COUNCIL DECISION

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

(2002/811/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC of the European Parliament and of the Council [1], and in particular the first paragraph of Annex VII thereto,

Having regard to the proposal from the Commission,

Whereas:

(1) Directive 2001/18/EC stipulates that, before a genetically modified organism (hereinafter referred to as GMO) as or in products is placed on the market, a notification must be submitted to the competent authority of the Member State where such a GMO is to be placed on the market for the first time.

(2) According to Directive 2001/18/EC, the notifier must ensure that monitoring and reporting on the deliberate release of GMOs are carried out in accordance with the conditions specified in the authorisation for the placing on the market of a GMO pursuant to Article 13(2), Article 19(3) and Article 20 of that Directive. Therefore, such notification must contain a plan for monitoring, including a proposal for the time-period of the monitoring plan, in accordance with Annex VII to Directive 2001/18/EC.

(3) Annex VII to Directive 2001/18/EC should be supplemented by notes providing detailed guidance on the objectives, general principles and design of the monitoring plan referred to in that Annex.

(4) The committee set up under Article 30(2) of Directive 2001/18/EC was consulted on 12 June 2002 and has not delivered an opinion on the Commission's proposal for a Decision,

HAS ADOPTED THIS DECISION:

Article 1

The guidance notes set out in the Annex to this Decision shall be used as a supplement to Annex VII of Directive 2001/18/EC.

Article 2

This Decision is addressed to the Member States.

Done at Luxembourg, 3 October 2002.

For the Council

The President

F. HANSEN

[1] OJ L 106, 17.4.2001, p. 1.

ANNEX

INTRODUCTION

Directive 2001/18/EC introduces an obligation for notifiers to implement monitoring plans in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market.

Notifiers are required, under Article 13(2)(e) of that Directive, to submit as part of the notification for the placing on the market of a GMO, a plan for monitoring in accordance with Annex VII of that Directive. This should include a proposal for the time-period of the monitoring plan, which may be different from the proposed period for the consent. Annex VII describes in general terms the objective to be achieved and the general principles to be followed to design a monitoring plan referred to in Article 13(2), Article 19(3) and Article 20.

This guidance note supplements the information provided in Annex VII, and in the context of the Directive:

— expands on the objectives for monitoring,

— expands on the general principles for monitoring,

— provides an outline for a general framework for the development of appropriate post-market monitoring plans.

Following the placing on the market of a GMO, the notifier, under Article 20(1) of the Directive, has a legal obligation to ensure that monitoring and reporting are carried out according to the conditions specified in the consent. Article 19(3)(f) details that the written consent should, in all cases, explicitly specify monitoring requirements in accordance with Annex VII, including obligations to report to the Commission and competent authorities. In addition, to ensure transparency in accordance with Article 20(4), the results of the monitoring should also be made publicly available.

Monitoring plans for GMOs to be placed on the market will clearly need to be developed on a case by case basis taking account of the environmental risk assessment, the modified characteristics specific to the GMO in question, their intended use and the receiving environment. This guidance note makes reference to a general framework but does not attempt to provide explicit details for the development of monitoring plans to cover all GMOs.

It might be necessary to complement this framework with more specific, supplementary guidance on monitoring plans or checklists with regard to particular traits, crops or groups of GMOs.

Monitoring can be defined, in general as the systematic measurement of variables and processes over time and 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. Against this background, it is essential to identify the type of effects or variables to be monitoring and importantly, the tools and systems to measure them and an appropriate time-period for measurements. Monitoring results may, however, be important in the development of further research.

Effective monitoring and general surveillance requires that appropriate methodology has been developed and is available prior to the commencement of monitoring programmes. Monitoring should not be regarded as research per se but as a means to evaluate or verify results and assumptions arising from previous research and evaluation of potential risk and research.

A. **OBJECTIVES**

Before a GMO or a combination of GMOs as or in products is placed on the market, a notification must be submitted to the competent authority of the Member State where the GMO is to be placed on the market for the first time. This notification should, in accordance with Article 13(2), contain a technical dossier of information including a full environmental risk assessment.

The environmental risk assessment aims, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment arising from its placing on the market. This assessment may also need to take account of potential long-term effects associated with the interaction with other organisms and the environment. The evaluation of such potential adverse effects should be founded on common methodology based on independently verifiable scientific evidence.

