

ECOLOGICAL MONITORING OF GENETICALLY MODIFIED ORGANISMS

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Agroecosystem with rich wild flora and ruderal biotope (A. Traxler)

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SUMMARY

There is great uncertainty about potential environmental effects of genetically modified organisms (GMOs). Ecological monitoring is one of the few instruments to increase environmental safety in the commercial use of GMOs. Its main goal is to protect the national targets of nature conservation (e.g. biodiversity, habitats and species).

The objectives of ecological monitoring of genetically modified organisms (GMOs) are

- to detect possible adverse effects on the environment,
- to prevent adverse effects (early warning system),
- to protect ecological targets of nature conservation,
- · to periodically re-evaluate the risks of GMOs and
- to gain knowledge of the application of a new technology.

There is broad agreement that ecological monitoring is necessary to control the potential risks of the deliberate release and placing on the market of GMOs. That is particularly emphasized in the new Directive 2001/18/EC, where suggestions, basic targets and methods of ecological monitoring are extensively elaborated. In detail, however, there are still uncertainties on how ecological monitoring is to be implemented. Targets, methods, duration and locations of monitoring are addressed only marginally in different monitoring concepts (AMMANN & VOGEL, 1999; MAYER et al., 1995; NEEMANN et al., 1999; RAPS et al., 1999; SRU, 1998; SUKOPP, 1998; FEDERAL ENVIRONMENT AGENCY BERLIN, 1999).

The future implementation and handling of ecological monitoring is not yet clarified. For example, the term "ecological damage" with respect to GMOs is not properly defined. Is the simple occurrence of a GMO in ruderal biotops to be considered an ecological damage (intrinsic damage) or must local native plant populations be suppressed due to competitive mechanisms to reach the level of damage? Closely linked to this issue are the "suspension criteria" for ecological monitoring. What are the adverse effects that must occur to dismiss or postpone a notification for the placing on the market of a GMO or to withdraw a product from the market? Ecological monitoring should not be misused as a half-hearted excuse; rather, it must follow clearly-defined, targeted assessment criteria like suspension criteria.

When molecular biologists, representatives of industry and ecologists gather to discuss about monitoring of GMOs, it often appears that opposite worlds meet. "Undesirable weed versus precious little jewel" is a case in point. Cause-effect models, anticipation and exact measurability are met by complex, unforeseeable ecosystem reactions and environmental effects that may occur in 100 years (see Fig. 1). Surprisingly enough, there is broad agreement among all interest groups on the necessity of ecological monitoring. In detail, however, representatives of industry on the one hand and ecologists on the other have the most divergent views on the nature, extent and duration of the investigations to be carried out.

Ecological monitoring must be planned and carried out by ecologists in co-operation with molecular biologists and cannot be accepted as a burdensome necessity involved in the release of a GMO.

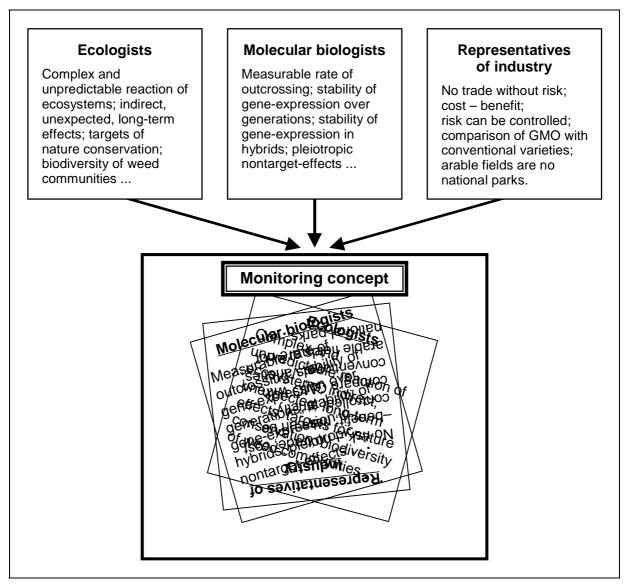


Fig. 1: When ecologists, molecular biologists and representatives of industry discuss a monitoring programme for GMOs, the outcome reflects their divergent views. At present, there is still disagreement on monitoring plans.

This survey is to establish a framework concept for the ecological monitoring of genetically modified organisms (only higher plants, i.e. spermatophytes). The framework concept has been elaborated along the lines of the Directive 2001/18/EC (COUNCIL OF THE EUROPEAN UNION, 2001) and is open to future amendments and adjustments. Since the Directive becomes effective in march 2001, guidance notes to describe more precisely the environmental monitoring scheme will have to be elaborated and added to Annex VII (monitoring plan for the placing on the market of GMOs). The framework concept presented here contains preliminary proposals for these guidance notes that are to be incorporated into a national discussion and ultimately into discussions on an EU level.

Each notification for the deliberate release or placing on the market of GMOs must contain a detailed monitoring plan on a case-by-case basis. Our framework concept is designed to serve as a guideline for the development and evaluation of case-specific monitoring plans. The guidelines proposed here sketch the basic requirements for the ecological monitoring of GMOs and should be generally applicable.

The framework monitoring concept makes suggestions with respect to:

- · case-specific monitoring,
- general surveillance
- monitoring on the state of the art
- · and ecosystem monitoring.

Case-specific monitoring is confined to hypothesis-based investigations in test fields and adjacent land and is limited in time. It centres on investigating into the behaviour of a particular GMO.

General surveillance is conceived as a representative nation-wide long-term monitoring programme without any time restrictions. It is designed to observe the effects of all consented GMOs. Sampling plots are to be made part of national environmental monitoring schemes to primarily identify indirect, unanticipated and delayed effects. It focuses on the observation and conservation of ecological targets rather than on a particular GMO.

Monitoring on the state of the art is to collect and structure international monitoring results and related risk assessments. It is an instrument to periodically adjust current monitoring plans in terms of methodology and subject matter.

Ecosystem monitoring at one or few locations may supply new findings by focusing interdisciplinary studies taking into consideration abiotic and biotic factors. Such detailed findings, for methodological and financial reasons may not be gathered by case-specific and general monitoring on a broad geographical scale.

Risk assessment of GMOs is primarily centred on the new transgenic plants but neglects that there have to be basic data on **ecological targets** that may be affected by GMOs and that may not have been sufficiently investigated into. These two angles continue in the divergent views on the monitoring of GMOs. Molecular biologists and representatives of industry put the GMO in the centre, whereas ecologists focus on environmental aspects.

This survey attempts to establish basic guidelines to meet the various requirements of ecological monitoring, including for example the subdivision of Europe into biogeographical regions to select test sites. Furthermore, the national ecological targets of Austria for example are looked at that are to be at the centre of the monitoring scheme (see chapter 5).

Such ecological targets provide the objects of interest and issues of monitoring. The objective of ecological monitoring is to prevent that ecological damage be done to the targets in question.

