

Monitoring Working Group Report

on the

Environmental monitoring of GMOs

General Surveillance (GS)

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1 Introduction

A monitoring plan of genetically modified (GM) plants is mandatory in all applications for deliberate release submitted under Directive 2001/18/EC and Regulation (EC) 1829/2003.

Council Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC¹ describes the objectives and general principles to be followed when designing the monitoring plan.

In the Council Decision 2002/811/EC monitoring is defined “...as the systematic measurement of variables and processes over time...” and it “...assumes that there are specific reasons for collection of such data, for example, to ensure that certain standards or conditions are being met or to examine potential changes with respect to certain baselines.” As indicated in Council Decision 2002/811/EC, monitoring should serve as an early warning system in order to allow a “more rapid reassessment and implementation of measures to reduce any consequences to the environment”.

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. Therefore in this document more elaboration of the details is given respectively discussed.

2 Scope of General Surveillance

The objective of Case Specific Monitoring (CSM) is “to confirm that any assumption regarding the occurrence of potential adverse effects of the GMO or its use in the

¹ Council Decision 2002/811/EC of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

e.r.a. are correct”, whereas the objective of GS is “to identify the occurrence of adverse effects of the GMO or its use on human health and the environment which were not anticipated in the environmental risk assessment (ERA)” (Annex VII of Directive 2001/18/EC).

Council Decision 2002/811/EC further specifies that in contrast to CSM, the focus of GS is on unanticipated “indirect, delayed and / or on cumulative adverse effects” and that “GS should be carried out over a longer time period and possibly a wider area”. The focus of GS should include the unanticipated influence of the GMO on and interactions of the GMO with all possibly affected organisms and ecosystems including; “*effects on ecological functions; dispersal, establishment and persistence of GMOs in non-target environments or ecosystems; out-crossing with wild relatives in natural populations; unintended changes in the basic behaviour of the organisms and changes in biodiversity*”.

2.1 Delineation of CSM and GS

Directive 2001/18/EC and Council Decision 2002/18/EC provide very general definitions of CSM and GS. This leaves room for interpretation.

Some experts understand that in the EFSA guidelines for risk assessment² these definitions are more narrowly interpreted as follows: Potential effects that have been clearly identified in the ERA as a risk should be monitored under CSM; while under GS only absolutely unanticipated adverse effects should be monitored. Some experts consider that it is important to be aware that potential hazards for the environment may have been identified, but their risk is hard to predict due to lack of scientific understanding or lack of appropriate methods for measurement and detection. This represents a grey border area that is not covered using this narrow interpretation.

² EFSA (2006) Guidance Document of the Scientific Panel on genetically modified organisms for the Risk Assessment of genetically modified plants and derived food and feed. May 2006.

Other experts understand that the EFSA guideline specifies the definitions as follows: There is no clear borderline between risk assessment and risk management in relation to monitoring. 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. General surveillance is an overseeing strategy to identify the occurrence 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.

In its Guidance Note³ the British Advisory Committee on Releases to the Environment (ACRE) have introduced an additional category; adverse effects representing a grey border area between CSM and GS that is not specified by the EFSA interpretation:

Category I: *Anticipated effects.* Potential risks in the ERA as worthy of investigation via case-specific monitoring as well as those assessed as being extremely unlikely to occur and to cause harm.

Category II: *Interactive or cumulative effects that are difficult or impossible to predict.* Potential effects that are difficult to predict or assess fully in a single dossier and its risk assessment. E.g. effects that might arise as a result of an increase in the scale of cultivation and potential effects arising as a result of interaction between the GM crop and future varieties (GM and non-GM) that are released.

³ ACRE (2004) Guidance on Best Practice in the Design of Post-market monitoring plans in submissions to the Advisory Committee on Releases to the Environment. Department for Environment, Food and Rural Affairs: London. Guidance Note 16. http://www.defra.gov.uk/environment/acre/postmarket/acre_postmarketmonitor-draft.pdf