Individual GMOs are likely to differ considerably in terms of the inherent characteristics of the modified species as well as the specific modification and resultant characteristics. These characteristics will largely determine the nature of any potential effects arising from the placing on the market of a GMO.

It is also necessary to confirm that the pre-market risk assessment for a GMO is accurate, following its placing on the market. Moreover, the possibility of the occurrence of potential adverse effects that were not foreseen in the evaluation cannot be ignored. Post-market monitoring, as required under Article 20 of the Directive, is foreseen for this purpose.

Against this background, it is foreseen that the objectives of post-market monitoring, as detailed under Annex VII, are to:

— confirm that any assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and

— 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.

B. **GENERAL PRINCIPLES**

Monitoring as detailed in Articles 13, 19 and 20 of Directive 2001/18/EC and in the context of this guidance note refers to post-market monitoring, which takes place after consent for the placing of a GMO on the market has been granted.

Article 13(2)(e) of the Directive requires notifiers to submit, as part of their notifications, a plan for monitoring in accordance with Annex VII.

The consent should, under Article 19(3)(f), specify the time period of the monitoring plan and, where appropriate, any obligations on persons selling the product or any user of it, *inter alia*, in the case of cultivation, concerning a level of information deemed appropriate on their location.

On the basis of reports submitted by notifiers, in accordance with the consent and the framework for the monitoring plan specified, the competent authority receiving the original notification should inform the Commission and the Competent Authorities about the results and may, as detailed in Article 20(1), and, where necessary, in consultation with the other Member states, adapt the monitoring plan after the first monitoring period.

Planning is essential with respect to all types of monitoring and when developing monitoring plans, both case-specific monitoring and general surveillance should be considered. In addition, monitoring of potential adverse cumulative long-term effects should be considered as a compulsory part of the monitoring plan.

Case-specific monitoring should, when included in the monitoring plan, focus on potential effects arising from the placing on the market of a GMO that have been highlighted as a result of the conclusions and assumptions of the environmental risk assessment. However, whilst it is possible to predict that certain effects may occur, on the basis of risk assessment and available scientific information, it is considerably more difficult to plan for potential effects or variables that cannot be foreseen or predicted. It may, however, be possible through appropriate planning of monitoring and surveillance plans to optimise the chances for early detection of such effects. The design of the monitoring plan should, therefore incorporate general surveillance for unanticipated or unforeseen adverse effects.

The cost-effectiveness of case-specific monitoring and general surveillance should be taken into account in this context. Furthermore, the monitoring plan should be in accordance with the latest scientific insights and practices.

Member States may themselves also assist with monitoring via the general duty under Article 4(5), which requires that the competent authority organises inspections and other control measures as appropriate, to ensure compliance with the Directive. Indeed, Member States are entitled, in accordance with the Treaty, to take further measures for monitoring and inspection, for example by national authorities, of GMOs as or in products placed on the market. However, it should be recognised that such action is not a substitute for the monitoring plan for which notifiers are responsible (although, with the consent of the relevant parties, may form part of it).

Interpretation of the data collected via monitoring should take account of existing environmental conditions and activities in order to determine an appropriate baseline. General surveillance and environmental monitoring programmes in general may similarly assist in this context. Where unexpected changes in the environment are observed, further risk assessment may need to be considered to establish whether they have arisen as a consequence of the placing on the market of the GMO or as a result of other factors. Against this background, measures necessary to protect human health and the environment may also have to be considered.

C. **DESIGN OF MONITORING PLAN**

The design of monitoring plans should be founded on a framework comprising three key sections, namely:

1. Monitoring strategy;

2. Monitoring methodology;

3. Analysis, reporting, review.

1. **Monitoring strategy**

The monitoring strategy importantly requires identification of the potential effects that may arise from the placing on the market of a GMO, the degree to which they need to be monitored and an appropriate approach(s) and time-scale(s) over which to monitor.

In the first instance, the likelihood of potential direct, indirect, immediate or delayed adverse effects arising from the GMO should be considered in line with its intended use and the receiving environment.

Direct effects refer to primary effects on human health or the environment that are a result of the GMO itself and which do not occur through a causal chain of events. For example, when considering a crop modified for resistance against a specific insect, direct effects may include death and changes in the population of both target and non-target insects that arise as a result of the toxin produced by the GMO.

