Opinion of the Scientific Panel on Genetically Modified Organisms on the Post Market Environmental Monitoring (PMEM) of genetically modified plants[1]

(Question No EFSA-Q-2004-061)

Opinion adopted on 25 January 2006

SUMMARY

A plan for Post Market Environmental Monitoring (PMEM) of genetically modified (GM) plants is mandatory in all applications for deliberate release submitted under EU Directive 2001/18/EC and EU Regulation 1829/2003. PMEM aims at identifying possible unanticipated adverse effects on human health or the environment which could arise directly or indirectly from GM plants. PMEM is composed of case-specific monitoring and general surveillance of GM plants. Case-specific monitoring is not obligatory but may be required to verify the environmental risk assessment, whereas a general surveillance plan must be part of the application. The European Food Safety Authority (EFSA) is responsible for assessing the scientific quality of PMEM plans submitted with each application. In this opinion, the GMO Panel presents more specific guidance for applicants for developing PMEM plans. The GMO Panel concludes that general surveillance can not be hypothesis driven, but should, when possible, make use of existing monitoring systems in addition to more focused monitoring systems (*e.g.* farm questionnaires). Data quality, management and statistical analysis are of high importance in the design of general surveillance plans and comparison should be made with baseline data. In addition the EFSA GMO Panel explains the scientific rationale for this guidance and makes a number of recommendations for the management and conduct of PMEM by both applicants and risk managers.

Keywords: Directive 2001/18/EC, Guidance notes 2002/811/EC, Regulation (EC) 1829/2003, GMOs, GM plants, monitoring, post market environmental monitoring (PMEM), case-specific monitoring, general surveillance, risk assessment, risk management, reporting.

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BACKGROUND

According to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms (EC, 2001), Post Market Environmental Monitoring (PMEM) of genetically modified (GM) plants is mandatory. PMEM aims at identifying possible unanticipated adverse effects on human health or the environment which could arise directly or indirectly from GM plants.

Annex VII of Directive 2001/18/EC sets out the principles and objectives of the environmental monitoring plan. The Directive has been supplemented by Guidance notes 2002/811/EC (EC, 2002) providing guidance on the objectives, general principles and design of the monitoring plan. The Guidance notes provide useful general information and principles required in the monitoring plan, but they do not clearly indicate approaches and methods that should be used either in case-specific monitoring or in general surveillance which are both components of the monitoring plan. Currently, there is no European consensus on how monitoring plans shall be designed, although Member States are initiating national monitoring programmes (Sanvido *et al.*, 2005) and in 2004 the European Commission and the Competent Authorities for Directive 2001/18/EC established a working group on monitoring.

Applicants are required under Article 13(2)(e) of Directive 2001/18/EC and under Articles 5(5)(b) and 17(5)(b) of Regulation (EC) 1829/2003 (EC, 2003) to submit a PMEM plan as part of the notification for the placing on the market of a GM plant. The EFSA GMO Panel assesses the scientific quality of the PMEM plans in notifications submitted under Directive 2001/18/EC (if transmitted to EFSA) and in all applications for food/feed containing or consisting of GMOs submitted under Regulation (EC) 1829/2003.

In accordance with Articles 5(8) and 17(8) of Regulation (EC) 1829/2003 on GM food and feed, the GMO Panel developed a detailed guidance document for the risk assessment of GM plants and derived food and feed (EFSA, 2004a) to assist the applicant in the preparation and presentation of an application. However, in that guidance document, the part dedicated to environmental monitoring (11.4 - General surveillance of the impact of GM Plant) was not completed pending further consideration and consultation by the GMO Panel.

In April 2004, the EFSA GMO Panel tasked itself to give full consideration to the general surveillance of the environmental impact of GM plants and established a working group on PMEM. The working group assessed how monitoring systems might be developed in practice. It also addressed future requirements for monitoring assuming the commercialisation of several GM plants in many regions and Member States. In particular, the PMEM working group looked at how environmental impacts on a broad scale should be monitored, and how data from numerous monitoring programmes for individual GM plants should be collated, integrated and analysed. The EFSA PMEM working group developed a series of conclusions from the public

consultation process on the best approaches for PMEM and recommendations which are beyond the scope of the guidance for applicants on general surveillance.

These conclusions and recommendations form the basis for the approaches and methods for case-specific monitoring and general surveillance proposed in the EFSA Guidance Document and indicate the underlying philosophy behind the proposed guidance.

TERMS OF REFERENCE

Recognising the importance and complexity of developing PMEM plans, the GMO Panel decided to develop specific guidance on general surveillance of unanticipated adverse effects of GM plants.

In April 2004, the GMO Panel received the mandate to set up a working group on PMEM to i) develop guidance for applicants and risk assessors for the scientific evaluation of PMEM plans; ii) invite and consult external experts for case-studies on monitoring plans; iii) organise consultation workshops with stakeholders and to iv) complement its Guidance Document of the Scientific Panel on GMOs for the Risk Assessment of GM plants and Derived Food and Feed and v) assist EFSA in building a mutual understanding with the Commission, Member States and applicants on the assessment of specific PMEM plans.

ASSESSMENT

1. Introduction

Monitoring in general can be defined as the systematic measurement of variables and analyses of processes over time and assumes that there are specific reasons to collect such data (see section 3.1 of this opinion). For example, monitoring can be performed to ensure that certain standards or conditions are being met, or to examine potential changes with respect to certain baselines. Against this background, it is essential to identify the type of effects or variables to be monitored, an appropriate time-period for measurements and the tools and systems to measure them. Monitoring results, however, may lead to adjustments of certain parts of the original monitoring plan, or may be important in the development of further research.

According to Annex VII of Directive 2001/18/EC (EC, 2001), the objectives of (an environmental) monitoring plan are

- to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and
- 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 environmental risk assessment.

The design of the monitoring plan should:

- be detailed on a case-by-case basis taking into account the environmental risk assessment,
- take into account the characteristics of the GMO, the characteristics and scale of its intended use and the range of relevant environmental conditions where the GMO is expected to be released,

- incorporate general surveillance for unanticipated adverse effects and, if necessary, (case-) specific monitoring focusing on adverse effects identified in the environmental risk assessment:

  - case-specific monitoring should be carried out for a sufficient time period to detect immediate[2] and direct[3] effects as well as, where appropriate, delayed[4] or indirect[5] effects which have been identified in the environmental risk assessment,

  - general surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder should be provided,

- facilitate the observation, in a systematic manner, of the release of a GMO in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment,

- identify who (notifier, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the competent authority will be informed on any observed adverse effects on human health and the environment (time points and intervals for reports on the results of the monitoring should be indicated),

- give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and environment,

- enable the consent holder or the competent authority, where appropriate, to take the measures necessary to protect human health and the environment.

There is no clear borderline between risk assessment and risk management in relation to PMEM. Also, the borderline between case-specific monitoring and general surveillance might not always be easy to identify because of the element of uncertainty linked to any risk assessment.