Category III: Unanticipated effects. Complete unknowns, i.e. potential effects not identified in the ERA, which can only be addressed by GS. Within the three categories, there is a gradual differentiation in the predictability of effects. Effects covered under category I are anticipated and therefore fall under CSM, those under category III are unanticipated and therefore fall under GS, but effects covered under category II can either fall under CSM, GS or under both simultaneously. Effects of category II falling within the scope of GS should be monitored using the CSM approach. This has to be decided on a case-by-case basis. *“Together, the potential effects of scale and time may be considered as the cumulative effects of the release of that particular GM crop. In certain situations it will be appropriate to consider cumulative effects case-specifically, whereas in others, general monitoring might be more suitable. In either case, the applicant should explain why a particular monitoring strategy has been chosen.”* ACRE 2004 Some experts consider that the border area between CSM and GS in general should be flexibly handled and, in case of doubt, should be reconsidered. Various criteria might be considered to support such a decision. E.g. the kind of effect, which should be monitored; the kind of indicator; the scale of monitoring; or the kind of protection objects, that are chosen. The criteria for monitoring need to be elaborated on a case by case basis.

3. Unanticipated effects; scope and types

In general, it is possible to distinguish between two different categories / types of unanticipated adverse effects:

- Those which have not been identified in the risk assessment of an individual GMO notification and are completely unanticipated, and
- Those for which the nature of possible change is more or less predictable, for example cumulative effects from increasing the scale of cultivation in a wide area and for a long time period or by releasing different types of GMOs with the same transgenes (e.g. herbicide tolerance or different Bt-toxins).

Within MGW it is generally accepted, that it would not be possible to monitor for all possible effects in all compartments and at all levels in the environment. The challenge is to identify a number of key environmental indicators and parameters that are appropriate to address the requirements of GS. Within the MGW there are different opinions on the scope and types of monitoring that is need to be carried out under GS.

1. Some members of the working group think that GS should focus on completely unanticipated effects. Monitoring those “unforeseen” effects leads to the approach where the parameters need to be selected without any relation to the GMO and / or its trait and the intended use. In this case it is proposed to define specific safeguard subjects or to link GS to the chosen environmental protection goals for biodiversity, water and soil and to monitor indicators representing these safeguard subjects,

thereby using already existing monitoring programs. The decision on which safeguard subjects will be monitored will be with the individual member states. Some members of the working group suggest linking the safeguard subjects for GS to “environmental damage” as defined in Directive 2004/35/ of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage. However, other members of the working group consider this Directive less suitable, as it is only marginally relevant for GMOs and is considered to be too narrow with respect to the definition of environmental damage and the safeguard subjects it takes into consideration. Specifically, it only acknowledges damage to sites protected under the Flora-Fauna-Habitat- and Birds-Directive but does not explicitly consider other protection goals. Protection also depends on how the Directive is transferred into national laws that may lead to different interpretations of environmental damage in different EU member states. However, this approach has not yet been discussed within the working group and the applicability of this Directive for GS of GMOs has not been evaluated.

2. Some members of the MWG think that GS should, besides a general unfocused observation (as suggested under point 1), which covers a range of indicators demonstrating the state and trends of the environment where the GMO is grown or released, also include more specific parameters related to the GMO/trait and the scope of its use since this will lead to a more meaningful and focused monitoring. For instance pathways by which a GM crop might impact on the environment should be considered when identifying indicators and parameters for GS. Such parameters for GS may also be derived from the assumptions formulated in the ERA.

3. Some members are of the opinion that GS should also consider effects that are identified but difficult to predict, e.g. interactive or cumulative effects, that is the effects of category II of ACRE. The frequency or the occurrence of a certain effect may be unknown while the possible adverse effect itself can be clearly determined. In other cases, the occurrence of an effect may be foreseen but the adverse consequences are undetermined. Furthermore, an unanticipated effect can also be an effect for which the likelihood of occurrence or the extents of the effect were incorrectly assessed in the ERA.

4. Other experts consider unanticipated effects as effects that were not anticipated in the risk assessment. Thus a specific risk cannot be identified and no hypothesis can be tested and it is difficult to propose specific methods to carry out GS. They consider GS as a “general overseeing strategy of geographical regions where GM plants are grown without having any specific hypothesis on adverse effects. The identification of an adverse effect that is potentially linked to specific GM plants would trigger the need for a specific study to evaluate harm and determine the cause. Some experts even consider that “complete unknowns” should not be monitored as the choice of parameters, sites, times and methods for their monitoring are impossible.

Dispersal, establishment and persistence of GMOs and GMO-products

Certain GMOs introduced into the environment by their placing on the market can disperse and persist in the environment in an uncontrolled manner. They may harbour a potential for adverse environmental impacts.