Indirect effects refer to effects on human health or the environment occurring through a causal chain of events. For example, in the above case indirect effects may arise where a reduction in the population of target insects impacts on populations of other organisms that normally feed on these insects.

Indirect effects may involve interactions between a number of organisms and the environment making it more difficult to predict any potential effect. Observations of indirect effects are also likely to be delayed. These factors must, however, be considered as part of the strategy.

Immediate effects refer to effects on human health or the environment that are observed during the period of the release of the GMO. Immediate effects may be direct or indirect.

Delayed effects refer 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. The build-up of resistance by insects to the Bt-toxin through continued exposure is an example of a delayed effect.

Immediate and delayed effects may themselves be either direct or indirect but imply a time-scale for change. Direct effects are more likely to appear in the immediate or short term at a level that can be detected. Indirect effects may take a longer time period to manifest but nevertheless may need to be taken into account.

It is very difficult if not impossible to predict the appearance of potential unforeseen or unanticipated effects that were not highlighted in the risk assessment. General surveillance for potential unforeseen or unanticipated effects should, therefore, be considered as a part of the monitoring strategy.

1.1. Risk assessment

The monitoring strategy should identify how evaluations obtained from the risk assessment are to be confirmed in line with the use of that GMO and the receiving environment. This should take account of the conclusions and assumptions from the risk assessment, based on scientific evaluation and the recommendations of expert committees. In addition, issues arising from the risk assessment that are subject to a degree of uncertainty, for example possible effects that may appear only where releases are of a large-scale, may also be required as part of the monitoring strategy. Reference to the guidance notes to supplement Annex II, on the principles for the environmental risk assessment, of Directive 2001/18/EC should assist in this respect.

1.2. Background information

Background information pertaining to the GMO in question, including data and information from experimental releases, scientific publications and relevant comparable evidence from other releases, may all be used in the planning and design of the monitoring plan. In particular, data gained through available risk research studies and monitoring of experimental releases will importantly assist in this context.

1.3. Approach

The approach of the monitoring strategy should be described. In many cases, focus is likely to be placed on primary concerns (needs to know) and the establishment of a cyclic monitoring process in order to be able to continuously improve the quality of the programme.

The approach should provide the means to detect potential adverse effects at an early stage of manifestation. Early detection of any adverse effects attributable to a GMO will allow for more rapid reassessment and implementation of measures to reduce any consequences to the environment.

The design of monitoring plans for GMOs should be built using a step-by-step approach taking account of existing data and monitoring methodology. A step-by-step approach will in many cases also need to take account of the scale of release. The first step may be founded on evidence from experimental trials with subsequent steps based on large-scale field trials and ultimately to surveys on commercial plots. Experience and information gained through the monitoring of experimental releases of GMOs is, therefore, likely to be useful in designing the post marketing monitoring regime required for the placing on the market of GMOs.

Existing observation programmes could also be adapted to the needs of monitoring GMOs as a means to ensure comparability and to limit the expenditure of resources in developing the approach. This would include existing environment observation programmes in the field of agriculture, food surveys, nature conservation, ecological long-term monitoring programmes, soil observation and veterinary surveys. Inclusion of such programmes as part of the monitoring plan would firstly require that notifiers gain an appropriate agreement with the persons or organisations, including national authorities, conducting such work.

This section focuses on case-specific monitoring and general surveillance in accordance with the two general objectives under Annex VII although consideration of other types of monitoring system is not precluded.

1.3.1. *Case-specific monitoring*

Case-specific monitoring serves to confirm that scientifically sound assumptions, in the environmental risk assessment, regarding potential adverse effects arising from a GMO and its use are correct.

The approach should:

— focus on all the potential effects on human health and the environment identified in the risk assessment, taking into account i.e. different locations, soil types, climatic conditions, and

— define a specified time period in which to obtain results.

The first step in developing a monitoring plan for case-specific monitoring is to determine the case-specific objectives of the monitoring strategy. This includes determining which assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use were made in the environmental risk assessment and should to be confirmed by the case-specific monitoring. Where the conclusions of the risk assessment identifies an absence of risk or negligible risk, however, then case-specific monitoring may not be required.

Potential adverse effects that are identified in the environmental risk assessment should only be included in the monitoring plan on the basis that monitoring could contribute to the confirmation or rejection of the assumptions associated with these effects.

