goals. However the scale of effects can only be assessed if comparable baselines are
630 also available for that indicator.

631 When considering the protection goals and indicators to be recorded, there is also a need to
632 establish the temporal and/or spatial relationship of this indicator with the presence of GMPs and
633 to be able to compare this indicator in areas where the GMP is not being grown. The design thus
634 allows an association to be postulated between an observed effect and the GMP. However,
635 correlation does not imply causation, so if a correlation is indicated, then specific cause-effect
636 studies and assessments of harm should be performed (see chapter IV.B.1).

637 There is a need for GS plans using both appropriate existing and novel general monitoring
638 systems to be able to compare impacts of GMPs and their cultivation with those of conventional
639 plants as a baseline. The baseline is generally the comparable conventional production system
640 which is the alternative to the GM system and is being replaced by the GM system. Direct
641 comparison with current non-GM plant reference areas should be used if available, but reference
642 can also be made to historical baseline data or previous knowledge and experience of the
643 ”observer” (e.g. farmers, inspectors, wildlife surveyors) in relation to the situation prior to the
644 introduction of the GMP. Those conducting monitoring should record any unusual events and
645 include them in reports. Monitors should not assess the impact of any unusual event at the time of
646 recording and should not to exclude them because they do not appear to be adverse. Assessment
647 of the frequency of an event is conducted when monitoring data are being analysed.

648 There is also a need to take into account the fact that the GM event will occur in different genetic
649 backgrounds of new varieties which may have impacts independent of the GM event and thus it is
650 important to record variety effects so that they can subsequently be distinguished from those of
651 GMP related effects.

652 **e) Data quality, management and statistical analyses**

653 The design of the monitoring programme will influence the quality and usefulness of resulting
654 data, hence efforts should be made to ensure that data from all the monitoring systems used can
655 be statistically analysed (Wilhelm et al., 2003, 2004a,b, 2010; Graef et al., 2008). Meta-analyses
656 (e.g. Marvier et al., 2007) of different datasets might be useful. If relationships between datasets
657 can be identified, it will contribute to the credibility of monitoring.

658 The GS plan should

659 - take account of the scale of commercialisation as well as the historical baseline
660 knowledge in different areas to be monitored,

661 - take account of the multi-level structures in European agricultural production and
662 agricultural practices,

663 - consider the geographical areas to be studied and which existing environmental
664 monitoring programmes could be useful for inclusion,

- consider national cultivation registers of GM plants (including co-existence measures) as they can provide useful data,
- describe the approaches used for data collection, management and examination within GS (e.g. data from general monitoring networks and farmer questionnaires),
- define the type and size of effects to be monitored,
- 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.

The EFSA GMO Panel encourages applicants to demonstrate the independence of their monitoring plans by establishing effective quality assurance and auditing schemes and recommends that raw data and analyses of monitoring data are made available to national Competent Authorities and the European Commission, when requested.

2. General Surveillance methodology

a) Monitoring focused on the cultivation of the GMP and its sites of cultivation

(1) Overall approach

Questionnaires, directed at farms or production systems where GMPs are grown, are considered a useful method to 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). For GM crops, the focused monitoring of the GM crop, its immediate environment and its management is usually done through farmer questionnaires, in order to obtain first hand information from those cultivating the GM crop at the field and farm scale. 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[12]. In the case of other GMPs (e.g. trees, ornamentals) questionnaires relevant to their production and processing systems will be required. This section focuses on monitoring approaches for GM crop production using farmer questionnaires, but the general principles are applicable to other GMPs and their production systems.

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

It is recognised that the information supplied by farmers will be limited to observations they can make on their areas of experience, which relate mostly to the areas on their farms cultivated with the GM and non-GM crop. The impacts on biota will be limited mostly to biota directly interacting with the crop and its management. However, this information can give early indications of effects which can then be examined in the other monitoring approaches to determine the scale of an effect and its possible impacts.

Applicants may consider additional approaches to production system monitoring 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.