Some experts of the MWG consider the presence of a GMO as such as a risk indicator even if an adverse effect has not yet been identified. Therefore some experts of the MWG consider that the dispersal, establishment and persistence of GMOs into target, non-target environments or other ecosystems are an important component of GS.

Other experts of the MWG think that the establishment, persistence and spread of a GM plant are not an environmental hazard in itself. Also they consider the dispersal of pollen or seeds and gene flow per se not as environmental hazards. In their opinion the focus of GS 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.

Further experts consider that the dispersal, persistence and accumulation of GMOs, transgenes (e.g. by vertical gene flow to wild relatives) or GMO-products (e.g. Bt-toxin) into the environment harbour the potential for adverse effects. Therefore, monitoring the “exposition” of GMOs or its products is a key element of GS.

Some experts are of the opinion that - because of its ecological importance - vertical gene flow from GMOs to wild relatives should be covered either by CSM or by GS. If a potential for gene transfer to sexually compatible species is identified in ERA this should be monitored by CSM. Therefore, all potential hybrid partners and their regional occurrence need to be known.

Transgenes or GMO-products (e.g. toxins) released e.g. by decomposition processes, can also persist and accumulate in e.g. soil or aquatic sediments over long periods. The persistence and accumulation of transgenes or GMO-products in environmental media may give rise to cumulative or unforeseen environmental impacts. Thus some experts are of the opinion that monitoring of transgenes need also to be covered by GS.

3.2 The role of hypothesis and experiments within GS

The question whether the selection of parameters for GS should be “hypothesis-based” or “hypothesis-free”, as well as the question whether the selection of indicators should be unspecific or related to the GMO/trait and the scope of application of the product, remains a point of discussion.

Some experts think that all monitoring should start with theories and assumptions concerning final effects or at least types of effects and that this is also true for unanticipated effects.

Some experts also suggest that monitoring plans can be designed so that key parameters are monitored. These are parameters that must be altered if a risk “downstreams” is realized (for instance if unanticipated spread of a GM plant happens - unanticipated effects on other organisms may arise). Accordingly, monitoring plans need to have some flexibility so that additional monitoring is initiated as a response to the detection of unanticipated effects on key parameters.

Furthermore, some experts are of the opinion that in GS directed studies with an experimental set up shall be carried out. This is because unfocused monitoring of unanticipated effects will result in qualitative data rather than quantitative data. GS does not have to be unfocused by definition. A focused approach, which means the investigation of a certain factor for which no risk is identified, should be used; especially for studies initiated for complementing other studies but also to some extent to broaden surveillance.

Other experts are of the opinion that only possible risks identified in the environmental risk assessment should be studied in hypothesis-driven experiments and tests. 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.

4 Implementation of GS

4.1 Parameters and elements of monitoring

As stated in Council Decision 2002/811/EC (point 1.3.2) *“The type of general surveillance, including locations, areas and any parameters to be measured, will largely depend on the type of unanticipated adverse effect is being surveyed. For example any unanticipated adverse effects on the cultivated ecosystem such as changes in bio-diversity, cumulative environmental impacts from multiple release and interaction may require a different approach to GS of other effects arising from gene transfer...”* In general, indicators have to be chosen carefully taking into account characteristics of the GM crop, exposure, protection subjects and protection goals. It has to be taken into account that regional differences within the EU make it virtually impossible to select EU-wide applicable indicators, particularly indicator species due to different environmental and climatic conditions. The selection should be made in agreement with national authorities (subsidiary principle). The approach to do this is controversially debated not only in the Working Group but also in other fora. Especially the question whether the selection of parameters for GS should be “hypothesis-based” or “hypothesis-free”, as well as the question whether the selection of indicators should be unspecific or related to the GMO/trait and the scope of application of the product, is still under discussion.

4.2 Duration of monitoring

Adverse impacts of GMOs on the environment may take many years to become manifest. Therefore, GS should be carried out over a sufficiently long time in order to detect not only indirect effects but also delayed, cumulative and long term effects.

According to Council Decision 2002/811/EC (point 1.5) it should also be considered whether it is necessary to extend the monitoring plan beyond the period of the consent. In any case, a proposal for the time-period of the monitoring plan that may be different from the proposed period for the consent must be attached to the notification (Directive 2001/18/EC, Art. 13, 2 e). The time period of the monitoring plan will explicitly be specified in the written consent (Directive 2001/18/EC, Art. 19).