If the intended use of a GMO includes cultivation, then consideration may have to be given to the monitoring of potential risks arising from pollen transfer, dissemination and persistence of these GMOs. The degree to which these phenomena are likely to occur will also be dependent on the scale of this use and the receiving environment including the proximity to and scale of production of sexually compatible conventional crop species and wild relatives.

Conversely, potential environmental risks arising from GMOs approved only for import and processing will likely often be assessed as extremely limited given that they will not be intentionally introduced into the environment and that they are unlikely to disseminate.

Potential effects on human health or the environment arising from the release or placing on the market of a GMO will firstly depend on the inherent nature of a GMO and its specific genetic modification. For example, potential effects arising from transfer of pollen from genetically modified crops to non GM-crops or related wild-type plants will, in the first instance be largely dependent on whether the genetically modified crop is out-crossing or self-pollinating. The presence of wild relatives may also need to be considered in this context.

However, any subsequent effects for example, the potential development of insect resistance to the Bt-toxin will only be linked to GMOs modified to express this specific toxin. This would not be the case for GMOs modified for herbicide tolerance alone, as these GMOs do not contain a Bt-toxin gene.

Similarly, it would only be relevant to monitor the potential transfer of antibiotic resistance genes and the possible consequences with respect to GMOs that include antibiotic marker genes as part of the modification.

After identification of the objectives on the basis of potential adverse effects, the next step should be to identify the parameters that need to be measured in order to achieve these objectives. Parameters as well as the methods used to measure and evaluate them must be valid and fit-for-purpose.

1.3.2. *General surveillance*

General surveillance is largely based on routine observation ('look — see' approach) and should be used to identify the occurrence of unforeseen adverse effects of the GMO or its use for human health and the environment that were not predicted in the risk assessment. This is likely to involve observation of phenotypic characteristics but more detailed analyses are not precluded.

In contrast to case-specific monitoring, general surveillance should:

— Seek to identify and record any indirect, delayed and/or cumulative adverse effects that have not been anticipated in the risk assessment,

— Be carried out over a longer time period and possibly a wider area.

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 releases and interactions may require a different approach to general surveillance of other effects arising from gene transfer.

General surveillance could, where compatible, make use of established routine surveillance practises such as monitoring of agricultural crops, plant protection, veterinary and medical products as well as ecological monitoring, environmental observation and nature conservation programmes. The monitoring plan may also provide details as to how relevant information collected through established routine surveillance practices conducted by third parties will be retrieved by, or made available to, the consent holder.

If established routine surveillance practise is used in the general surveillance, this practise should be described as well as the changes in the practise needed to fulfil a relevant general surveillance.

1.4. Baselines

Determination of the baseline status of the receiving environment is a pre-requisite for the identification and evaluation of changes observed via monitoring. In short, the 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.

Reliable information about the status of the receiving environment, on the basis of adequate environmental observation systems, may, therefore, be required prior to implementation of monitoring programmes and environmental policy actions. Environment observation programmes are designed to take proven or suspected and plausible ecosystem relationships into account and may assist in the determination of, the:

— status of the environment and changes therein,

— causes of such changes, and

— expected development of the environment.

Examples of indicators of the status of the receiving environment may include animals, plants and micro-organisms from different organism groups and ecosystems. Relevant indicators may be considered on the basis of the characteristics of the GMO in question and the parameters to be monitored. Sexual compatibility of other organisms with the GMO may also be relevant in this context. For a particular indicator species, a number of possible measurement parameters or fitness variables will exist, including the likes of numbers, growth rate, bio-mass, reproductive effort, population rate of increase/decrease and genetic diversity.

It may also be appropriate to consider baselines in relation to changes in management practice resulting from the use of GMOs. This could include changes in pesticide usage with respect to the cultivation of crop species modified for tolerance to herbicides and resistance to insects. It may also be appropriate when considering the monitoring plan for herbicide-tolerant genetically modified crops, to consider herbicide use for conventional crops as part of an appropriate baseline.

1.5. Time-period

Monitoring should be carried out over a time period of sufficient length to detect not only immediate potential effects, where appropriate, but also delayed effects which have been identified in the environmental risk assessment. Consideration should also be given to the interplay between the estimated level of risk and the duration of the release. A prolonged period of release may increase the risk of cumulative effects. The non-appearance of immediate effects over a prolonged period, on the other hand, may allow monitoring to focus on delayed and indirect effects. It should also be considered whether it is necessary to extend the monitoring plan beyond the period of the consent. This may be the case, for example, where the persistence of GMOs in the environment has the potential to be significant.