Appropriate case-specific monitoring measures should be developed on a case-by-case approach depending upon the outcomes of the risk assessment. Possible risks identified in the environmental risk assessment should be studied in hypothesis-driven experiments and tests.

The objective of general surveillance is to identify the occurrence of unanticipated adverse effects of GM plants or their use on human health or the environment that were not anticipated in the environmental risk assessment. Since no specific risk is identified, no hypothesis of risk can be tested, so it is difficult to propose specific methods to carry out general surveillance.

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[2] According to Directive 2001/18/EC Annex II, "immediate effects" refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect.

[3] According to Directive 2001/18/EC Annex II, "direct effects" refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events.

[4] According to Directive 2001/18/EC Annex II, "delayed effects" refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

[5] According to Directive 2001/18/EC Annex II, "indirect effects" refers to effects on human health or the environment occurring throught a causal of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management.

With this EFSA PMEM opinion, the EFSA GMO Panel aims to clarify the tasks, tools, responsibility, and future requirements for post market environmental monitoring at both the national and European scale. The PMEM opinion includes chapters for i) introduction; ii) methodology; iii) detailed guidance for applicants; iv) the diversity of views expressed during the consultation process; v) wider issues to be considered by applicants and risk managers; vi) conclusions and recommendations. The conclusions and recommendations might be useful to both applicants and risk managers both in Member States and at the European Commission.

2. Methodology

The task of the PMEM working group was to provide scientific opinion and guidance on PMEM of GM plants focussing on general surveillance since the methods and approaches for this have not been developed in most EU countries. The working group organised a series of meetings, including 3 stakeholder consultation workshops and a public consultation through the EFSA web site in order to establish a rationale and general framework for general surveillance as a component of PMEM.

All stakeholder workshops considered the following topics: (1) rationale for general surveillance, (2) existing surveillance networks, and (3) use of GMO-focused monitoring (*e.g.* farm questionnaires). Separate workshops[6] were held with experts from the plant biotechnology industries, from environmental organisations, and from the Member States including members of the Monitoring working group established by the European Commission and Competent Authorities for Directive 2001/18/EC. In total, the EFSA PMEM working group invited 37 representatives from Member State Authorities, environmental organisations, industries, and public research institutions. The written consultation brought responses from 29 different parties. All contributions were evaluated and used by the working group in developing the guidance and this opinion. A new chapter on Guidance for general surveillance was adopted at the EFSA GMO Panel meeting on December 7, 2005 (EFSA, 2005f).

Chapter 3 below describes the full EFSA guidance for applicants on how to establish environmental monitoring plans. Chapter 4 discusses a number of valuable comments and suggestions made during the public and stakeholder consultations that were not considered to be relevant for guiding applicants, but which are potentially of importance in developing effective monitoring systems, and how they were used in formulating the guidance and PMEM opinion.

During the exploratory work of the EFSA PMEM working group several issues were identified as going beyond the scope of what is required from applicants in environmental monitoring plans. The EFSA GMO Panel discusses these issues in this PMEM opinion and makes recommendations for their implementation in chapter 5.

3. Guidance for the applicants

This chapter 3 corresponds to chapter 11 'Post Market Environmental Monitoring' of the EFSA Guidance Document on Risk Assessment of Genetically Modified Plants and derived food and feed (EFSA, 2004a). Sub-chapter 3.4 corresponds to the new chapter 11.4 which describes the Guidance on general surveillance (EFSA, 2005f). The text is reproduced in this opinion for information and completeness purposes.

[6] http://www.efsa.eu.int/science/gmo/gmo_consultations/732_en.html

3.1 General

The Regulation (EC) 1829/2003 reinforces the obligation for applicants to implement, when appropriate, a GMO monitoring plan for Environmental Monitoring according to Annex VII of the Directive 2001/18/EC (Regulation (EC) 1829/2003 Art. 5(5)(b) and Art 17(5)(b)) and a proposal for the post-market monitoring regarding use of the food and feed for human and animal consumption (Regulation (EC) 1829/2003 Art. 5(3)(k) and Art. 17(3)(k)). The latter is not described in any detail in the Regulation (EC) 1829/2003. Section III, D 7.11 of the Guidance Document refers to the post-market monitoring of GM food/feed (EFSA, 2004a).

In reference to Directive 2001/18/EC, the Environmental Monitoring is introduced in order to identify any direct or indirect, immediate and/or delayed adverse effects of GMOs, their products and their management to human health or the environment, after the GMO has been placed on the market. Since the Regulation (EC) 1829/2003 explicitly refers to Annex VII of Directive 2001/18/EC the structure and content of the environmental monitoring plan should be designed in accordance with the Council Decision 2002/811/EC supplementing Annex VII (strategy, methodology, analysis, reporting; EC, 2002, see also ACRE, 2004; Wilhelm *et al.*, 2003).

An environmental monitoring plan is required for applications for placing on the market of GMOs or food/feed containing or consisting of GMOs conforming with Annex VII to Directive 2001/18/EC. It is explained in the Guidance notes supplementing Annex VII that the extent of the market release shall be taken into account. Thus, the monitoring plan should be targeted rather than considering every possible environmental aspect.

Applications concerning only food/feed or ingredients (for example, imported into but not cultivated within the EU) will not normally be required to describe a detailed environmental monitoring plan if the applicant has clearly shown that environmental exposure is absent or will be at levels or in a form that does present negligible risks to other living organisms or the abiotic environment.

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. Against this background, it is essential to identify the type of effects or variables to be monitored, an appropriate time-period for measurements and, importantly, the tools and systems to measure them. Monitoring results, however, may lead to adjustments of certain parts of the original monitoring plan, or may be important in the development of further research.

The Council Decision 2002/811/EC (EC, 2002) provides no clear differentiation between the monitoring principles of either case-specific monitoring or general surveillance (Den Nijs and Bartsch, 2004). This opinion provides further assistance in the following sections.

3.2 Interplay between environmental risk assessment and monitoring

3.2.1 Monitoring of effects: Foreseen and unanticipated

The environmental monitoring of the GM plant will have two focuses: (1) the possible effects of the GM plant, identified in the formal risk assessment procedure, and (2) to identify the occurrence of adverse unanticipated effects of the GM plant or its use which were not anticipated in the environmental risk assessment. Where there is scientific evidence of a potential adverse effect linked to the genetic modification, then case-specific monitoring should be carried out after placing on the market, in order to confirm the assumptions of the

environmental risk assessment. Consequently, case-specific monitoring is not obligatory and is only required to verify the risk assessment, whereas a general surveillance plan must be part of the application. Applicants who are proposing to have no case-specific monitoring are encouraged to provide arguments in support of this position. These arguments should relate to the assumptions applicants have made in the environmental risk assessment, as well as to the lack of any identified adverse effects in tier 1, 2, or 3 tests (see Section II, 3 of the EFSA Guidance Document, EFSA, 2004a).