Currently used monitoring techniques and survey parameters are outlined as well as the methodological limits in identifying ecological effects. This monitoring concept covers fields like plant ecology, ornithology, entomology and soil ecology. The living communities affected by GMOs are much more varied; important groups of animals, such as mammals, reptiles and amphibians could for practical reasons not be considered here. There is need for action and further investigation in this field.

In case of future notifications for GMOs the following issues must be clarified with regard to efficient ecological monitoring:

- determination of the executing institutions
- definition of threshold values, suspension criteria and limits of acceptable change (see chapter 3.9.5)
- · definition of ecological damage
- establishment of a national and international information network (see chapter 3.5.1).

The following issues should be discussed at the earliest possible stage:

- planning of a nation-wide, representative monitoring network for animals and plants (see chapter 3.1.2)
- definition of the ecological targets likely to be affected by GMOs (see chapter 5)
- financing.

1 INTRODUCTION

This survey is the English translation of an abridged version of a monography (M-126) published by the Federal Environment Agency of Austria (TRAXLER et al. 2000). The English version is aimed at highlighting those contents that are of use for the EU-wide and international discussion on the establishment of supplementary guidelines to Annex VII of the Directive 2001/18/EC.

- The following chapters of the German version have been significantly abridged:
- all aspects specifically relating to Austria
- financing of monitoring
- identification parameters and monitoring methods
- · case examples of genetically modified oilseed rape and maize
- · ecological targets of Austria
- · regional aspects in Austria.

The ecological aspects of monitoring must be discussed!

For all we know at present, no GMOs that have been consented to be placed on the market on an EU-wide level according to Directive 90/220/EEC (which has been amended by Directive 2001/18/EC) have as yet been commercially planted. There has thus been no practical experience with ecological monitoring after GMOs have been placed on the market.

This survey has developed a first framework concept for the monitoring of GMOs designed to provide assistance to notifiers and competent authorities. Future notifications for the release or placing on the market of GMOs can be evaluated in relation to the monitoring plan to be submitted on the basis of the following framework concept (see figure 2).

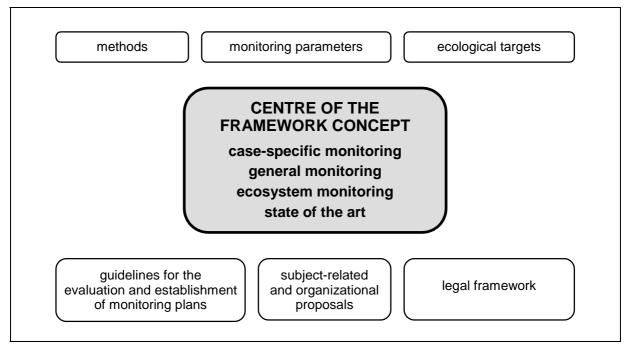


Fig. 2: Structure of the framework concept for the ecological monitoring of GMOs in terms of subject matter.

The development of this monitoring concept does by no means give a "clean bill of health" for releasing or placing GMOs on the market, rather, it establishes criteria, feasible methods, useful infrastructure and expert knowledge, in order to clarify without time restriction points of view in an international expert discussion. Constant in-depth discussion among representatives of industry, users, molecular biologists and ecologists is necessary to understand and assess divergent points of view.

Monitoring does not work wonders!

Monitoring is certainly no infallible cure-all to make good on mistakes in risk assessment, unforeseen adverse effects of GMOs or to repair the damage done.

One commonplace example for the efficiency of monitoring would be a ghost-driver warning in the traffic news. This early warning system may lead to the prevention of an accident, in the worst case, however, a fatal accident cannot be avoided. Still, this monitoring system does not give any indication as to the cause of the ghost journey (Did the driver take the wrong junction? Was it a test of courage?). The causal analysis and the question of fault can only be clarified in follow-up investigations.

Ecological monitoring is necessary, yet it has its drawbacks. Efficient monitoring is rather expensive, time-consuming and limited in terms of methodology. Still, it is the only way to

- prove hypotheses on an empirical basis,
- detect unforeseen effects,
- possibly prevent adverse effects in time,
- to gain knowledge of the ecological risks of GMOs.

Ecological monitoring is a module in its own right!

This survey is concerned with monitoring strategies to detect ecologically relevant effects of GMOs, but not with monitoring of the agricultural performance of cultivated plants (e.g. yields) or molecular-biological monitoring (genotypical stability of GMOs). These features must be clarified in supplementary agricultural and molecular-biological monitoring, though certain findings may well be relevant for ecological issues and hypotheses.

Ecological monitoring is not in the centre of the studies currently being carried out on the subject of releases (RAPS et al., 1999). Primarily, it is the agronomical efficiency and genetic stability of GMOs that is being investigated into, on the basis of which environmental effects are assessed. Such topics which are of significance for product development of the GMO and also for ecology are tackled as well (competitive behaviour, outcrossing or introgression) and often used as the only basis for ecological conclusions. But there is no ecological approach in itself.

Ecological monitoring requires its own ecologically relevant issues, which would necessitate a separate research design. However, the issues are not primarily whether the GMO supplies a higher yield or whether it is more competitive than comparable conventional varieties in relation to other common weeds. It is much more important to clarify if a genetically modified cultivated plant affects or does harm to ecological targets or if it has the necessary potential to do so.

Competitive experiments in ecological monitoring measure the competitive behaviour of GMOs in relation to species of precious habitats or of habitats that lend themselves to the GMO as means for further dispersal. A competitive experiment between transgenic rape and its competitor, barley, may be interesting agronomically, yet there are more pressing ecological issues on the subject of the competitive behaviour of GMOs. Ecological monitoring must not be considered an unloved appendix of agricultural field experiments, but is to be considered a module in its own right that is to be designed, carried out and evaluated by ecologists.

Ecological targets have to be determined on a national level!

In planning ecological monitoring, it has to be clarified what ecological targets are likely to be affected. Such targets must largely be determined on a national level. The exemplary list of Austrian ecological targets (largely confined to agroecosystems) in chapter 5 is to help determine the subjects and test objects of ecological monitoring. A **case-specific monitoring plan** is to clarify what species or habitats of a geographically limited test field are to form a fixed part of the monitoring plan. In **general surveillance**, which is primarily aimed at detecting long-term, indirect or unanticipated effects, it is the entirety of national ecological targets that forms the basis for long-term observation.

Unclear hypotheses supply unclear results!

In practice, such wordings of EU Directives as the "prevention of adverse effects on the environment" cannot be examined in biotic nature conservation. In the monitoring of hazardous substances there are statutory threshold values that basically must not be exceeded. In the monitoring of GMOs no clearly measurable threshold values have been defined. Monitoring by means of such poorly designed measures is solely based on pure observation and the (sometimes controversial) subsequent interpretation of results. It lacks the "flashing warning light" that triggers targeted measures. Observations are being made, but there is no surveil-lance, nor control. Ecological damage that has not been defined prior to measuring, is hardly verifiable and creates too much room for subjective interpretation.