(2) 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 region for proper analysis). Issues of human and animal health (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 the 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 location of the fields should be assessed by GPS and recorded,
- 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 should be fully described,
- where appropriate, observe the field/fields in subsequent years for any unusual residual effects,
- provide information on other GMPs being grown on the same sites or farms or on adjacent 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,
- establish independent audits to ensure the independence and integrity of all monitoring data.

Examples of farmer questionnaires have been developed (Wilhelm, 2004a,b; Schmidt et al., 2008) and the example of the farmer questionnaire submitted in the 2009 PMEM report on GM maize MON810 is publicly available[13]. It should be noted that this farmer questionnaire, submitted in the 2009 PMEM report on the cultivation of GM maize MON810, is currently being evaluated by the EFSA GMO Panel under a separate mandate from the European Commission. The early results from this evaluation are considered in the present draft opinion which describes general considerations in designing and operating farmer questionnaires. However, this assessment is ongoing and its final conclusions will be fully considered at a later stage, when finalising the present scientific opinion. At that time, more specific guidance could be delivered.

(3) Statistical design and analysis

Applicants should describe the effect size and provide a scientific justification for the selection of the effect size that will be required to be detected for 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.

Farmer questionnaires should be analysed by the applicant and reports submitted at the agreed time intervals (usually annually) to Competent Authorities and the European Commission. The applicants should make raw data available from Member States, the European Commission or EFSA.

(4) Indicators and Parameters to be measured

The parameters to be recorded will depend on the GMP, the event, the regions in which it is grown, the management requirements, the post-harvest handling, storage, processing and any consumption/exposure by livestock and humans.

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

The information collected could typically include:

1. *Background data, for example*
   - Specific 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.

2. *Data informing on possible change in behaviour and performance of GMP, for example:*
   - Information on any other GMPs currently or previously grown on the farm or in nearby fields, 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).

3. *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,
   - Responses of humans and livestock.

4. *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).

Farmers should be asked to comment on any differences occurring between the GMP and the non-GM comparator and to record and/or comment on any unusual effects observed in the field or on their farm.

(5) Data collection

Focussed questionnaires and interviews are generally accepted by respondents. 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 be independently audited to show that they are 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 cropping systems (e.g. pesticide and fertiliser applications), are likely to be of added value when filling in the questionnaires.

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, a comparative response is required when comparing GM and non-GMPs, e.g. was parameter X greater, same or less than in the non-GM comparator. 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).

(6) Duration of Monitoring an exposed site

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 and be consumed by livestock and/or the farmers family. The design of GS plans therefore needs to include these aspects of human, animal and environmental exposure. GMP may be grown in sequence or in rotation with other GMPs. It is important that higher levels and duration of exposure, and the interactions with other GMPs are also considered when selecting sites and conducting monitoring.

(7) Management and Stewardship of GMPs by applicants

In order to develop monitoring at 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 or other stakeholders about the GMP and its management and the need to supply data on seed sales, areas sown, plant management, etc.

- developing reporting systems so that all 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.

b) General 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 terrestrial biodiversity, water and air quality. In addition, many Member States have monitoring systems in place to monitor agricultural practices and their environmental impacts. These monitoring systems are recording changes in diversity of flora and fauna associated with certain agricultural practices. Directive 2009/128/EC (EC, 2009a) 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 schemes (see Table 2) include monitoring of many of the assessment endpoints related to the environmental protection goals listed in Table 1.

In GS, existing surveillance 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 the impacts of GM plants because they have been designed for other purposes (Gathmann, 2008). Moreover, the existing monitoring networks will differ from country to country and it may not be feasible or practicable to modify existing surveillance systems in order to make them suitable for GS of the effects of GMPs. 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 systems 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 GMOs as a means to ensure comparability and to limit the expenditure of resources. Applicants may identify changes that could be made to existing environmental monitoring programmes to improve the quality or usefulness of the data collected. This would include existing environment observation systems in the field of agriculture, food surveys, nature conservation, ecological long-term monitoring programmes, soil observation and veterinary surveys.