3.2.2 Monitoring framework

Council Decision (2002/811/EC) (EC, 2002) explicitly suggests that general surveillance should include long-term monitoring, to allow for unexpected effects that may occur after longer periods of environmental exposure. Changes in the management and cultivation techniques of new GM crops may affect the environment *e.g.* through changes in agrochemical usage. Directive 2001/18/EC requires that the impacts of any such indirect effects, *e.g.* changes of cultivation methods, should be addressed by the monitoring plan based on the outcome of the environmental risk assessment. The environmental monitoring plan should describe in detail the monitoring strategy, methodology, analysis, reporting and review as laid down in Council Decision 2002/811/EC. In this respect,

(a) GM plant-based parameters will depend on the particular GM plant, event and environment combination. Key parameters to be observed may refer to species/ecosystem biodiversity, soil functionality, sustainable agriculture, or plant health. Indicators should be measurable, appropriate, adequate in terms of statistical power, and comparable with existing baseline data. Minimum requirements for the selection of indicator species are published by Sanvido *et al.* (2004).

(b) background and baseline environmental data *e.g.* soil parameters, climatic conditions, general crop management data *e.g.* fertilisers, crop protection, crop rotations and previous crop history should be collected, where appropriate, to permit the assessment of the relevant parameters listed under a).

3.3 Case-specific GM plant monitoring

The main objective of case-specific monitoring is to determine the significance of any adverse effects identified in the risk assessment (see Sections III, D 8, 9 and 10 of EFSA Guidance Document on Risk Assessment, EFSA, 2004a). The assessment of risk should be based on Annex II of the Directive (2001/18/EC).

Case-specific monitoring should be targeted at those environmental factors most likely to be adversely affected by the GM plant which were identified in the environmental risk assessment. The scientific approach should be designed in order to test the specific hypothesis of expected adverse effects derived from the environmental risk assessment. The monitoring programme design should also reflect levels of exposure in different geographical regions and other specific site influences. Such monitoring may be carried out at a limited number of sites ('local monitoring'), where exposure is greatest and intensive recording and data collection can take place. This would be particularly appropriate when it is envisaged that there will be a phased or gradual introduction of the GM crop into a limited number of regions in various EU Member States. The scale of the monitoring should be increased as the area and range of the GM crop expands and the crop is grown in more regions. The monitoring should consist of the systematic recording of relevant parameters at representative locations where there is significant and repeated growing of the GM crop. This might also be defined according to the extent of the cultivation of the GM crop, the occurrence of targeted pest species or particular climatic/eco-regions. The methods selected, the duration of the monitoring, the extent or number of areas

and the parameters to be monitored will be determined on a case-by-case basis. Whilst the planning and execution of case-specific monitoring is under the applicant's responsibility, it may be appropriate for the applicant to involve public institutions to contribute to the agreed work.

3.4 General surveillance for unanticipated adverse effects

The objective of general surveillance is to identify the occurrence of unanticipated adverse effects of the genetically modified (GM) plants or its use on human health or the environment that were not anticipated in the environmental risk assessment. General surveillance applies where no adverse effect has been identified in the environmental risk assessment, but is always required in order to detect unanticipated adverse effects (EC, 2002). Monitoring of potential adverse cumulative long-term effects and areas of uncertainty identified in the environmental risk assessment are important objectives of monitoring (EC, 2002) which should be considered initially within case-specific monitoring. When there is a negligible degree of uncertainty in the environmental risk assessment then no case-specific monitoring is indicated. However, general surveillance is always required for monitoring any unanticipated adverse effects.

An effect can be defined as an alteration that results in values that are outside the normal variation range given the constant change and flux of the agriculture, the agricultural practices, the rural environment and the associated biota in the European Union. A major challenge of general surveillance is determining whether:

- an unusual effect has been observed
- the effect is adverse and
- the adverse effect is associated with the GM plant or its cultivation.

The use of a range of monitoring systems to supply data and the ability to compare data from these different sources will help to indicate whether an effect is unusual and adverse. The identification of an adverse effect which is potentially linked to specific GM plants would trigger the need for a specific study to evaluate harm and determine cause.

An objective of the Directive 2001/18/EC (EC, 2001) is to protect the environment including biodiversity, water and soil. The GMO Panel is of the opinion that one important task within general surveillance is to link monitoring to these environmental protection goals. Recently, EU 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.

Within a broader concept of environmental issues, unanticipated adverse effects on human health have also to be addressed in the monitoring plan presented by the applicant. The scope of monitoring for unanticipated adverse effects on human health is defined, according to Directive 2001/18/EC, as monitoring for unanticipated adverse effects that may result from handling of the GM plant.

It might prove very difficult to design monitoring (including general surveillance) for unanticipated adverse health effects. However, knowing that the release of GM plants needs to be considered in context of their interaction with other environmental components, monitoring for effects on human health could be considered in conjunction with human population screening methods currently used by public health organisations (considering especially such elements as incidences of allergic reactions) and as part of the suggested plant production and farm questionnaires.

3.4.1 Approach and principles of general surveillance

Applications concerning food/feed uses and import and processing do not require scientific information on possible environmental effects associated with the cultivation of the plant. The extent of general surveillance for these GM plants will depend on the level of environmental exposure. Therefore the GMO Panel differentiates between general surveillance plans as part of applications for import/processing and applications for cultivation.

3.4.1.1 Approach and principles for GM plants intended for import and processing only

General surveillance plans as part of applications for import and processing will need to take account of the modified characteristics specific to the GM plants in question, their intended use and the receiving environment (EC, 2002). The extent of the general surveillance plan will depend on the level of environmental exposure, the establishment, persistence and spread of the GM plant and does not require scientific information on possible environmental effects associated with the cultivation of the plant. The applicant has to show that environmental exposure will be at levels or in a form that does not present a risk to other living organisms or the abiotic environment (see section 11.1 of the Guidance Document).

In the case of non-viable GM material (*e.g.* derived products not containing any living GMOs) and according to Directive 2001/18/EC, the applicant does not have to provide any environmental monitoring plan (including general surveillance).

In the case of imported GM products containing viable propagating material, general surveillance plans should consider that if substantial loss, spillage or establishment is possible, appropriate management systems should be in place to restrict environmental exposure.

The EFSA GMO Panel has assessed general surveillance plans as part of applications for import and processing of maize and oilseed rape (*e.g.* EFSA, 2003, 2004b, 2004c, 2004d, 2005a, 2005b, 2005c, 2006b). Monitoring plans of GMOs applications submitted Regulation (EC) 1829/2003, for which an opinion in accordance with Articles 6.5 and 18.5 has been published, are available on EFSA web page[7].

3.4.1.2 Approach and principles for GM plants intended for cultivation

General surveillance plans as part of applications for cultivation will need to take account of the full environmental effects of the GM plant including its cultivation.

The GMO Panel is of the opinion that general surveillance is a general overseeing of the geographical regions where GM plants are grown without having any specific hypothesis on adverse effects on human health or the environment. As general surveillance is not hypothesis-driven, it is not conducted using directed experimental approaches (see also ACRE, 2004; Sanvido *et al.*, 2005). However, robust scientific methodology should be applied wherever possible in order to evaluate empirical knowledge. This especially refers to defining sample sizes, sampling and recording methods, in order to produce statistically valid data for determining causes and effects.