2 LEGAL PROVISIONS GOVERNING THE MONITORING OF GMOS

In the EU the use of GMOs is, among others, governed by the following Directives:

- **90/220/EEC** Council Directive of April 23, 1990 on the deliberate release into the environment of genetically modified organisms
- 94/15/EC Commission Directive of 15 April 1994 adapting to technical progress for the first time Council Directive 90/220/EEC on the Deliberate Release into the environment of geneteically modified organisms,
- 2001/18/EC Council Directive of March 12, 2001 on the deliberate release into the environment of genetically modified organisms and repealing Concil Directive 90/220/EEC
- **90/219/EEC** Council Directive of 23 April 1990 on the Contained Use of genetically modified microorganisms,
- **98/81/EC** Council Directive of 26 October 1998 amending Directive 90/219/EEC on the Contained Use of genetically modified microorganisms.

Basically, Directive 90/219/EEC (micro-organisms in contained systems) is an environmental protection directive, whereas Directive 2001/18/EC is a Single Market Directive. The former requires only minimum standards. Member countries can thus take reinforced safety measures. The release Directive 2001/18/EC, by contrast, establishes minimum and maximum standards that cannot be surpassed by even higher safety standards on a national level (LESKIEN, 1992).

Since the survey in question is concerned only with the release and placing on the market of transgenic higher plants instead of micro-organisms, reference is made only to Directive 90/220/EEC and the new Directive 2001/18/EC.

The amendment of the Directive 90/220/EC has come into force in April 2001 (Directive 2001/18/EC). National legislations of the member states have to be adjusted to the amended Directive until October 2002. The same applies to observation and monitoring (e.g.: Art. 20, Annex VII of the Directive 2001/18/EC).

2.1 Monitoring according to Directive 90/220/EEC

Directive 90/220/EC only rudimentarily referred to the surveillance of environmental effects of GMOs in releases and after placing them on the market. Ecological monitoring was basically only part of the interdisciplinary monitoring plan that for instance also relates to safeguarding human health.

In both notifications for releases (Part B, Art. 5/2/V) and notifications for placing GMOs on the market (Part C, Art. 11/1) each notifier has to include information on monitoring.

Annex II (V/A) of Directive 90/220/EC lists the information and data required in notifications with respect to monitoring and control.

Monitoring procedure:

- 1. methods to identify GMOs and to monitor their effects,
- 2. specificity, susceptibility and reliability of surveillance procedures,
- 3. procedures to identify the transmission of genetic properties transmitted to other organisms,
- 4. duration and frequency of surveillance.

In the first adjustment of Directive 90/220/EEC by way of Directive 94/15/EC Annex II was reworded. According to Annex II notifications for releases now require the description of surveillance techniques and – plans.

Summing up one can say that according to Directive 90/220/EEC product notifications for GMOs require information with regard to control and surveillance. However, there are no provisions as to their degree of accuracy. A monitoring plan was requested only after the first adjustment of the Directive for releases.

The reason for the amendment of Directive 90/220/EEC was, inter alia, the following consideration: "It is necessary to introduce into this Directive an obligation to implement a monitoring plan 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." (COUNCIL OF THE EUROPEAN UNION, 1999).

2.2 Monitoring according to Directive 2001/18/EC

2.2.1 The new Annex VII (monitoring plan for the placing on the market of GMOs)

The Directive 2001/18/EC includes much more detailled data for surveillance than the Directive 90/220/EEC. The newly established Annex VII lists objectives, general principles and design of the monitoring plan (applicable only to the placing on the market).

The objectives of the 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
- 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 provide for

- the general surveillance of unanticipated adverse effects
- · case-specific monitoring.

Case-specific monitoring should be carried out over a sufficient time period in order to detect immediate as well as direct, but also delayed and indirect effects identified in the environmental risk assessment. Note: Case-specific monitoring thus attempts, on a strictly hypothesis driven basis, to evaluate the presumed effects identified in the environmental risk assessment. The subject matters of the studies are laid down in the hypotheses of the environmental risk assessment.

Surveillance (general monitoring) could, if appropriate, make use of 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 that will be made available to the consent-holder should be provided. Note: To clarify ecological issues it is useful to make use of established ecological monitoring programmes and inventories.

2.2.2 Specifying Annex VII by way of guidance notes

Annex VII (monitoring plan) is to be supplemented and specified by further guidance notes, which are to be established 18 months after entry into force of the new Directive in accordance with the procedure laid down in Art. 30/2 (17 October 2002).

The general principles (Annex VII/C) shall be adjusted to technological progress (Part D, Art. 27).

2.2.3 Establishment and Assessment of Monitoring Plans

If in a member state a notification for **deliberate release** is filed, it must include a monitoring plan (including the relevant methodology) according to the relevant Parts of Annex III with respect to the detection of environmental effects (Part B, Art. 5/2/v and Annex III B/G). Also, it must include proposals for post release monitoring.

A notification for the **placing on the market** must include a monitoring plan according to Annex VII, including a proposal with respect to the time period for which the monitoring plan is to remain in place (Part C, Art. 13/2/e and Part C, Art. 19/3/f). The duration of the consent to the placing on the market of GMOs is confined to 10 years (Part C, Art. 15/4), with the monitoring plan remaining in place for a shorter or for a longer period. No later than 9 months prior to the expiry of the consent the application for renewal must contain a report on the results of the monitoring (reporting duty for monitoring) (Part C, Art. 17/2/b). The competent authority of the country where the notification was filed may adjust the original monitoring plan on the basis of the abovementioned reports (Part C, Art. 20/1).

Monitoring of the placing on the market of GMOs is actually governed by Article 20 (monitoring and handling of new information). The notifier is responsible for monitoring and reporting to the Commission and the competent authorities of the member states. The competent authority forwards to the Commission an assessment report with clear information on the proposed monitoring plan (Annex VI/5). The competent authorities of the other member states have the opportunity of communicating to the Commission new information on the risks the GMO poses on human health or the environment and thus lodge reasonable objections to the further placing on the market of the particular GMO (Part C, Art. 20/2 and 3).

Already at the stage of the environmental risk assessment certain strategies to manage the risks of deliberate release or deliberate placing on the market of GMOs may be proposed (Annex II/C2/5). Under this item, special requirements to be imposed on a monitoring programme may be articulated.

Member states have the opportunity of provisionally restricting or prohibiting the sale or use of the particular GMO in their sovereign territories if new scientific findings come up that have an impact on environmental risk assessment or the potential risks to human health or the environment (Note: Such findings may be derived from literature, related research or from a monitoring programme). The reasons for such decision and the conditions for modified consent must be sent to the Commission and to the other member states (Part C, Art. 23/1 safeguard clause). The Commission has then to consult the competent Scientific Committees on the issues addressed (Part D, Art. 28/1). However, the placing on the market of GMOs that meet the requirements of Directive 2001/18/EC must neither be prohibited, nor restricted, nor hindered (Part C, Art. 22; free circulation).