The duration of GS may depend on:

- A specific GMO and/or the release of other GMOs in a specific area
- The scale of release of a specific GMO/several GMOs
- The GS objectives:
 - The type of indicators (e.g. butterflies, soil quality etc.)
 - The parameters to be monitored (e.g. abundance etc.)
 - The defined effect sizes of the parameters chosen
- The monitoring interval of networks involved in GS

GS should be carried out over a sufficiently long time in order to detect not only immediate effects but also delayed, cumulative and long term effects. However, practicality and proportionality of the monitoring has to be taken into account. The monitoring period should be reviewed periodically and adapted to the results obtained.

4.3 Monitoring area of GS

According to Council Decision 2002/811/EC (point 2.2) *any reference or control areas must be sufficiently representative in the terms of the environment and conditions of use*. Areas monitored under GS can include selected agricultural fields cultivated with GMOs, neighbouring cultivated and non-cultivated areas, post-harvest areas, surrounding habitats or protected areas (Council Decision 2002/811/EC, point 2.2.). For some crops it might be necessary to focus on certain habitat types which are more prone to invasion than others, such as disturbed areas and species-rich communities (Council Decision 2002/811/EC, point 2.2.)

The area where effects are most likely to become manifest may depend on the GMO involved and its characteristics such as reproduction, persistence and dissemination.

Apart from the GMO and its characteristics the following criteria might be applied in order to choose monitoring areas for GS:

- Agricultural/non-agricultural areas
- Proximity to crop production areas/GMO cultivation
- Intensity of GMO cultivation
- Linkage with crop production areas (e.g. via transport routes)
- Sensitivity towards establishment of GMOs (e.g. disturbed habitats)
- Sensitivity towards environmental changes/protected areas
- Overlap with monitoring sites of existing programs

The suitable monitoring area for GS is not settled among the MGW.

Some experts are of the opinion that in general appropriate monitoring areas should be chosen in consideration of the biogeographic variation, the wide variety of different climatic conditions in Europe as well as the different land use forms and management practices in the Member States.

Furthermore, some experts suggest that GS should cover a selected but wide geographic area, while others suggest a more targeted and systematic selection of suitable monitoring areas; further experts suggest that GS should cover an area based on the theory of plausible effects from the particular GMO.

These differences among the MGW has implications for the choice of strategy for monitoring. For instance GS covering a wide geographic area implies a general observation of the environment and requires a representative nationwide selection of appropriate monitoring areas. While selection of suitable monitoring areas ("e.g. monitoring hot spots") and monitoring of more specific parameters related to the GMO/trait and the scope of its use, other additional criteria regarding monitoring areas need to be taken into account.

Monitoring hot spots would constitute a selection of areas which are supposed to be particularly sensitive to environmental changes and/or which harbour a biodiversity or protection entities that need to be protected (Traxler et al. 2005⁴). This approach would limit the resources needed for nationwide and EU-wide implementation of GS. However, depending on the level of the safeguard subjects the question of how to select the appropriate indicators may stay the same. For the protection goal “biodiversity” for instance, indicators and parameters still have to be defined and selected. In contrast protection goals for nature conservation purposes are more concrete and encompass for example protected species or habitats.

Some experts consider the need for the establishment of reference areas which are used for comparison purposes and represent a baseline without GMP cultivation if no other baselines (e.g. time baseline) are available (see also Chapter 4.3. Baselines).

4.4 Baselines

According to Council Decision 2002/811/EC (point 1.4) the “determination of the baseline status of the receiving environment is a pre-requisite for the identification and evaluation of changes observed via monitoring. Baseline serves as a point of reference against which any effects arising from the placing on the market of a GMO can be compared. This baseline should, therefore, be determined prior to attempting to detect and monitor any such effects. Parallel monitoring of ‘GMO-areas’ and comparable ‘non-GMO reference areas’ may provide an alternative and may be important where environments are highly dynamic”.

According to the Council Decision this baseline status does not only refer to the environment but also to possible changes in management practice resulting from the use of GMOs, such as changes in pesticide usage, e. g. when cultivating herbicide tolerant or insect resistant GM crops (Council Decision 2002/811/EC point 1.4).