Existing surveillance systems should be used where practical (*e.g.* routine farm recording systems) and any 'unusual' effect, not occurring in similar situations within conventional cropping, should be recorded (*e.g.* effects on soil).

[7] http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html

The establishment, persistence and spread of a GM plant is not an environmental hazard in itself. Similarly, dispersal of pollen and seeds and gene flow *per se* are not environmental hazards and thus the focus of general surveillance should be on recording any unanticipated consequences of the cultivation of the GM plant, such as unforeseen weediness, invasiveness or changes in plant population dynamics or populations of biota associated with the GM plants. However, an unanticipated adverse effect is most likely to occur where the level of environmental exposure is highest. Thus, an evaluation of how and where the GM plant will be grown and the associated environmental exposure is considered a good starting point in any general surveillance plan.

General surveillance of the impact of GM plant should

- be applicable, in a proportionate and cost-effective manner, for monitoring the GM plant in a range of representative environments, reflecting the range and distribution of farming and environments exposed to the GM plants and its cultivation. If unusual effects on human health or the environment are reported, more focussed in-depth studies should be carried out in order to determine the cause and its relationship with GM plants. Such additional studies would be case-specific monitoring studies as they would require an experimental approach to confirm the specific hypothesis that an observed effect is associated with the GM plant,

- complement available general environmental monitoring. The higher the ecological integration and scale (from the individual to a population, from single farm to regions) the more difficult it is to distinguish potential effects of the GM plants from other factors. Initially, general surveillance should focus on each event individually. Additionally, when several GM plants have been commercialised, the interactions between these GM plants and their management may need to be considered where appropriate.

The EFSA GMO Panel has assessed general surveillance plans as part of applications for cultivation (*e.g.* EFSA, 2005d, 2005d, 2006a). Monitoring plans of GMOs applications submitted under Regulation (EC) 1829/2003, for which an opinion in accordance with Articles 6.5 and 18.5 has been published, are available on EFSA web page[8].

3.4.2 Main elements of general surveillance

The applicant should:

- define the methods and approaches that will be used to conduct general surveillance of regions where the GM plant occurs,
- refer to introduction, stewardship and exploitation plans for the GM plant, and
- make proposals for the time period, area covered, and the frequency of monitoring.

3.4.2.1 Existing monitoring systems

Applicants will have developed plans for the introduction, marketing, management and stewardship of the GM plant. The GMO Panel is of the opinion that applicants should include these into the monitoring plans, where appropriate, as they will contain some data of relevance to the implementation of the monitoring plan.

[8] http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html

General surveillance should, when compatible, make use of established routine surveillance practices such as monitoring of agricultural plants, variety/seed registration, plant protection, plant health, soil surveys as well as ecological monitoring and environmental observations (EC, 2002).

Many of the existing monitoring systems and networks collecting environmental data are unlikely always to provide data of relevance that may be used in monitoring impacts of GM plants. The design of the existing monitoring programs, the targets (*e.g.* birds, plant protection, *etc.*), the time, frequency and scale of data collection, sampling, analysis and reporting methods may not suit the monitoring of GM plants because they have been designed for other purposes. Moreover, the existing monitoring systems 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 general surveillance of GM plants. Thus applicants may not consider existing networks to be sufficiently useful sources of information for monitoring. There may be a need for additional environmental surveys and to amend the monitoring objectives of existing monitoring systems (see also Sanvido *et al.*, 2004, 2005).

Because existing monitoring systems can be of variable quality and consistency, it is important that the consistency and reliability of surveys utilised in general surveillance 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 systems, it is important for the applicant to describe the processes and criteria that will be used for selecting and evaluating existing monitoring systems for supplying data related to the unanticipated adverse effects of GM plants in the general surveillance.

Specifically the applicant should

- describe which general observations could be monitored through existing monitoring schemes,
- identify the type of existing monitoring systems that would be appropriate for this in the countries where the GM plant will be grown (*e.g.* monitoring of agricultural cultivars and plant protection surveys),
- describe the criteria and generic approach used to evaluate existing monitoring networks and how appropriate networks will be selected,
- describe how arrangements for collecting, collating and analysing data will be made,
- identify which category of additional surveys could be required to contribute to the general surveillance (*e.g.* public institutions, farm associations) in selected regions or Member States,
- describe how formal agreements, procedures and communication will be established with the Commission and Member States or other third parties before commercial market introduction, although detailed arrangements may not have been agreed at the time of the application.

According to Council Decision 2002/811/EC 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 structure of their involvement should be detailed.

3.4.2.2 Use of GMO-focussed monitoring systems

In addition to using existing monitoring systems, applicants are encouraged to develop new and more focused monitoring systems especially at the production level. Questionnaires, directed at farms where GM plants are grown, are considered a useful method to collecting first hand data on the performance and impact of a GM plant and for comparing it with conventional plants (ACRE, 2004; Sandivo *et al.* 2005; Wilhelm *et al.*, 2004). Experience from other established surveillance and monitoring systems (*e.g.* the approach used for consumer and pharmaceutical surveillance systems) could be used in designing questionnaires. Special emphasis should be given to the statistical design of such questionnaires. Issues of human health (*e.g.* due to exposure and handling of GM plants) may also be integrated into farm questionnaires.

As appropriate, the applicants should

- inform growers, seed suppliers or other stakeholders about the GM plant and the need to supply data on seed sales, areas sown, plant management *etc*...,
- be pro-active in developing reporting systems so that farmers (or their agents and advisors) intending to purchase genetically modified seeds will be fully informed about the GM plant, the importance of the monitoring programme and the reporting of unanticipated effects during and after the cultivation of the GM plant,
- describe the number of farmers/growers involved, the area covered, the reporting methods and the suitability of the data collected for statistical analysis,
- establish independent audits to ensure the independence and integrity of all monitoring data,
- indicate the likely frequency of inspections.

Farm questionnaires should

- be designed to ensure the statistical validity and representativeness of the collected data, including the proportion of fields growing the GM plant 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 GM plants as well as data on impacts on farming systems and the farm environment,
- use a field or group of fields growing the GM plant as the basic unit for monitoring,
- observe the field/fields in subsequent years for any unusual residual effects,
- be user friendly and also information rich,
- be constructed to encourage independent and objective responses from farmers, land managers and others involved with the GM plant or its products.

Questionnaires adapted to agronomists or other stakeholders working on the farms growing the GM plants may also be useful sources of information. Focussed questionnaires and interviews are generally accepted by respondents. Professional interviewers may be an additional help.

Examples of farm questionnaires have been developed by Wilhelm *et al.* (2004,), Schmidt *et al.,* (2004) and some farm questionnaires have already been assessed by the GMO Panel (EFSA, 2005d, 2005e).