Inclusion of such programmes as part of the monitoring 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 programmes 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 surveillance systems. Many of the exisiting 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. Thus the EFSA GMO Panel is of the opinion that 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 GMOs and pesticides. Improvement or adaptation of existing national environmental monitoring programmes will help to measure whether certain protection goals are being harmed and whether the harm is associated with GMPs or the many other environmental stresses associated with agricultural practices. 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 surveillance 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. Responsibilities for selecting, adapting and using the existing monitoring networks should be shared between Member States and applicants submitting a GS plan.

In particular, Member States are expected to

- describe 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 for this 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.

Applicants are expected to proactively identify, in cooperation with Member States, appropriate existing monitoring networks, and the types of measurements that could be useful for GS depending on the time and geographical range of market introduction. In addition, they should propose changes to the data collection that might be required in order to improve data quality and analysis by the aforementioned networks.

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 (e.g. data collection by volunteers or professionals),
- 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 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.

The EFSA GMO Panel is of the opinion that GS should not establish principally new measures to observe protection goals systematically, apart from the farmer questionnaires. Such an approach would be disproportionate in relation to all the other potential environmental stressors, many of which are not monitored. However, if gaps in information relating to protection goals are identified, then risk managers in Member States should consider whether these merit additional monitoring in order to assess impacts of all new potential stressors, including GMPs.

c) Monitoring and 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 as their particular event. The results of these studies should be reviewed and the implications of the results 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. These publications should be listed, summarised and details provided as per the Appendix of EC, 2009c. The literature review should identify all relevant publications which have emerged after submission of the original application during the reporting period. 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.

The review should also include consideration of literature on related GMPs and similar events. The EFSA GMO Panel recommends that applicants follow the EFSA Guidance Document[14] on systematic literature review methodology to select relevant papers likely to have an impact on the previous ERA of the GMP.

Applicants shall present an analysis and conclusions of the review annually. Applicants should report whether the literature indicates 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 monitoring plans.

General Surveillance of GM plants intended for Import & Processing

Applications concerning food/feed uses and import and processing (but no cultivation) do not require scientific information on possible environmental effects associated with the cultivation of the plant. The extent of GS for these GMPs will depend on the level of environmental exposure and the protection goals including indicators selected. Therefore the EFSA GMO Panel differentiates between general surveillance plans as part of applications for import/processing and applications for cultivation.

The import of GM material for food and feed production can lead to environmental exposure, e.g. by accidental spillage of viable seeds, manure from the use of processed plant material containing transgenic material. 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.

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

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 need to report using the standard reporting format for non-cultivation applications. GS plans should monitor whether unanticipated levels of loss, spillage and establishment are occurring (e.g. Lee et al., 2009 ; Masaharu et al., 2009 ; Nishizawa et al., 2009) and/or if there are any adverse environmental consequences,

In the case of non-viable GM material (e.g. derived products not containing any living GMOs) and according to Directive 2001/18/EC (EC, 2001), the applicant does not have to provide any environmental monitoring plan (including GS) unless a potential adverse environmental effect has been identified in the ERA.

C. REPORTING THE RESULTS OF MONITORING

(1) 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 monitoring reports to the Commission, the Competent Authorities of the Member States, and, where appropriate, to EFSA. The monitoring 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, 2009c). Applicants should describe the methods, frequency and timing of reporting in their monitoring 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 monitoring so that the interactions between GMPs and their cultivation are considered in the monitoring plans and the monitoring reports. Where GM events stacked by hybridisation are being cultivated together with their lower stacks including single events, then applicants should share monitoring results and compile monitoring reports which consider the results of the monitoring of both the single and stacked events. The EFSA GMO Panel recommends that integrative systems allowing applicants to cooperate and share monitoring plans and monitoring 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 national Competent Authorities also have an important role in establishing liaison with applicants in order to coordinate data collection and analyses from different monitoring programmes. 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 Member State and EU level (e.g. Delos et al., 2007; 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 systems that may be relevant to areas where GMPs will or are being cultivated.

(2) Guidance

Applicants should make available 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 Europran Commission and EFSA.