2.2.4 Exchange of information and reporting duties with respect to monitoring

The representatives of the member states meet on a regular basis to exchange experiences with monitoring (Part D, Art. 31/1). Every three years, the member states, inter alia, submit a report on the measures being taken to implement the Directive (also monitoring) as well as a fact-finding report on experiences with GMOs that have been placed on the market (Part D, Art. 31/3). A summary of the reports is published by the Commission (Part D, Art. 31/4) and submitted to the European Parliament and the Council (Part D, Art. 31/5). The Commission draws up a separate report on experiences with releases and the placing on the market of GMOs which assesses all effects (with special regard to the diversity of eco-systems in Europe) and the possible necessity of widening the scope of regulation (Part D, Art. 31/6).

2.2.5 Confidentiality

Methods and plans of monitoring must not be treated confidentially, they must be accessible (Part D, Art. 25/4); the same applies to reports on the results of monitoring.

2.3 Overlapping of Directive 2001/18/EC with other EU-Directives

The ecological impact of releases and the placing on the market of GMOs is basically governed by Directive 2001/18/EC. Yet, other Directives may also become applicable, as is the case with herbicide-resistant varieties in relation to possible environmental effects due to altered use of herbicide. Quote: In this context the competent authorities concerned with the implementation of this Directive and of those instruments, within the Commission and at national level, should coordinate their action as far as possible; (COUNCIL OF THE EURO-PEAN UNION, 1999).

2.4 National legal provisions in relation to targets of nature conservation

It is understood that the targets of nature conservation are more precisely defined and better adjusted to practical implementation in national legislations of the member countries than in the general wording of the EU Directives. Nature protection laws are designed to provide assistance in defining national targets of nature conservation as precisely as possible (e.g. protected species and biotops) and to evaluate the ecological risk and the ecological damage that may be caused by GMOs with a view to national interests. This is of particular importance in case of objection by the competent national authority of a member state, for then the presumed effect of the GMO or the risk to the environment thus identified must be evaluated and provided with an ecological and legal framework; such step should, among others, preferably be made in line with nature conservation laws. There is controversy as to which laws are to be applied in individual cases and to what extent transgenic plants are also subject to national laws concerning Nature Protection. These issues, however, are subject to legal interpretation and thus not part of this survey. Here the application of national nature conservation laws is considered only as possible assistance in defining targets of nature conservation, conservation targets, ecological risk and damage.

2.5 Convention on Biological Diversity

At the UNCED conference in Rio de Janeiro in 1992, 104 countries signed and subsequently ratified the international "Convention on Biological Diversity". The objective of said Convention is to provide maximum protection of biodiversity and biological resources. The Convention on Biological Diversity is not a mere declaration of intent, but obliges the Parties to identify their biodiversity and to monitor their development (BEIERKUHNLEIN, 1999).

The shortcomings of the implementation of the Biodiversity Convention, it is claimed, are, among others, split-up competencies and inadequate financial equipment (DICK & TIEFEN-BACH, 1996).

The discussion on the implementation of the Biodiversity Convention points out that the insitu conservation of biodiversity can be maintained only by means of thorough nature conservation schemes that should exceed declared areas of nature conservation.

As far as the conservation targets of cultivated lands are concerned (Articles 8c and 10), methods of cultivation (**sustainable land-use**) to protect biodiversity are called for that preserve the ecological balance. Sustainable land-use refers to the utilization of parts of biodiversity in a manner that does not lead to a (long-term) diminution. Also, traditional forms of land-use shall be preserved to safeguard biodiversity. Unclear definitions of biodiversity in agriculture are deemed a deficit in implementing sustainable land-use. To make a contribution to the implementation of the Biodiversity Convention the securing of rare gene combinations by means of creating gene conservation forests with a 200 to 500 metres buffer zone was discussed (DICK & TIEFENBACH, 1996). Undesirable pollen dispersal, such as may possibly be caused by transgenic forest trees in the future, is thus to be avoided.

Article 7 (identification and monitoring) of the Biodiversity Convention provides for monitoring of biodiversity. Such monitoring of biodiversity may, according to general surveillance (Annex VII of the Directive 2001/18/EC), be implemented in the field of monitoring GMOs as well.

3 FRAMEWORK CONCEPT AND GUIDELINES FOR MONITORING OF GMOS

3.1 Framework concept for ecological monitoring of genetically modified organisms

Ecological monitoring refers to the regular and systematic observation of ecosystems by means of identifying ecologically significant parameters (e.g. plant-, population- and land ecology).

Monitoring is the generic term for surveillance and observation systems and may pursue the most diverse objectives (early warning system, benefit check in nature conservation, enforcement of legal provisions).

Basically, the monitoring of GMOs is a kind of "regulatory monitoring" that observes statutorily defined target parameters (environmental effects of GMOs according to Directive 2001/18/EC) and may, as appropriate, also trigger interference. Also, new knowledge on the effects of GMOs is to be acquired that may be taken into consideration when assessing the risks of GMOs.

The following is a preliminary proposal for a framework concept for the monitoring of GMOs in releases and after placing on the market of GMOs.

According to the Directive 2001/18/EC environmental monitoring includes

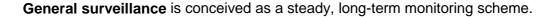
- case-specific monitoring and
- general surveillance (see chapters 2.2.1 and 3.6).

This terminological and conceptional distinction is of vital significance in terms of future allocation of competences and financing.

Tab. 1: Distinction between case-specific monitoring and general surveillance.

case-specific monitoring	general surveillance
strictly tied to hypotheses and aimed at a particular GMO	general surveillance of all GMOs with a consent by means of hypotheses held in general terms
detects the relationships of cause and effect	supplies indications as to the potential effects of GMOs
focused on direct and immediate environmental effects.	focused on indirect, delayed and unanticipated environmental effects.
clear results may be expected soon	indications may be expected only in biologically relevant periods of time
the ecological behaviour of the GMO is at the centre	the observation and conservation of ecological targets is at the centre
investigations into test plots of land and adjacent land	representative sampling plots on a national level
limited period of time	unlimited period of time

With respect to releases and placing on the market case-specific and general surveillance each have different focuses in terms of time period and intensity of research (see figure 3). Time period and intensity of research in **case-specific monitoring** depend on the monitoring results achieved and the present assessment of environmental effects of the respective GMO (see chapter 3.9.1).



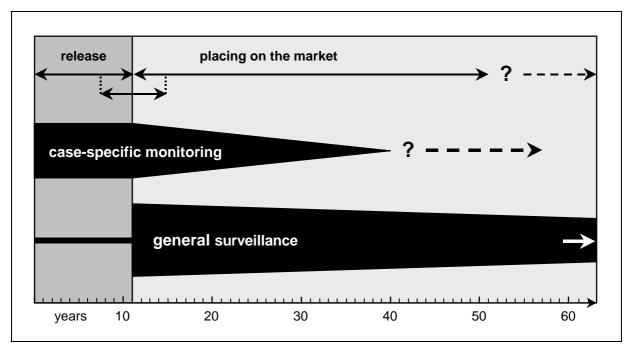


Fig. 3: Focus of case-specific monitoring and general surveillance for releases and placing on the market along the time axis. The significance of each monitoring strategy is exemplified by the boldness of the black banner. The distinction suggested in this figure between case-specific monitoring and general surveillance is not always feasible in practice. This is just to emphasize the focus. For instance, case-specific monitoring may also identify indirect, unanticipated and delayed effects.