Farm questionnaires should be distributed, completed and collated annually via an arranged reporting system (*e.g.* farm questionnaire forms or online systems). These should be analysed by the applicant and reports submitted at the agreed time intervals (usually annually) to appropriate Competent Authorities. The results of the farm questionnaires will allow the

applicant to record the implementation of recommended management and stewardship of the GM plant (*e.g.* good agricultural practice, hazard analyses, critical point compliance) and to identify unanticipated adverse effects.

3.4.3 Importance of a baseline

There is a need for general surveillance plans using both existing and novel monitoring systems to be able to compare impacts of GM plants and their cultivation with those of conventional plants. The baseline is the current status quo *e.g.* current conventional cropping or historical agricultural or environmental data. Direct comparison with non-GM plant reference areas should be used if available, but reference can also be made to the "historical knowledge" and experiences of the "observer" (*e.g.* farmers, inspectors, wildlife surveyors) in relation to the situation prior to the introduction of the GM plant (see initiative developed by FAO, 2005). It will be important to inform observers to report any unusual events and not to attempt to anticipate impacts.

There is also a need to take into account the fact that the GM event will occur in a changing genetic background of new varieties which may have an impact independent of the GM event and thus it is the event that needs to be monitored in any variety.

3.4.4 Data quality, management and statistical analyses

The design of the monitoring programme will influence the quality and usefulness of resulting data and efforts should be made to ensure that data can be statistically analysed from all monitoring systems used (Wilhelm *et al*., 2003, 2004; Schmidt et al., 2004). Meta analyses of different datasets might be necessary. If relationships between datasets can be identified, it will contribute to the credibility of monitoring.

The general surveillance plan should

- take account of the scale of commercialisation as well as the historical baseline knowledge in different areas to be monitored,
- consider the geographical regions to be studied and which existing environmental monitoring programmes could be useful for inclusion,
- consider national cultivation registers of GM plants (including co-existence measures) as they can provide useful data,
- describe the generic approach used for data collection, management and exploitation within general surveillance (*e.g.* data from existing networks and questionnaires),
- describe the concept for identification of unusual adverse effects related to GM plants including a detailed statistical concept,
- include a comprehensive description of the steps of data analysis, statistical methods, procedures, and statistical significance requirements,
- 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 should describe the way of data pooling/matching with GM cultivation in time and space,

- contain data from case-specific monitoring that might complement the general surveillance data.

3.5 Reporting the results of monitoring

Following the placing on the market of a GM plant, 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. Applicants should describe the methods, frequency and timing of reporting in their monitoring plan. Although no timeframe for reporting is specified in Council Decision 2002/811/EC (EC, 2002), reports, allowing for specific adaptations, preferably should be submitted

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

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

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

Flow of information on the cultivation of GM:

Where GM plants are grown the following procedures should be complied with:

(a) All GM seeds must be labelled with the variety, and should also contain information on the construct, the supplier's name and address, full instructions on any specific cultivation requirements, and reporting procedures for any incidents, including the address of the Consent Holder for the marketing of the seeds.

(b) The farmer/grower is required to declare the variety, sowing date, amount of cultivated crops and exact geographic location to the national cultivation register according to Directive 2001/18/EC - Art 31 (3b).

(c) The farmer should record all relevant cropping and management data for that GM crop and these data should be available for inspection.

Flow of information in instances where GM plants are thought to have caused unusual or adverse effects:

If adverse effects have been detected in areas where GM plants are grown or where there is a suspicion that the GM plants may be associated with an incident, the following procedures should be complied with:

(a) The applicant shall immediately inform the appropriate Competent Authority and take measures necessary to protect human health and the environment in conjunction with the CA. In addition, the applicant shall discuss revision of the information and

conditions specified in the application with the CA. Unusual occurrences may be observed by farmers, agronomists or others. They should be reported immediately to the applicant. According to Article 20 of Directive 2001/18/EC, the applicant should then decide whether these occurrences are unusual effects and report to the Competent Authorities. Applicants are strongly encouraged to report observations at an early stage and enter discussions with CA's on the need for further studies or measures.

(b) The applicant will inform those concerned with the cultivation of the GM plant asking them to immediately communicate any new adverse effects they may detect to a specified information point.

(c) The applicant should carry out a preliminary examination in order to verify whether a GM plant-related effect has really occurred and provide the competent authority with a report on the result of its preliminary investigations, including an assessment of potential harm.

(d) If information becomes available to the applicant which could have consequences for the risks of the GM plant(s) to human health or the environment it shall immediately forward the information to the Commission and the competent authorities of the Member States.

(e) Where adverse effects on the environment are observed, further assessment should be considered to establish whether they are a consequence of the GM plant or its use, as such effects may be the result of environmental factors other than the placing on the market of the GM plant in question. The competent authority should inform the Commission of the reported observation and, together with the applicant and scientific institutions or experts investigate the causes and consequences of the reported incident. The competent authority should submit a report to the Commission and EFSA on the extent of any environmental damage, remedial measures taken, liability and recommendations for the future use/management of the GM plant.

3.6 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 based on reviews of 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. Implementation of the revised monitoring plan remains the responsibility of the applicant unless otherwise determined by the competent authority.

4. The diversity of views on general surveillance expressed during the consultation process

During the public consultation and during the three consultation workshops with stakeholders organised by EFSA between April 2004 and September 2005, a number of views and issues were raised in relation to general surveillance for consideration by the GMO Panel.

4.1 Definitions of case-specific monitoring and general surveillance

Several comments were submitted referring to the definition and relationship between case-specific monitoring and general surveillance. The borderline between case-specific monitoring and general surveillance may not always be easy to identify because of the element of uncertainty in any risk assessment (see section 3.2.1 of this opinion).

Some contributors proposed that general surveillance should also apply to adverse effects identified in the environmental risk assessment but which might develop in an unexpected manner and that case-specific monitoring should also apply to confirm that there is no or a negligible risk. However the EFSA GMO Panel considered that this approach would lead to case-specific monitoring of all GM plants in every environment to confirm the assumptions of the risk assessment, as well as to a targeted or experimental approach to general surveillance. This approach would not be in line with the definitions given in Directive 2001/18/EC.

General surveillance could potentially be interpreted as an unconditional surveillance of all areas exposed to the GM Plant or likely to be affected by its cultivation in order to detect any unanticipated effect. From a practical viewpoint, this approach of unlimited surveillance is not feasible for either applicants or third parties (*e.g.* for national surveillance organisations). Therefore a more targeted and systematic approach is needed. This starts with identifying areas where potential harm is most likely to be detected and the selection of the most appropriate indicators of harm for monitoring. There is little point basing general surveillance on monitoring population shifts in complex ecosystems or ecosystems remote from any exposure, especially if they are sensitive to a range of other influences, are already in flux, have poorly defined limits or baselines, and little connection with actual harm.