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

- Register of all GMP releases with GPS references and farm references within that Member State,
- Compiling monitoring reports and appropriate raw data from all CSM and farmer questionnaires conducted in that Member States,
- 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.

Member States establishing these reporting centres should also agree to share information and data with other national reporting centres so that they can conduct analyses across wider regions.

The reporting centres would have a role in developing harmonised methodologies, protocols and procedures to ensure environmental monitoring datasets can be analysed at national and EU level for post market monitoring. They would 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 would 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 terrestrial 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 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, 2009a), Member States are required to develop a framework for sustainable use of pesticides. According to this Directive, Member States are asked to set up 'National Action Plans for IPM' (by 2011), including measures to reduce risks for the environment and human health. 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.

This recommendation would be in line with the conclusions[15] of the Council on GMOs in 2008 , including independent and active monitoring by Member States.

[15] http://register.consilium.europa.eu/pdf/en/08/st16/st16882.en08.pdf

D. 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.

V. Conclusion: Overall Guidance & Summary of 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 preliminary conclusions and recommendations set in the chapters of the present draft opinion are summarised hereunder:

Case-Specific Monitoring (CSM)

The 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 should be conducted as a comparative study using appropriate comparators for both the GMP and its management. 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 subjects related to the assessment endpoints identified in the ERA,
- Recording impacts on functional or production systems related to sustainability, IPM, etc,
- Recording the implementation of risk management strategies,
- 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 always required for viable GMP introductions 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 enpoints of environmental 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 Tables 1 and 2),
- 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 programmes,
- 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 requirements 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. However, in reality, the data they collect is often not in a useable form. 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. If necessary they should modify them to fit these purposes where practical. Applicants and Member States should then consider the use of these monitoring networks in GS plans for GMPs.
In addition, it is 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 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 is 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.

1194
1195 Applicants shall present an analysis and conclusions of their PMEM annually. Applicants shall
1196 report whether the PMEM results indicate any potential adverse environmental impacts
1197 associated with the GMP and its cultivation and whether these findings alter the conclusions of
1198 the ERA, the requirements for risk management or the PMEM plans.
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APPENDIX I

MONITORING GENETICALLY MODIFIED HERBICIDE TOLERANT (GMHT) PLANTS

The ERA includes the evaluation of the overall environmental impact of the specific herbicide programmes associated with these GMHT plants in addition to the environmental impacts directly associated with the GMP itself. The EFSA GMO Panel already proposed an approach[16] to be followed in the frame of the ERA of GMHT plants, specifically in relation to assessing the environmental impacts of the specific cultivation practices (*i.e.* herbicide treatments) associated with these plants. During the ERA of a GMHT plant, the main concerns are reduction in biodiversity, shifts in weed populations and evolution of weed resistance to the non-selective herbicides. Indeed, effects on weed populations and hence biodiversity are very dependent on the use and the management of the herbicides in GMHT crop production systems and in conventional systems. The EFSA GMO Panel noted that Directive 91/414/EEC (EC, 1991) does not contain a requirement to minimise impacts on biodiversity or to assess the impacts of pesticides on biodiversity or to monitor for effects on biodiversity of pesticide usage. The EFSA GMO Panel therefore recommended that weed management practices are developed for HT plants that maintain botanical diversity at or above levels in conventional crops and considered that monitoring should be conducted either of the implementation of these practices or on the efficacy of the management (see EFSA, 2009a). However, specific management and monitoring requirements after marketing of plant protection products are also laid down under Directive 2009/128/EC (EC, 2009a) and Regulation No 1107/2009 (EC, 2009b). The EFSA GMO Panel therefore recommends that monitoring of herbicide usage and impacts is conducted as part of the stewardship of the herbicides by the agrochemical companies involved, under the auspices of the pesticide regulatory systems operating in Member States, in order to record compliance with the approved uses of the herbicides on GMHT plants, levels of weed control and development of resistant weeds.

[16] See http://www.efsa.europa.eu/en/efsajournal/pub/1613.htm