3.1.1 Case-specific monitoring

Case-specific monitoring is strictly tied to hypotheses and is based on the potential risks that are identified in risk assessment. The hypotheses are confirmed or dismissed in targeted experiments. Case-specific monitoring supplies clear answers to clear and specific questions (hypotheses); poorly defined questions can be answered only in general terms.

Clearly specified hypotheses should include well-defined standards (threshold values) that can be verified in experiments. Such threshold values may for instance define the level of unacceptable environmental risks or effects and perform a warning function (flashing light) in a monitoring early warning system (see figure 4).

The typical issues in case-specific monitoring are for instance the control of the spread of GMOs, the flow of genes in areas of biological land cultivation (see table 2) or the monitoring of weed diversity in a release field. Case-specific monitoring should be so focused as to identify direct and immediate effects. Case-specific monitoring is thus predominantly (but not exclusively) implemented in releases and in the first decades following the placing on the market (see figure 3).

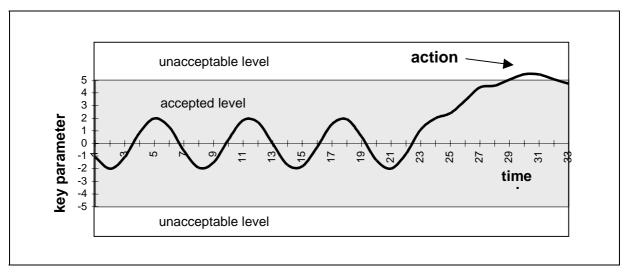


Fig. 4: Definition of an acceptable level of fluctuation of a key parameter. When the acceptable level is exceeded, action takes place (e.g. in-depth experiments, increased safety measures or suspension of the release).

If the system of LATOUR & REILING (1994) for "comparative environmental threat analysis" were modified, the following standards for case-specific monitoring of transgenic maize could be established (see table 2):

Tab. 2: Structured elaboration of the hypotheses in case-specific monitoring by way of defining threshold values (modified according to LATOUR & REILING, 1994).

Threat	level of protection	objective of protection	method of calculation
Geneflow in areas of biological land cultivation	freedom of genetic engineering according to the regulations on organic farming	areas of biological land cultivation	PCR-analysis of maize seeds from biological cultivation. threshold value: e.g. 0.1 % transgenic seeds

3.1.2 General surveillance

The implementation of "general surveillance" according to Annex VII in the Directive 2001/18/EC in particular is considered the most difficult challenge in that there have as yet been hardly any feasible concepts.

General surveillance should be conceived as an interdisciplinary, ecological long-term monitoring scheme that is to monitor notably indirect, delayed and unanticipated environmental effects of GMOs. Its use is thus largely confined to the period after the GMO has been placed on the market. It is naturally difficult to identify unanticipated or delayed effects of GMOs, since an ecosystem would theoretically have to be investigated completely, which is not feasible. Monitoring can thus only be limited to such sampling parameters as can be controlled rather cheaply and effectively. In the field of plant ecology, for instance, it would be confined to the diversity of species and plant composition of defined test sites (permanent plots, regional or national sampling grids). Such common parameters change without the influence of GMOs, since ecosystems are influenced by a variety of factors (climate, succession phenomena, etc).

General surveillance can thus hardly identify direct cause-effect relationships. Still, it can detect signs that indicate effects of GMOs. Such signs can be clarified in further in-depth investigations (similarly to case-specific monitoring).

For instance, as part of general surveillance the diversity of weeds in agroecosystems may be surveyed in a time series. Such studies are independent of a particular GMO and cannot be carried out on a case-by-case basis. The question can thus only be if unanticipated effects of all GMOs placed on the market occur. The concept of ecological monitoring readily lends itself to answer this very question, aiming above all at the conservation of ecologically valuable habitats instead of being primarily based on the study of effects of a certain GMO. Summing up one can assume that in the long run general monitoring supplies precious indications of indirect, unanticipated effects; studies will however be complicated and costly. One must not expect that within the first 5 to 10 years results will be supplied that indicates the effects of GMOs. Efficient general surveillance is to take place in terms of place and subject matter where effects are most likely to occur. General surveillance is thus not free of hypotheses, but establishes only general hypotheses. Case-specific monitoring, by contrast, relies on clearly defined hypotheses (issues). It is wrong to conclude that general monitoring is less efficient than case-specific monitoring, just because it is more expensive, supplies only indications and achieves only delayed results. General monitoring resolves guite different issues that case-specific monitoring fails to resolve.

It is wise to integrate general surveillance into a **national environmental monitoring** scheme, i.e. into a monitoring network that is representative for the member country.

A number of environmental parameters, such as air quality, ozone, water quality, soil quality, forest quality are under national control. By contrast, there is hardly any national network to monitor the diversity of habitats and species for nature conservation. National monitoring networks for plants and animals would not only be in the service of monitoring GMOs, but would also serve the manifold requirements of international nature conservation Directives and Conventions (e.g. the Fauna-Flora-Habitat Directive, Bird Protection Directive, Biodiversity Convention). General surveillance of GMOs would thus only be part of environmental monitoring and fieldwork could be done together with other investigations.

Some EU member countries already have many prerequisites for national environmental monitoring of organisms and habitats (biotop mappings, floristic mappings, forest inventories); still, the relevant data are scattered over different institutes. It is thus necessary to integrate all data into one central database. To meet the specific requirements of the Directive 2001/18/EC, additional monitoring parameters are to be introduced. Afterwards, observations are to be repeated regularly (long-term monitoring). The organisational establishment of a national environmental monitoring scheme takes (including a test phase) a number of years and should be projected as soon as possible.

Among international examples for nation-wide monitoring programmes is the "Countryside Survey 1990" in Great Britain and the "Ökologische Flächenstichprobe" in Germany.

One of the most comprehensive projects to survey the changing countryside on a nation-wide scale was carried out in Great Britain by way of the "Countryside Survey 1990" (BARR et al., 1993). Satellite data were combined with field datas. The fieldwork was carried out in sixyear intervals (1978, 1984, 1990). The sampling units were areas of 1 km² size. The data gathered in the "Countryside Survey 1990" make up a gigantic ecological database (Countryside Information System; CIS), in which for each square kilometre of the land grid information can be retrieved (e.g. agriculture, soils, climate, allocation of the species, socio-economic data). The data are graphically processed by means of the GIS; and any issue can be demonstrated in a map relating to nation-wide areas.