The proposed time-period of the monitoring plan should be indicated, including an outline of the likely frequency of visits/inspections and any intervals for review of the monitoring plan. This should take account of the likely appearance of any potential effects as highlighted in the risk assessment. For example, consideration should be given to any adverse effect resulting from the dissemination, reproduction and persistence/survival of a GMO in the environment following its placing on the market. This may be a matter of days or months for genetically modified microbes released in bio-remediation programmes but could extend to a number of years where certain crop species are concerned. The likelihood of dissemination and persistence of the modified sequences themselves should also be considered in terms of crosses with sexually compatible species.

The planning of inspections will largely be dependent on the type of effect to be monitored. For example, effects arising from pollen transfer will only be visible following flowering although it would be pertinent to visit a site prior to flowering to establish the extent to which sexually compatible species are present in the vicinity. Similarly, monitoring for the appearance of volunteers in subsequent growing seasons will be linked to the time of seed shed and persistence and germination of the subsequent seed bank.

Prior visits may also be necessary, as appropriate, prior to the onset of monitoring in order to establish relevant baselines.

Monitoring plans and their time-periods should not be fixed indefinitely but reviewed and amended in light of results obtained during the monitoring programme.

1.6. Assigning responsibilities

Ultimately, it is the notifier/consent holder who is responsible, under the Directive, for ensuring that a monitoring plan is included in the notification, put in place and appropriately implemented.

In the first instance, responsibility is placed on notifiers to submit as part of their notification, under Article 13(2)(e) of the Directive, a plan for monitoring in accordance with Annex VII. The suitability of the proposed monitoring plan is one of the criteria by which any application for the placing on the market of a GMO should be judged. The plan should be judged solely on the basis of whether or not it is adequate, which requires fulfilment of the requirements laid down in the Directive itself as opposed to strict alignment with this guidance note.

Article 20(1) subsequently requires that following the placing on the market of a GMO as or in a product, the notifier shall ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent. This should be achieved through appropriate implementation of the monitoring plan.

Responsibilities for each step of the monitoring plan should, therefore, be clearly assigned in the notification. This would apply to both case-specific monitoring and also general surveillance as part of the monitoring plan. Whilst the notifier retains responsibility for ensuring that monitoring is carried out, this does not preclude that third parties such as consultants and users could be involved in the monitoring by carrying out various tasks the monitoring plan requires. In case of general surveillance this could include the Commission, Member States and/or CAs. Where third parties are employed or contracted to conduct monitoring studies, the structure of their involvement should be detailed. The notifier/consent holder is responsible for the compilation of the monitoring data and results and has to ensure the transmission of this information to Commission and the Competent Authorities according to the monitoring plan particularly with respect to the identification of any adverse effects.

It should similarly be noted that it is not precluded that Member States carry out additional monitoring in the form of case-specific monitoring or general surveillance. The aim of such surveillance is to enable the risk manager to take appropriate measures without delay should any undesirable and unidentified effects arise in the framework of prior risk assessment. This should not, however, be considered a substitute for the monitoring plan, which remains under the responsibility of the notifier for implementation (although, with the consent of relevant parties, may form part of it).

1.7. Existing systems

It may be possible to extend existing monitoring or general surveillance systems to address potential adverse effects arising from the placing on the market of GMOs. These systems may include observation programmes in the field of agriculture, food surveys, nature conservation, long-term ecological monitoring systems, environment observation programmes and veterinary surveys.

For example, seed production systems that follow OECD certification rules and therefore include routine inspections of fields and surrounding areas could be adapted to on-field monitoring for specified parameters.

Monitoring and surveillance of conventional commercial crops is already carried out, as a matter of course in Member States, with regard to calculation of fertiliser application as well as pest, disease and weed control. This type of monitoring and surveillance is conducted on a regular basis throughout the growing season by consultants selling the relevant agronomic products and the growers themselves.

It may, therefore, be possible to attach a similar service to sales of genetically modified seed, where representatives of the company, or contracted consultants, to provide at least some form of general surveillance. Instruction concerning surveillance, monitoring and reporting could be distributed to growers purchasing genetically modified seed stocks and contractual agreements could be formulated as a condition of sale or use.