⁴ Traxler et al. (2005). Biodiversitäts-Hotspots der Agrarlandschaft als Eckpfeiler für Risikoabschätzung und Monitoring von GVO. Forschungsbericht 5/2005, BMGF, Sektion IV. www.gentechnik.gv.at.

When establishing a baseline status the natural variation should be taken into account.

For the identification and evaluation of changes that are observed during monitoring, it is for some experts necessary to determine the baseline status of the receiving environment or certain management practices before potential effects caused by GMO cultivation are monitored. As an alternative to comparison in time, comparisons with appropriate reference areas should be considered where feasible. It should be taken into account that baselines may differ depending on the geographical region.

For some experts the time period and the replication of baseline observations will depend on the selected monitoring parameter. For example, the replication and time period necessary for baseline evaluations of vegetation or plants will be different from those of non-target animals (e.g. Lepidoptera). Ideally, baseline observations should be undertaken over an extended period of time.

For some experts, 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.

It is a controversial issue among the MWG members whether the experience of a certain observer in agricultural areas, e.g. the farmer, can also represent a baseline in agricultural areas. Some experts consider that depending on the experience of the observer, there might be an obligation to seek further baseline data prior to the release of the GMO for a limited period of time. Other experts consider this approach as not sufficient and emphasize the need for sound scientific methods for the collection of baseline data.

Baseline data may be provided from existing monitoring programmes or may be established specifically for the purpose of comparison with GMO monitoring results. Criteria for establishing baseline data may be:

- Crop-specific characteristics and the GM traits of GMOs cultivated in a certain area including the potential for interactive/cumulative adverse effects).
- Indicators and parameters chosen for observation
- Type of environment (highly dynamic versus stable)
- Availability of existing programs to be used
- Suitability of existing programs with respect to parameters monitored, time period and frequency/sample size (see also Chapter on existing monitoring programs)

- Availability of reference areas (non-GMO areas)

4.5 Methods

4.4.1 Choice of methods

According to Council Decision 2002/811/EC (point 2.4) the methodology to monitor indicators and parameters/elements should be clearly identified and outlined by the applicant, including techniques for sampling and analysis. “Standard methodology, such as the European CEN Standards and OECD-methods for monitoring organisms in the environment should be followed where appropriate”. “Standardisation ensures the compliance with fundamental quality criteria such as correctness, comparability and reproducibility” (VDI 4330 Part 1⁵). It would be desirable, if monitoring data from different regions or EU Member States would be comparable and open to evaluation. Therefore, preferably standardised methods should be applied wherever appropriate. If standardised scientific methods are not available, existing methods corresponding to the state of the art should be used if possible. Moreover, concerted methodologies should provide a framework for the comparison of different approaches and the application of specific methods. In case of increased scientific understanding or new GM specific questions new methods might be required. Thus, the development of new methods as well as their standardisation is necessary. Scientific progress should appropriately be considered in the development of new methodologies.

Some experts stated that in general when one is performing monitoring research that involves testing of hypotheses one needs to identify a reasonable degree of power in addition to specifying significance. It is important to be careful in avoiding Type-II errors (false negative, failure to reject the null hypothesis). Especially, since the null hypothesis that is tested is often: there are no adverse effects by GMO use and release. For instance the UK Farm Scale Evaluations (FSE) were designed to test

⁵ VDI 4330 Part 1 (2006): Monitoring the ecological effects of genetically modified organisms. Genetically modified plants. Basic principles and strategies.

the null hypothesis; that for each crop, the effect on the abundance and diversity of wildlife of the management of the GM crop does not differ from the effect of the management of conventional agriculture. This entails a shift from the traditionally focus on protection against Type-I errors (false positive rejection of the null hypothesis), where hypothesis testing usually operates on the basis of limiting Type-I errors. Hence, in monitoring strategies, standards and burden of proof have to be differentiated from those used in fields where there are high certainty and high consensus among scientists. In these circumstances reliability depends on statistical power. Statistical power refers to the probability of correctly rejecting the null hypothesis, i.e. statistically detecting an effect if it exists. Poorly designed monitoring programs usually do not have sufficient power to detect changes. Power analysis may also help research planning (give indications of sample size and duration of project) and contribute to clarifying the interpretation of the results.