In Germany, the "Ökologische Flächenstichprobe" is being prepared to be a nation-wide sampling survey of the countryside that is roughly similar to the "Countryside Survey 1990" in terms of methodology (BACK et al., 1996). It is aimed at establishing a nation-wide, uniform

information system on the state and change of types of biotops (from TRAXLER, 1998). In Austria, a number of initiatives on the biodiversity of cultivated land are being carried out that aim at representatively identifying indicator organisms and structures of cultivated land in a national survey grid (WRBKA et al., 1999).

3.1.3 Ecosystem monitoring of environmental effects of GMOs

The requirements of Directive 2001/18/EC in relation to the monitoring of environmental effects of GMOs are at least theoretically based on ecosystems. In practice, on an international level, ecological monitoring of GMOs is currently confined to few survey parameters and issues. However, it would be possible to establish a long-term ecosystem monitoring scheme for the environmental effects of GMOs in one or more locations after GMOs have been placed on the market. Such scheme should be similar in scope to projects like "Integrated Monitoring" (MIRTL, 1996), the MAB project "Ecosystem Research Berchtesgarden" (KERNER et al., 1991) or the "Pilot Project for Biosphere Reservoirs" (SCHÖNTHALER et al., 1994).

These projects are aimed at initiating interdisciplinary environmental monitoring on an integrated, ecosystem basis. For instance, vegetation-related monitoring is implemented at the levels of individual, population and countryside and is only part of an "ecological balance model" used to study ecosystem quantities. One important focus is the balancing of substances, energy and water in ecosystems. The high degree of interdisciplinarity and the fact that abiotic and biotic processes are considered in their entirety would combine to supply significant findings for the monitoring and risk assessment of GMOs. Ecosystem monitoring could be carried out in addition to the limited programmes for case-specific monitoring and general surveillance. Ecosystem observation of GMOs is of course to be adjusted methodologically to the special requirements. The costs of ecosystem studies are considerable!

3.1.4 Monitoring of the state of the art

The monitoring programmes for GMOs must remain open to change. It does not make sense to verify the outcrossing of oilseed rape "for the twohundredth time" in field experiments, if this does not change anything in the basic conclusion and in risk assessment. For instance, it is enough to know that the probability of outcrossing under open environment conditions is high and actually takes place ("need to know – nice to know").

Since it became known that from the outcrossing potential resulted a potential risk to the environment, monitoring studies concerning environmental effects of outcrossing should in future be reinforced.

Thus, it is necessary to observe the state of the art on a long-term basis, which could also be termed monitoring. For this purpose, all relevant studies must be upgraded and processed in terms of subject matter. Such monitoring is carried out for example by TAB – the Technology Assessment Bureau of the German Parliament (TAB, 1999). The findings of such monitoring should be processed by way of an international database that is accessible to the public. Institutions that work on environmental effects of GMOs should on their own account forward their findings to the monitoring institution. It should be considered that the authorities of the EU member country take part in coordinating the flow of data of national studies and projects to a central European monitoring institute.

By means of such monitoring, ecological monitoring should be examined on a regular basis (e.g. every 3 to 5 years) as to the "meaningfulness" of the studies carried out in relation to the state of the art.

3.1.5 Monitoring as early warning system

An important function of ecological monitoring of GMOs is the early detection of undesired effects (cognitive aspect). **Early warning systems** based on organisms are not as efficient as technological early warning systems (e.g. measuring air pollutants) and often supply results too late, due to the slow and complex reaction of organisms and ecosystems. Early warning systems require clearly defined and measurable ecological standards (threshold values) that can be examined in time series (normative aspect according to AMMAN & VOGEL, 1999). When the standard is exceeded (like the flashing warning light in technological monitoring), a defined chain of action is triggered (examination, cause analysis, consequences for the causative substance, safety measures).

Early warning systems (in the field of organisms) are called for in many monitoring systems, yet seldom implemented. The definition of biotic threshold values often founders on account of the complexity of ecosystems reactions. Organisms and populations react to the most different environmental parameters in similar ways, and it is difficult to relate this reaction to a particular causative substance (e.g. a GMO). Still, the OECD for instance calls for the introduction of quantifiable environmental targets that can be examined in monitoring programmes. One example for one of the few monitoring programmes, in which quantifiable biotic parameters are examined, is the monitoring of biodiversity in Switzerland (HINTERMANN & WEBER AG, 1999). By means of 32 quantitative indicators biodiversity in Switzerland is observed in a nation-wide sampling grid. Another control programme using quantitatively controllable quality standards is carried out in the Swiss canton of Aargau (MAURER et al., 1997).

Since as yet a measurable ecological damage of GMOs has not been defined, the early warning function of undesired effects of GMOs can currently not be properly fulfilled. Monitoring remains confined to the general observation of certain parameters. Thus, findings can only afterwards be discussed and assessed. The flashing warning light and consequential actions are missing.

The threshold values for the monitoring of GMOs must thus be defined on a case-by-case basis for each individual experiment. General Directives to define threshold values should in future be developed on the level of the European Union.

3.2 Guidelines for the establishment and examination of ecological monitoring plans

The framework concept for monitoring GMOs (see chapter 3.1) should serve to establish general guidelines that enable

- monitoring plans by way of notifications for deliberate release or placing on the market to be examined as to their suitability for ecological monitoring and
- ecological monitoring plans for GMOs to be established.

The general guidelines for monitoring concepts are recommendations and should largely be non-case-specific and applicable to the consent of genetically modified plants. They are the basis for elaborating guidelines that are to be established of the Directive 2001/18/EC until 17 October 2002.

3.2.1 Guidelines for ecological monitoring for releases

1. Required data on the ecological environment of a release site

- Are there detailed data on the floristic and faunistic variety of species and on the structure of the habitats in and around the vicinity of the release site (from databases, biotop mappings, floristic mapping and additional field work; see chapter 3.11.3)?
- Are the species and habitats allocated to the respective degrees of threat and protection according to the "Red Lists", various relevant Directives and applicable national nature protection laws (see chapters 5.3, 5.5, 5.6)?
- o Is the release site allocated to the respective biogeographical region defined by the member state (see chapter 6.1)? Is there any indication of whether the preliminary studies carried out are roughly comparable to the situation of the region of the release site?

2. Method and design

- Are ecologically relevant issues strictly separated from issues of agriculture and molecular biology? Is there a separate module for ecological monitoring?
- Does the monitoring concept methodically suit the special risks of the habitat in which the GMO is released (see chapter 3.10.1)?
- Does the experiment design match the conceivable criteria of a "conclusive" statistics and is the subjective aspect kept as low as possible both in evaluation and assessment (see chapters 3.9.6 and 3.11.5)?
- Do size and experimental design of the release site meet the specific requirements of the particular issue to be studied? Notably zoological studies, given the high degree of mobility of animals, require sufficiently vast areas and sufficient distance to the reference area with the conventional reference variety (see chapters 3.11.1, 3.11.2, 3.11.5).
- Is the duration of the monitoring scheme conceived so as to be able to observe (at least) short-term changes?
- Are the monitoring parameters selected so as to swiftly detect environmental effects in an early warning function?
- Does the release site and its surrounding environment have appropriate habitats that can be surveyed for the purpose of ecological monitoring or are these habitats excluded on account of safety aspects (see chapter 3.8.1)? Has a middle course been found in the selection of the release site in order to postpone ecological issues not only to the period after placing on the market, yet keeping with a high safety level in case of unexpected environmental hazards?
- Is at least part of the ecological investigation carried out by independent institutes, and not by the notifier itself, in an attempt to increase the objectivity and acceptance of the monitoring?