It is certainly feasible that growers or agronomic consultants could conduct surveys of major unforeseen changes or effects such as dissemination and establishment of volunteer plants in adjacent areas if clear instructions are provided. Under these circumstances, it is foreseen that monitoring and surveillance for adverse effects could be incorporated into routine practices for determining agronomic inputs for pest and weed control.

2. **Monitoring methodology**

This section provides guidance as to the types of parameters and elements that may need to be identified and monitored as part of a monitoring programme as well as the means to conduct such monitoring, including areas to monitor and frequency of monitoring.

2.1. Monitoring parameters/elements

Firstly, it will be necessary to identify the relevant parameters/elements to be monitored with appropriate justification for their selection. This will largely be dependent upon the conclusions of the environmental risk assessment. Decisions as to the parameters or elements to be monitored must be taken on a case-by-case basis in line with the modified characteristics of the GMO in question. This would include the likes of monitoring of intended effects on target organisms arising from the modification, an example of which would be monitoring of corn borer populations with respect to the cultivation of Bt-maize varieties.

However, non-specific elements may also need to be considered as part of the monitoring plan and examples of such elements are presented as follows although others are not precluded:

— Effects on non-target organisms arising from the modification, including development of resistance in wild relatives or pest organisms, change in the host range or in the dispersal of pest organisms and viruses, development of new viruses,

— Dispersal, establishment and persistence into non-target environments or eco-systems,

— Out-crossing/breeding (e.g. occurrence, means and rates of out-crossing/breeding), with sexually compatible wild relatives in natural populations,

— Unintended changes in the basic behaviour of the organism, for example, changes in reproduction, number of progeny, growth behaviour and survival ability of the seeds,

— Changes in bio-diversity (e.g. in number or composition of species).

2.2. Areas/samples

The monitoring plan may include details as to where the monitoring will be carried out and over what area. This may be at the level of individual Member States, geographical regions, individual sites, plots or any other area(s) deemed appropriate.

The areas and/or samples to be monitored with respect to possible effects arising from the placing on the market of the GMO should be identified, including those for the purpose of reference or control. Any reference or control areas and/or samples must be sufficiently representative in terms of environment and conditions of use for meaningful conclusions to be drawn. Moreover, any sampling methodology should be scientifically and statistically sound. On this basis, such data can provide important information on the variation of indicators, which will increase the power of the effect detection.

When considering the areas to be monitored with regard to, for example, a genetically modified crop species, its characteristics (both inherent and modified) as well as its reproduction and dissemination and the types of ecosystems that may be affected could be considered in determining the habitats selected for monitoring. Relevant areas to monitor would include selected agricultural fields where the crop is commercially grown as well as surrounding habitats.

It may also be necessary to extend monitoring/surveillance to adjacent or neighbouring cultivated and non-cultivated areas, post-harvest surveillance areas for volunteer plants and protected areas. Certain types of habitats, such as disturbed areas and species-rich plant communities, are more prone to invasion than others. Disturbed areas with low vegetation and high abundance of herbs and grasses are particularly suitable for the purpose of monitoring. Firstly, they are widely distributed and often found close to more intensively cultivated agricultural areas. Secondly, these areas are often typical of roadsides, ditches and edges of fields where accidental loss and dispersal of seeds is most likely to occur in the first instance.

Monitoring for the possibility of transfer of genetic material to sexually compatible organic and conventional crops may also be considered. This will require evaluation of the extent to which such crops are grown in adjacent or neighbouring areas.

2.3. Inspections

The monitoring plan should indicate the likely frequency of inspections. This may include a timetable to indicate the timing and number of intended visits to a site. In this respect, as already detailed in sections 1.5 and 2.2, consideration should importantly be given to the time when potential adverse effects are most likely to appear as well as the area(s) to be monitored.

2.4. Sampling and analysis

The methodology to subsequently monitor these parameters/elements should also be clearly identified and outlined, including techniques for sampling and analysis. Standard methodology, as provided for by the likes of European CEN Standards and OECD-methods for monitoring organisms in the environment, should be followed where appropriate and reference to the source of the methodology provided. Methods used for monitoring should be scientifically sound and valid under the experimental conditions in which they are to be applied; therefore, consideration should be given to the characteristics of the methods, such as selectivity, specificity, reproducibility, any limitations, detection limits, and the availability of appropriate controls.