Other experts are of the opinion that the FSE were not 'monitoring' as such but rather basic research experiments. The experimental approach used in FSE has some merits for case-specific monitoring but no relevance for GS. They consider in general 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. 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.

4.5.2 Use of existing environmental monitoring programs

According to Directive 2001/18/EC and Council Decision 2002/811/EC 1.3.2, "GS could, where compatible, make use of established routine surveillance practices such as monitoring of agricultural crops and plant protection (...) products, as well as ecological monitoring, environmental observation and nature conservation programs."

Some experts are of the opinion that if consent holders intend to use existing programs for GS, at first the following questions have to be answered:

- Which indicators and parameters need to be covered by GS?
- Which existing programs are suitable to monitor these indicators?
- In case gaps are identified, how to close them?

Other experts are of the opinion that applicants should first define protection goals to be addressed within general surveillance. Then applicants should evaluate which 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 can be integrated within the GS.

In this context, the main communalities between GMO-monitoring and established monitoring programs and surveys have to be identified and established, in terms of content, organisation and structure.

With regard to contents and scope, links between existing programs and GS are possible if a. o. the programs:

- Cover the environmental media that are relevant to GS (biota, air, soil, water bodies).
- Monitor appropriate indicators and parameters that are relevant to GS.
- Enable amendments to extend the set of indicators/parameters and target species covered by the existing program (in case gaps are identified).
- Cover geographic areas that are relevant to GS (or an extension of the monitoring area is possible).
- It is possible to compile and evaluate the data obtained through existing programs in such a way that the various indicators of GS are covered (quality assessment of the usefulness of datasets).

With regard to organisation and structure, links between existing programs and GMO monitoring are more efficient if the program enable:

- Long-term environmental monitoring can be secured and the monitoring is performed at intervals that are relevant to GS.
- Access to raw data for further analyses
- Combination of sampling activities of existing programs with GMO monitoring
- The use of monitoring sites of existing programs as monitoring sites or as reference sites for GMO monitoring.

Knowing the limitations of existing monitoring systems, the applicant is requested 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:

1. Describe which general observations could be monitored through existing monitoring schemes,
2. 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),

3. Describe the criteria and generic approach used to evaluate existing monitoring networks and how appropriate networks will be selected,
4. Describe how arrangements for collecting, collating and analysing data will be made,
5. 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,
6. 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.

To get an overview of existing programs in the Member States, the Commission conducted a query asking the Member States' competent authorities to provide information on existing national environmental monitoring programs suitable for GS of GMOs. In 2005/2006, several Member States responded. The answers differ over a wide range concerning the degree of details given and also with respect to the kind of programs that are run in different Member States. There are clear differences between Member States and even sometimes between provinces in individual Member States regarding existing environmental monitoring programs (see Annex 1). Several Member States are running nationwide environmental monitoring programs, which are potentially suitable for GMO monitoring. There are also a lot of regional or federal monitoring programs. Many of these programs are heterogeneous and not harmonised at national level. Existing programs often rely on observations by volunteers. In addition, the spatial and temporal scales at which data are being collected vary greatly between the programs.

In several Member States existing environmental monitoring programs are not or rarely addressing agro-ecosystems. On the other hand, the potential non-target effects of GMO cultivation would probably affect organisms whose habitat either is an agricultural area or is somewhat related to it. Thus, existing monitoring programs would not cover areas of clear importance for GMO monitoring and hence no baseline data would be available. Therefore, it may be necessary to redirect or expand existing environmental monitoring programs or to establish new programs, which cover agro-ecosystems. This should be based on the principle of proportionality.

Only in few Member States specific programs for the monitoring of biodiversity are already implemented on a national level, none is established on the European Union level. So far the current environmental programs meet several but not all monitoring objectives and tasks of GS.

Some experts are of the opinion that many of the existing monitoring systems and networks collecting environmental data are unlikely to provide data of relevance that may be used in monitoring impacts of GMO. 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. For example some of the expert's note that a large part of the existing monitoring programs do not overlook effects in agro-ecosystems. As mentioned above, the existing monitoring systems 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. There may be a need for additional environmental surveys and to amend the monitoring objectives of existing monitoring systems GS can make use of existing environmental programs but currently not all objectives can be covered by these programs alone.