3. Assessment criteria

- Have clearly defined and measurable target values, threshold values and suspension values for case-specific monitoring been established (see chapters 3.1.1 and 3.9.5)? Have action plans and action procedures been defined if one of said values is exceeded?
- Is there any information on which ecological targets (see chapter 5) are most likely to be affected by GMOs (according to the state of the art)?

4. State of the art

 Are monitoring studies adjusted to the state of the art of risk assessment and environmental effects of GMOs ("need to know – nice to know") (see chapter 3.1.4)?

5. Increased safety devices

Particularly **high safety provisions** for monitoring are required in the following cases (see chapter 3.10):

- o increased stress tolerance of the GMO (aridity, temperature, salty soils)
- releases in habitats out of arable sites (e.g. grassland, semi-natural habitats) (see chapter 3.10.1),
- o introgression capacity in closely related wild species (see chapter 3.10.3),
- o increased invasive capacity of the GMO

6. Public relations

Has the public been involved in establishing the monitoring plans and are there detailed data on how and within what time frame (intermediate) findings are made accessible to the public (see chapter 3.4)?

3.2.2 Guidelines for ecological monitoring for the placing on the market

Basically, the guidelines for monitoring in notifications of deliberate releases can also be implemented for the evaluation of case-specific monitoring after the placing on the market of the GMOs. General monitoring should be administered centrally by the competent authority, with the notifier proposing investigation parameters that should be taken into consideration in this national environmental monitoring (see chapters 3.1.2 and 3.8).

The notification should clearly distinguish between the tasks of case-specific monitoring in test fields and those of general monitoring in a nation-wide control system. The proposed duration of case-specific monitoring in test fields is to be set out.

3.3 Financing

One of the most important issues in implementing environmental monitoring of GMOs has not been clarified. Who is to pay for monitoring studies: the beneficiary, the notifier, the government or some EU fund? The directive 2001/18/EC provides no information on this subject.

The Environment Agency of Berlin (FEDERAL ENVIRONMENTAL AGENCY BERLIN, 1999) proposes to impose on the notifier the post marketing approval monitoring costs and certain parts of the cultivation-related monitoring within the framework of the consent. Long-term environmental monitoring, however, shall be the responsibility of national and provincial governments both in terms of conceptualisation and financing.

This financing scheme appears quite feasible and would suggest that the monitoring in releases in the test site and its environment is financed by the notifier. After the placing on the market, the notifier for instance bears the cost of case-specific monitoring for a defined period of time (e.g. 20 years). The cost for general environmental monitoring of GMOs are born by national and provincial governments.

3.3.1 Estimated costs of monitoring for releases

The total cost for ecological monitoring can hardly be estimated, since they depend on the implementation in each specific case.

The following is an attempt to very roughly estimate the annual payroll for the proposed monitoring studies taking the example of hybrid oilseed rape (notifier: PGS) on a single release site. It is meant to give an awareness of the approximate level of the costs. Still, it has to be considered with great caution, given the vague and hypothetical basic assumptions for the estimate.

Tab. 3: Rough cost estimate for	ecological monitoring for the	e release of PGS hybrid oilssed rape.

field	Person months/year	costs in terms of Euro
co-ordination and public relations	6	21,800
plant ecology	24	87,200
ornithology	*1	*3,634
entomology	10	36,337
soil microbiology	12	43,605
scientific assistants	30	87,200
average annual costs		279,797

^{*} Given the small size of the area of the release site, only restricted ornithological monitoring can be carried out in this particular case!

One person month is estimated at 3634 Euro; scientific assistants at 2907 Euro. The payroll for ecological monitoring of GMOs on a hypothetical release site is estimated at approximately 280,000 Euro.

In the first two trial years (preliminary studies and test planning) and in the assessment phase in the final year the costs may be higher than during the routine operation of the research.

In addition, a number of further costs may be incurred, such as

- overhead costs of the institute carrying out the monitoring scheme
- costs for technological devices (measuring instruments, traps, analysis, etc.)
- costs for leasing test sites and costs for management, etc.

This example of financing is not supposed to give the impression that the proposed research programme should be carried out for decades in any release site. Given the present high need for knowledge and the high degree of insecurity in risk assessment, in the first decades after a GMO has been placed on the market, the monitoring programme should be carried out in a comprehensive manner. As experience with transgenic cultivated plants increases many ecological issues will be resolved and expenditure for monitoring will decline. The research programmes are to be examined steadily as to their meaningfulness and intensity and to be adjusted to the current state of the art (see chapter 3.1.4).

Still, it has to be noted that ecological monitoring is only part of the research on a release site that is necessary to assess the risk. Costs for supplementary ecological research, agricultural monitoring, molecular-biological research etc. must be added.

3.3.2 Financing of post-marketing monitoring

After the placing on the market of GMOs, several research sites in cultivated land instead of the few release sites should be surveyed for **case-specific monitoring**. This will in total cause higher cost that cannot be estimated in this survey.

It can generally be assumed that the cost for case-specific monitoring will decrease as time goes by. As more and more knowledge is gained, the need for research gradually declines. The general implementation of monitoring (conceptual development, test planning, evaluation) will become ever more simplified on account of standardized guidelines.

If the **general monitoring** observation of GMOs is integrated into a standardized national environmental observation system, the tremendous costs will be split up. That part of research that concerns the monitoring of GMOs can be carried out simultaneously with other ecological studies (e.g. floristic mapping, bird mappings, etc.).

Since environmental surveillance is a long-lasting institution, the annual costs have to projected on an annual basis.

3.4 Participation of the public

3.4.1 Participation of the public as set out in the EU Directives 90/220/EEC and 2001/18/EC

The EU Directive 90/220/EEC (COUNCIL OF THE EUROPEAN COMMUNITIES, 1990), Article 7 leaves it at the discretion of the member states to provide for the hearing of certain groups or the public when a notification for the deliberate release into the environment of GMOs is filed. There are no more precise stipulations with respect to carrying out such hearings; EU member states have made use of this option with respect to legal enforcement and practical use in different ways (BERGSCHMIDT; 1995). There are no provisions in Directive 90/220/EEC as to the placing on the market of products that contain or consist of GMOs.