The monitoring plan should also indicate how the methodology is expected to be updated, if appropriate, according to the selected monitoring approach/strategy.

Statistical analysis could also be employed when designing the appropriate sampling and testing methodology, in order to determine optimal sample sizes and minimum monitoring periods for the required statistical level of effect detection.

2.5. Collection and collation of data

The monitoring plan should, for both case-specific monitoring and general surveillance, identify how, by whom and how often data is to be collected and collated. This may be of particular importance where third parties are employed or contracted to collect data. Notifiers may need to provide standard mechanisms, formats and protocols for data collection and recording as a means to ensure consistency. For example, standardised recording sheets or direct logging or registration of data on standardised 'spread-sheets' via portable computers could be provided. The notifier may also need to detail how the data will be collated, importantly how information is to be retrieved from third parties, such as consultants or users.

Deadlines and intervals for reports detailing the results of the monitoring should also be indicated.

3. **Analysis, reporting, review**

The monitoring plan should indicate how often the data is reviewed and discussed in an overall analysis.

3.1. Evaluation

Evaluation of data should, where appropriate, include statistical analysis with appropriate standard error values to enable subsequent decisions to be taken on a sound basis. These will include decisions as to whether evaluations highlighted in the risk assessment are correct. In this respect, correct baselines and/or controls relating to the status of the receiving environment are also paramount for accurate evaluations. Use of statistical analysis should also provide information as to whether the type of methodology, including sampling and testing, is appropriate.

The evaluation of results from monitoring and surveys may reveal whether other parameters should be monitored under the programme. Appropriate responses to any preliminary findings may also need to be examined, in particular, where potential negative impacts on vulnerable habitats and organism groups are suggested.

The interpretation of the data collected by monitoring may need to be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment may be required to establish whether they are a consequence of the GMO or its use, or whether such changes may be the result of environmental factors other than the placing of the GMO on the market. It may be necessary to re-evaluate the baselines used for comparison in this respect.

The monitoring plan should be structured in such a way, that the results of both the case-specific monitoring and general surveillance as well as additional research could clearly be used in the decision-making process for renewal of approval for products.

3.2. Reporting

Following the placing on the market of a GMO, the notifier under Article 20(1) of the Directive, has a legal obligation to ensure that monitoring and reporting are carried out according to the conditions specified in the consent. The reports of this monitoring must be submitted to the Commission and the competent authorities of the Member States although no time frame for submission is laid down. This information should also be made publicly available in line with the requirements of Article 20(4) of the Directive. Against this background, notifiers should describe the conditions of reporting in the monitoring plan.

In addition, an indication as to how relevant information collected through any established or routine surveillance practises will be made available to the consent holder and competent authorities should also be provided in the monitoring plan.

Notifiers/consent holders should ensure transparency of the results and measures of the monitoring programmes and the monitoring plan should identify how the gathered information is reported/published. This could for example be achieved via:

— information sheets to users and other stakeholders,

— workshops to present and exchange information with stakeholders,

— archived in-company documents,

— inclusion on company web-sites,

— publication of information in trade and scientific publications.

The provisions of Article 20 of the Directive also relate to reporting. In accordance with Article 20(2), if new information concerning risk becomes available from users or other sources, the notifier is immediately required to take the measures necessary to protect human health and the environment, and inform the competent authority thereof.

In addition, the notifier is also required to revise the information and conditions specified in the notification.

3.3. Review and adaptation

Monitoring plans should not be viewed as static. It is fundamental that the monitoring plan and associated methodology is reviewed at appropriate intervals and updated or adapted as necessary.

Article 20(1) of the Directive allows the competent authority receiving the original notification, on the basis of reports submitted by notifiers and in accordance with the consent and the framework for the specified monitoring plan, to adapt the monitoring plan after the first monitoring period. However, implementation of the revised monitoring plan again remains under the responsibility of the notifier.

Reviews should examine the effectiveness and efficiency of data measurements and collection, including sampling and analysis. The review should also evaluate whether the monitoring measures are effective in addressing the evaluations and any questions arising from the risk assessments.

For example, if specific models are used for predictive purposes, a validation based on the data collected and subsequent appraisal may be conducted. Similarly, new developments and progress in sampling and analytic techniques should also be taken into account where appropriate.

Following such reviews, the adjustment of methods, monitoring goals and the monitoring programme may be necessary and should be adapted or upgraded as appropriate.