Hence the majority view, and the view the EFSA GMO Panel proposed, is that appropriate case-specific monitoring measures should be developed on a case-by-case approach depending upon the outcomes of the risk assessment. By contrast general surveillance is not necessarily crop, trait or field specific as it implies a generic approach to determining any unanticipated adverse effect of a GM crop and its use that was not associated with characteristics of the crop during the risk assessment. Thus general surveillance is an overseeing strategy to identify the occurence of any potential adverse effect. When such an effect has been detected, a detailed study of the observed phenomenon is required (*e.g.* as case-specific monitoring) to determine whether the effect is associated with the GM crop and is potentially harmful. This approach to monitoring clearly separates case-specific monitoring from general surveillance while maintaining links with the environmental risk assessment. The GMO Panel is of the opinion that, based on these conceptual differences, case-specific monitoring and general surveillance can be more clearly defined, as can their respective limits, and agrees with the views of Sanvido *et al.*, 2005 (see Table 1), ACRE (2004*), COGEM (2005).*

Table 1: Objectives of a monitoring programme for genetically modified plants (GMPs) according to EU Directive 2001/18/EC (EC, 2001) including the roles and limits of case-specific monitoring and general surveillance (taken from Sanvido *et al.* (2005)).

	Case-specific monitoring	General surveillance
Objectives according to 2001/18/EC	– To assess, if anticipated adverse environmental effects related to a specific GMP do occur (confirm assumptions of environmental risk assessment - ERA)	– To detect unanticipated adverse environmental effects which were not identified in the ERA
Approach	– Detection of changes related to GMP cultivation during a defined time period	– Assessment of state of the environment independent from any preconception and time period
What the program can provide	– Case-specific confirmation or rejection of a previously formulated hypothesis in comparison to a reference system – Draw conclusions on the cause of detected changes	– Provide information on the state of the environment and of possible environmental changes – Provide fundamentals to forecast the likely development of the environment (early warning system)
What the program can not provide	– Draw conclusions on the long term development of the environment	– Determine the cause of an environmental change – Draw conclusion on the effects of GMP cultivation

4.2 Feasibility of testing scientific hypotheses

There were comments about the scientific requirement for general surveillance to test hypotheses on adverse effects that might be caused by GM plants. Specifically there were proposals that general surveillance should test a general null hypothesis *i.e.* that the release and cultivation of a GM crop plant does not cause any adverse environmental effect.

As stated above, general surveillance is a general overseeing of the biogeographical regions where GM plants are grown. General surveillance will record whether shifts in the distributions or variability of monitored characters occur and whether these shifts are related to exposure to, or presence of, GM plants. General surveillance will tend to focus on areas of highest exposure to the GM plant without having any specific hypotheses on which components of an ecosystem may be adversely affected.

By contrast, to prove a hypothesis would require detailed studies of a selected range of environmental indicators in order to fulfil basic requirements (Legg and Nagy, 2005). This would be a disproportionate approach for general surveillance and might still miss an unanticipated adverse effect on a non-selected organism in the environment. Thus the GMO Panel does not consider that developing either specific or general hypotheses are helpful for conducting general surveillance.

4.3 Use of "historical knowledge" as baselines

The usefulness of "historical knowledge" was questioned. In addition, observation of "unusual effects" was not thought to be a suitable entry point in general surveillance.

The GMO Panel is of the opinion that the use of baselines and/or reference values is essential for a scientifically sound approach (see chapters 3.4.3 and 3.4.4. of this opinion). "Historical knowledge" can provide such a baseline or reference. Although "historical knowledge" may be biased by personal perception and experiences, it is possible to transfer such knowledge into a statistically sound evaluation scheme. Moreover, this provides a way to gain access to data that are otherwise not available for scientific evaluation. "Historical knowledge" is most detailed and more reliable if it is related to fields of interest for the observer. The methods of data acquisition need not necessarily obtain "correct" answers. In addition the "historical knowledge" may be limited to topics on which an observer has sufficient knowledge *e.g.* farm questionnaires ask questions related to past cropping experiences on farms. Although a single answer may not bear sufficient information about an "unusual" phenomenon, the strength of this approach is related to data collected from numerous sources and the analysis of the distributed answers. Hence, conclusions can be made by comparing the range of experiences in the absence of GM plants with those in the presence of GM plants.

In Europe most environments have been shaped by man and many are maintained by man's management. In addition, man is familiar with his crops and the environment in which they are grown. Consequently, selection of the baselines used for monitoring the release of GM plants into the environment should reflect current trends in cultivation of plants and management of land, and should not be fixed in time or space. In order to link cause and effect, environmental monitoring of the impact of GM plants must be able to identify environmental changes due to factors and human activities other than growing GM plants. The EFSA GMO Panel is thus of the opinion that "historical knowledge" and good baseline data are important for achieving this.

4.4 Difference between monitoring and biosafety research

Some stakeholders called for an intensive biovigilance programme to be conducted in identical long-term plots situated in biogeographical regions. This programme would constitute a source

of independent data of good quality, in parallel to the ones collected and analysed by the applicants in their PMEM. It was proposed that environmental monitoring should be a continuous scientific program, in order to detect cumulative long-term effects. At the same time, proposals were also made during an EFSA consultation workshop[9] for intensive general environmental monitoring including recording a larger set of environmental parameters and values. The EFSA GMO Panel is of the opinion that such a programme is biosafety research and therefore not part of PMEM. The guidance provided in Council Decision 2002/811/EC (EC, 2002) clearly states that monitoring is different from biosafety research.

General surveillance of GM plants should complement but not replace general environmental monitoring conducted by Member States (see section 3.4.1). The higher the ecological integration and scale (from the individual to a population, from single farms to regions) the more difficult it is to distinguish potential effects of GM plants from the impacts of other factors. Thus linking general surveillance to other environmental monitoring programmes will allow established baselines and trends to be adopted into general surveillance in order to facilitate identification of additional or unusual effects.

4.5 Monitoring at landscape level for protection goals

Some stakeholders asked for a comprehensive list of protection goals and for identification of particular landscapes or regions where monitoring should be focussed.

The GMO Panel has placed a specific emphasis on establishing farm questionnaires (GMO-focussed monitoring systems) to monitor any adverse impacts at this level (see chapter 2.4.2.3). Applicants will primarily consider general surveillance in the places where the GM crop is being grown and monitor for any adverse effects of its cultivation at the farm level. Nevertheless, the data collection from different farms can be analysed for patterns and trends discernable at a larger landscape scale.

However, surveillance for adverse impacts of GM plants at complex regional and/or national levels may be beyond the scope of farm monitoring or the applicant's direct capability. Also, increasing complexity and interaction of GM plants use with other land management systems may be better studied in other ways. Utilising existing surveillance systems established by land-use and environmental organisations was identified as a potential approach to increase the scope of the general surveillance. This approach would have the advantage of collecting information related to the combined effects of GM plants in a region as well as in general surveillance based on single application. Thus the GMO Panel considers that general surveillance should make use of new GMO-focussed monitoring, as well as existing monitoring surveys of regional environmental impacts, in order to determine landscape-scale effects.