Other experts are of the opinion that currently, there is no monitoring program that could identify the occurrence of potential effects that were not anticipated in the Environmental Risk Assessment and therefore would be suited for GS. Some of the existing monitoring programmes could provide supplementary information, but the GS of GMO has to be designed and implemented independently.

Also EFSA states that "In addition to using existing monitoring systems, applicants are encouraged to develop new and more focused monitoring systems especially at the production level" (EFSA 2006). One example stated by EFSA is farmer questionnaires (see Chapter 4.4.3).

Other experts are of the opinion that existing environmental programs can fulfil a substantial role within the GS objectives as 'look-see' approach.

In general, the value of existing environmental programs for GS is likely to be different for certain GMO/trait combinations and the scope of their use.

Some experts are of the opinion that further specification of indicators and parameters for GS would be needed to allow for a more detailed evaluation of existing programs with respect to their suitability for GS. Other experts consider that specification of indicators for relevant GS objectives is one of the first steps to identify appropriate existing programs.

In this context, Member States should be aware of the need to compile their existing national or regional environmental programs and evaluate their possible suitability for general surveillance of GMOs. Some experts are of the opinion that 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.

To ensure that applicants and competent authorities become aware of suitable programs within the different Member States, it would be useful to establish an EU-

wide information tool (e.g. internet portal). An information tool like an internet portal would be especially valuable since it will neither be possible to design a programme covering all possible effects nor link all existing programmes together. Thus, the need to associate and make use of information gained in different programmes will increase (see also Document on Data Harmonization)

4.4.3 Farmer questionnaires

Notifiers currently submit Farmer questionnaires as a tool for GS to gain information about on-farm effects by farmers.

Some experts are of the opinion that this approach considers almost exclusively qualitative data on agronomic issues like occurrence of pests, application of pesticides or the occurrence of weeds. These questionnaires will provide useful feedback to the consent holder for commercial and development purposes. However, Farmer questionnaires are not appropriate to monitor environmental effects on farm level respectively in the surrounding of GM crop fields or on regional level. On one hand, relevant environmental indicators and parameters are not addressed; on the other hand quantitative, high quality data are not included and therefore scientifically sound analysis are not possible. In order to obtain quality data from farmer questionnaires, special arrangements must be made. Moreover, although farmers have detailed knowledge of their land, they are not educated to collect scientific data with scientific methods. These experts are of the opinion that therefore, the key elements of GS have to be scientifically sound observations methods and surveys; in addition Farmer questionnaires could be a useful tool to complement the GS.

Other experts are of the opinion that 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 GMO and for comparing it with conventional plants (EFSA 2006). 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. For these experts, farm questionnaires are a scientifically sound methodology that fulfils key elements of GS.

5 Further assessments

Directive 2001/18/EC and Council Decision 2002/811/EC emphasize the need for further assessments where changes in the environment are observed to establish whether they are a consequence of the GMO or its use, as such changes may be a result of environmental factors other than the placing of the GMO on the market.

EFSA addresses this issue in its guidelines (EFSA 2006) and postulates in-depth studies in order to determine the underlying cause and a possible relationship with GM plants if unusual effects are reported.

Although it is clear that further studies including research is needed to identify causal chains and possible causal links to GMO cultivation after detecting unusual environmental effects, some experts are of the opinion that it still has to be decided which level of observed changes will trigger such further experimental studies. Furthermore it is still unclear, who will be responsible for in-depth studies, in general and when the approved marketing period has expired. Some experts are of the opinion that – due to the nature of unanticipated effects – decisions can realistically only triggered on a case by case basis.

In this context it has to be emphasized that particularly cumulative and long term effects as well as unanticipated effects may occur after the approved marketing period of a certain GMO or several GMOs has expired. Therefore it may become difficult to link observed long term effects to the presence of a specific GMO or several GMOs which were grown in previous years. Thus it might be useful to systematically collect and store information of cultivated GMOs and possibly also samples of GM cultivars at a national level in order to be able to conduct directed studies after the consent period of a certain GMO has expired. Directive 2001/18/EC already foresees in the prescription of the development of part C cultivation registers. Some member states already established such registers; they are an important tool in this context.

6 Final comments

The discussion in this document has the function of guidance and input into the construction of monitoring plans. The monitoring plan for a specific case must be designed taking into account the case specific factors and the questions that need to be answered.