In addition, the EFSA GMO Panel is of the opinion that general surveillance should not establish principally new measures to observe protection goals systematically. Such a focus would pose a disproportionate burden on applicants. In general, applicants should make use of existing general environmental monitoring where appropriate (see section 3.4.2.1 above). The discussion during the consultation workshop on conservation goals for general surveillance revealed the problem of distinguishing the case-specific monitoring from the general surveillance if conservation goals are named in detail[9]. Further discussion revealed that it is unlikely that reasonable bio-indicators (*e.g.* species) could be identified for particular conservation objectives. There is a strong argument to identify conservation goals and related characters/parameters on the basis of their functional considerations (*e.g.* regulation of pests) which are then monitored by both existing networks (chapter 3.4.2.1 of this opinion) or GMO-focussed monitoring systems like farm questionnaires (chapter 3.4.2.2 of this opinion).

[9] http://www.efsa.eu.int/science/gmo/gmo_consultations/732_en.html

4.6 Intensive monitoring of environmental exposure

Suggestions were made to intensively monitor for the occurrence of GM plants and their recombinant DNA in the environment in order to measure transgene dispersal and distribution in the environment and subsequently to relate this to any unanticipated adverse effects that might occur.

The EFSA GMO Panel is of the opinion that the occurrence of GM plants, as well as of recombinant DNA, in the environment is not an adverse effect *per se*. Monitoring their occurrence would require huge resources for the observation of natural and predictable processes and would require the generation and analysis of large amounts of data. It is questionable that any relevant data would be collected that give any indication of adverse effects. General surveillance as conducted in this Guidance should detect any *significant changes* in dispersal and distribution patterns of GM plants that may cause adverse effects. The EFSA GMO Panel therefore considers that routine recording of the incidence of GM plants and recombinant DNA is not an effective use of resources and strongly urges that the focus of monitoring should be on the detection of adverse effects associated with any observed changes in the environment.

4.7 Implementation of "good monitoring practices"

Suggestions were made to develop rules for "good monitoring practices" in combination with standardized and validated methods before GM plants are approved for cultivation.

The EFSA GMO Panel sees the development of "good monitoring practices" as an important step towards the collection of scientifically sound observations and data which can be subject to international scrutiny. Currently, there are few methods available that refer to data acquisition and analysis for specific environmental or ecological parameters. A code of "good monitoring practice" for general surveillance should include scientifically sound design of monitoring systems, data collection, analysis of data sets from different data sources and methods for interpreting results. As more experience of monitoring of GM plants is acquired over the next few years, the practicality of developing a quality assurance scheme for monitoring can be evaluated and considered for incorporation into the EFSA Guidance Document. However, the GMO Panel is of the opinion that at present a code of "good monitoring practices" is not feasible due to the lack of experience with PMEM.

4.8 Systematic monitoring of effects on human health

Suggestions were made to monitor for adverse effects on human health within the general surveillance part of the environmental monitoring plan.

The GMO Panel is of the opinion that it is very difficult to develop a general surveillance plan that could distinguish between effects of exposure to GM plants, genetic predisposition, lifestyle, environmental and social factors as the cause of any human health problems. Therefore the results of any monitoring of human health should be carefully scrutinised and results only published when analysis shows a link between exposure to a GM plant and a human health effect.

4.9 Responsibilities

The sole responsibility of the applicant to design and conduct the monitoring plan was questioned. There were concerns that there were no checks that the applicant was conducting the monitoring to a reasonable standard or reporting all results. Others considered that the

more complex aspects of the monitoring were beyond the technical and economic resources of applicants, especially Small and Medium Enterprises.

These comments deal primarily with the legal and regulatory set up of the monitoring regime with regard to liability and responsibility, which is not the scope of the EFSA Guidance Document. However, the EFSA GMO Panel would encourage applicants to establish effective quality assurance and auditing schemes and recommends that, if needed, analyses of monitoring data are available for inspection by national competent authorities. In addition, the applicant should consider using existing monitoring networks as these will be under the control of other organisations.

5. Wider issues to be considered by applicants and risk managers

During the work of the EFSA PMEM working group, several issues were identified that are outside the scope of environmental monitoring plan submitted by applicant. The EFSA GMO Panel discussed these issues and here makes recommendations to improve monitoring, to stimulate early contacts between applicants and relevant Member States, and to harmonise and coordinate data collection and analysis.

5.1 Involvement of national competent authorities in GMO monitoring plans

General surveillance is related to risk management[10]. A final adoption of the general surveillance plan provided by applicants falls outside the mandate of EFSA. However, the EFSA GMO Panel gives its opinion on the scientific quality of general surveillance plans including possible links to other monitoring activities at Member State or EU level.

As previously stated in this opinion, the specific objective of general surveillance is to identify unanticipated adverse effects of the GM plant or its use on human health and the environment, which were not predicted in the environmental risk assessment. The methods and approaches should be appropriate, proportional and cost-effective to allow for the detection of effects associated with the GM plants. Potential data sources and related monitoring networks should be identified by the applicant in close consultation with risk managers in Member States.

The applicant is responsible for developing and implementing the PMEM plan, as well as reporting on it. However the GMO Panel also considers that coordination at regional, national and EU levels is necessary for general surveillance and that this might often be beyond the control of the applicant alone. Thus the GMO Panel is of the opinion that risk managers at the national level should guide applicants in the selection of appropriate existing monitoring systems and in developing monitoring systems which may provide useful data.

5.2 Implementation of monitoring

General surveillance is applicable in regions and/or countries where the GM plant is likely to be commercialised. Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. The implementation of general surveillance data collection at

[10] Risk management means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options (EFSA, 2004a)

a regional and national scale will be dependent on the local circumstances prevailing at the time the consent is given. Thus detailed local arrangements will be developed by the applicant after the application has been accepted and will depend on where the crop will be grown, the scale of commercialisation, the nature of the cultivation systems and a range of other factors. Applicants are encouraged to establish contacts with national competent authorities at an early stage in the commercialisation planning.

5.3 Use of existing networks

Monitoring plans will be developed for general surveillance of GM plants wherever they are grown in the EU and thus need to be able to collate data from different national monitoring systems. However there are broad differences in the availability and adequacy of the environmental surveys and methods conducted by Member States which could lead to difficulties in coordinating GMO surveillance at EU level. The different monitoring systems will make it difficult to determine if any adverse effects noted are directly related to different environments or different management systems or merely due to the monitoring methods. For the integration of the monitoring systems in the various Member States it is essential to ensure similar quality standards, and to distinguish effects of a GM plant from effects of different environments and management programmes. The standardisation of national monitoring programmes across the Member States is a challenge and may not be practicable. Methods might well differ depending on the specific environment of the GM plant cultivation areas of certain EU Member States.

As stated in section 3.4.1.2 of this opinion, existing networks should be used in general surveillance where compatible. Many of these networks such as European biodiversity monitoring programmes are mainly focused on protected habitats or species (*e.g.* birds). They have little common language (scope, location, methodology) and systems are site-specific. In addition, there is little environmental monitoring of unprotected parts of landscapes (referring to Directive 2004/35/EC, EC, 2004) and very few long-term (>10 years) monitoring programmes. However, in Europe, a large part of the biodiversity of plants and animals is in unprotected parts of the landscape. General surveillance plans would benefit if applicants could make use of relevant environmental monitoring networks conducted by Member States in unprotected parts of the landscape. The use of these national monitoring programmes is outside the management and control of an individual applicant and thus it cannot be the task of an applicant alone to use, modify or improve existing surveillance systems. Thus the GMO Panel is of the opinion that it would be valuable if Member States would improve or adapt existing national environmental monitoring systems and implement additional monitoring and inspection as described in recital 44 of Directive 2001/18/EC. Where such additional national surveillance networks are in place, the applicant should be aware of relevant surveys in areas where the GM plants will be grown and should get in contact with the relevant Member States to have access to such data.

5.4 Use of GMO cultivation registers

According to Article 31 (3b) of Directive 2001/18/EC (EC, 2001), Member States shall establish public registers for recording the cultivation of GM plants. These registers will provide useful geographical information for PMEM as well as for additional monitoring programmes of Member States (see section 3.4.4. of this opinion). Applicants should consider the integration of such registers into the monitoring plan.

5.5 Data reporting and analyses

It is essential that all monitoring data (including those from new monitoring systems) are analysed and reported, even though evaluation of the usefulness of data from existing monitoring programmes is a demanding task. Initially, monitoring will focus on each

transformation event individually. However, when several GM plants have been commercialised, the interactions between these GM plants (*e.g.* their management regimes at the farm level) should be examined where appropriate. A mechanism will need to be found for considering the interaction of several different GM plants cultivated in regions but subject to different applications. The EFSA GMO Panel is of the opinion that in such cases, the national competent authorities have an important role in establishing liaison with several 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 EU to take decisions on the level of cultivation of a GM crop, either within a specific biogeographical region or across the whole of Europe. In order to reach these decisions the appropriate data and analyses need to be available for scrutiny at both Member States and EU level.

5.6 Systems for data reporting and analyses

The EFSA GMO Panel recommends that in Member States where GM plants are cultivated or imported, the existing systems for data reporting and analyses are developed further to facilitate the collection, collation, and analysis of data from PMEM studies. These systems could be developed in Member States, or in groups of countries with similar biogeographical conditions. The data reporting and analyses systems should particularly focus on examining data on unanticipated effects due to the cultivation of different GM plants. The GMO Panel is of the opinion that it would be useful if, in addition to the systems implemented at national level by Member States, a reporting and scientific analysis mechanism is developed by risk managers at the EU level.

5.7 International Harmonisation of PMEM

The EFSA GMO Panel considers that it is important that the European Commission, Member States and EFSA should be involved in discussions on environmental post market monitoring of GM plants being developed by international organisations, in order to promote harmonisation and integration of approaches. For example international initiatives such as the Pilot Monitoring Projects for collection, management and reporting of field data being developed by FAO should be followed carefully (FAO, 2005).

6. Conclusions and recommendations

6.1. Conclusions

Case-specific monitoring is designed to study potential risks and uncertainties identified in the environmental risk assessment. These potential risks should be monitored for their frequency and impacts using the general approaches and reporting methods described in the EFSA Guidance Document.

General surveillance is a general overseeing of the biogeographical regions where GM plants are grown without having any specific hypothesis on adverse effects on human health and the environment. General surveillance does not imply testing for specific assumptions, mechanistic causes or specific risks. Distinct from case-specific monitoring, general surveillance is not necessarily crop or trait specific as it implies a generic approach to determining any unanticipated adverse effect of a GM plant and its use that was not associated with characteristics of the plant during the risk assessment. However general surveillance should complement and not replace general environmental monitoring conducted by Member States.

General surveillance starts by identifying areas where exposure is greatest and where harm is most likely to be detected. Primarily, applicants will consider general surveillance in the places

where the GM crop is being grown and monitor for any adverse effects of its cultivation at the farm level. Data collected from different farms can be analysed for large-scale patterns and trends considering large-scale effects of GM plants in the agricultural landscapes. Therefore, a specific emphasis should be placed on establishing farm questionnaires to monitor any adverse impacts at farm level.

The use of baselines and/or reference values is essential for a scientifically sound approach. Selection of the baselines used for monitoring the release of GM plants into the environment should reflect current trends in cultivation of plants and management of land, and should not be fixed in time or space. Also "historical knowledge" of crop cultivation can provide an important baseline or reference. General surveillance needs to be implemented on a broad scale with low intensity.

General surveillance for adverse impacts of GM plants at complex regional and/or national levels may be beyond the applicant's direct capability. Increasing complexity and interaction of GM plant use with other land management systems should be studied in other ways. Utilising existing surveillance systems established by land-use and environmental organisations is a potential approach to increase the scope of the general surveillance. This approach would have the advantage of collecting information related to the combined effects of GM plants in a region as well in general surveillance based on single applications. Utilising other environmental monitoring programmes will allow higher ecological integration of data and use of their established base lines and trends.

The occurrence of GM plant, as well as recombinant DNA, is not an adverse effect *per se.* Intensive screening of the occurrence of GM plants and their recombinant DNA in the environment would overburden monitoring by handling data without clear relevance for the detection of adverse GM plant effects. The methods and approaches applied should be appropriate, proportional and cost-effective to allow for the detection of adverse effects resulting from the placing on the market of GM plants.

6.2 Recommendations

EFSA makes the following recommendations in relation to applications for the marketing of GM plants:

(1) Applicants should use the updated approaches to PMEM described in the EFSA Guidance Document (EFSA, 2005f) and in this EFSA PMEM opinion.

(2) Potential risks and uncertainties identified in the environmental risk assessment, such as risks due to large-scale or long-term exposure are subject to case-specific monitoring. These potential risks should be monitored for their frequency and impacts using the general approaches and reporting methods described in the EFSA Guidance Document.

(3) General surveillance should be a general vigilance programme designed to observe unanticipated adverse effects using both exisiting national surveillance programmes and monitoring measures that focus on the cultivation of the GM plant.

In additional, the EFSA GMO Panel developed the following recommendations which are outside the scope of the EFSA Guidance Document, but will enhance the conduct of post market environmental monitoring:

(4) Risk managers in Member States should guide applicants in the selection of appropriate existing monitoring systems and in developing systems which may provide

useful data in their country/region and in selecting existing surveillance systems as described in the EFSA Guidance Document and in this opinion.

(5) A mechanism should be established for considering the interactions of several different GM plants subject to different applications. The EFSA GMO Panel proposes that national Competent Authorities should establish liaison with different applicants in order to coordinate data collection and analysis from different monitoring programmes.

(6) Mechanisms should be developed by risk managers for reporting and collating monitoring data both at MS and EU level. This will facilitate scientific analysis of these data and provide scientific conclusions for informing decisions on the future cultivation of GM crops as well as future risk assessments.

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