Since the lack of transparency and public acceptance has been recognized as the main reason for strong opposition from social groups and political decision-makers against the use of genetic engineering in agriculture (COMMISSION OF THE EUROPEAN COMMUNITIES, 1996), public participation in the new Directive 2001/18/EC has been increasingly taken into consideration. EU Directive 2001/18/EC, which replaces 90/220/EEC makes compulsory provisions with respect to informing the public and hearing of the public (or certain groups, as appropriate) within a reasonable time period for notifications of releases as well as for the placing on the market. In the case of notifications for releases the member states have to set up appropriate regulations. For notifications of placing on the market, the European Commission plays a key role in informing the public (forwarding summaries of the notifications, of the assessment reports, of comments by scientific committees). The public may deliver to the European Commission statements to the assessment reports within 30 days. The confidentiality of certain data is to be taken care of.

In the Directive 2001/18/EC the participation of the public with respect to monitoring plans is not explicitly referred to. To the extent that monitoring plans are parts of the respective notifications, the public is, depending on the provision, informed or may make statements.

3.4.2 Proposals for the participation of the public in assessing monitoring plans

The participation of the public in establishing and assessing monitoring plans in line with the respective legal provisions is considered a possible contribution to improve acceptance and to increase objectivity in the discussion around the use of genetic engineering in agriculture. Potential effects of GMOs may have a geographically far-reaching and long-term effect on the environment and should be detected by means of appropriate monitoring programmes. Thus, it is useful to integrate the public in the knowledge and provide it with the opportunity of making statements for elaborating and assessing monitoring programmes from a democratic and socio-political angle.

Moreover, the chance of a broader view and possible scientific improvement of the monitoring programmes to be elaborated, which the participation of the public may bring, must not be underestimated.

As is set forth in the new Directive 2001/18/EC, the public is to be informed on monitoring programmes as part of the notification files for notifications for releases and the placing on the market of GMOs. Still, notifications for the placing on the market of a GMO should not only be accessible through the European Commission, but also through the authorities of the member countries in charge of the consent procedure along the lines of notifications for releases. The ultimately binding monitoring programmes in the form of consents should also be made transparent and accessible to the public.

What is also considered advantageous in terms of consenus-finding is the broader and interdisciplinary integration of various scientific fields and interest representatives (e.g. universities, research institutes) in preparing monitoring concepts and – programmes and the relevant criteria (PFANZAGL, 1999).

3.5 Organization, implementation, competence

3.5.1 Competence for the monitoring of GMOs

Case-specific monitoring of GMOs will probably partly be implemented by the notifier. General surveillance, by contrast, is largely the responsibility of the member country. Other significant studies are carried out by research institutes within the framework of existing monitoring programmes. The relevant monitoring data will presumably be surveyed by a number of institutions. The collection, structuring, forwarding and administration of monitoring data and findings should be carried out by a central coordination office for the monitoring of GMOs (see figure 5).

The practical monitoring work cannot be done by a single institution, since the most varied fields of research must be included. It should thus be clarified soon which institutions are basically considered for this purpose.

The most important issues of competence in relation to the monitoring of GMOs are:

- What institutions have the capacity in terms of scientific competence and staff to carry out the most varied fields of ecological monitoring?
- Who is to coordinate and finance the general surveillance?
- Who is to coordinate and examine the definition of threshold criteria and suspension criteria?
- Who is to collect and administer the monitoring data and findings?
- Who is to be in charge of public relations?

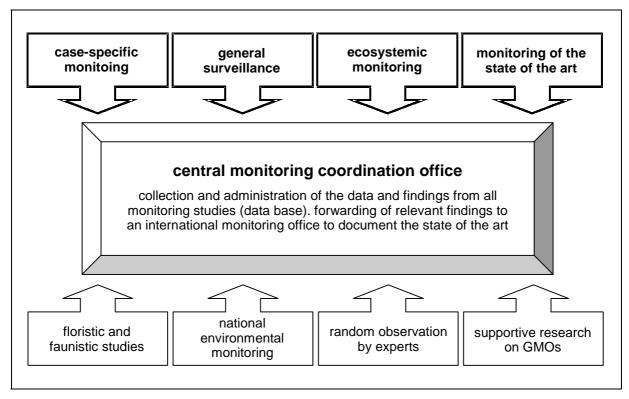


Fig. 5: A central coordination office should take care of the diverse tasks of monitoring GMOs.

3.6 Terminology

This chapter is to discuss certain terms that are used in connection with the monitoring of GMOs. It is to be noted that the definition of significant terms in monitoring GMOs is an important concern, but that has not yet been finished in Europe. Several task forces who were concerned with the terminology arrived at different conclusions. The Environmental Agency of Germany in Berlin (FEDERAL ENVIRONMENTAL AGENCY BERLIN, 1999) for instance construes the terms "case-specific monitoring" and "general surveillance" differently than the authors of this survey. The following terminology is thus a proposal for the European discussion that is ultimately to lead to a consistent terminology.

3.6.1 Safety research

Safety research refers to:

"the study of potential effects of genetically modified organisms in contained systems (laboratory, climate chamber, greenhouse, ...) and in releases as well as to the development of technologies designed to increase the safety of genetically modified organisms." (PFANZAGL, 1999).

Safety research is increasingly confined to research in contained systems (but partly also to releases) and is focused on damage prevention by increasing safety levels. Tests in contained systems are to clarify what risks could theoretically occur. The related studies are carried out under standardized ecological conditions. The results must thus not necessarily be relevant to open environments. Safety research supplies the fundamentals for risk assessment and concepts to recall GMOs in case of serious danger.

3.6.2 Unclear definition of related research and monitoring

The terms "related ecological research" and "monitoring" are not clearly separated in terms of meaning (see also AMMANN & VOGEL, 1999). Particularly as far as releases are concerned, it is not clarified what term for instance the calculation of the pollen travel distance or the hybridization rate are to be related to.

Related research is primarily concerned with the features of GMOs in comparison to conventionally cultivated varieties. Such features are for instance the germination rate, growth rate or the pollen weight of a GMO.

Monitoring is rather focused on the effects that may be caused by a GMO. If in an experiment a particular property (e.g. germination rate) is found to have changed, it is the task of monitoring to check if this triggers undesired effects (e.g. increased invasive potential). Related research must advance subjects and hypotheses that are clarified in the process of monitoring.

The unclear definition of the terms of monitoring and related research cannot be resolved in this survey and should be established in the general consensus, e.g. in the guidelines to be elaborated on Annex VII of the Directive 2001/18/EC. Still, the terminology is crucial for clarifying implementation competences and financing.

According to PFANZAGL (1999) "related ecological research" is defined as:

"studies limited in time of the ecological effects of genetically modified organisms in open environments, that is in releases or after placing on the market."

Such narrow definition of "related research" confined to releases and of "monitoring" confined to the placing on the market is not considered useful by the authors of this survey, since in the new Directive 2001/18/EC monitoring is also requested in releases.

The new Directive 2001/18/EC provides for two basic strategies in the field of **monitoring**:

- general surveillance of unanticipated adverse effects
- · case specific monitoring.

For more precise definitions, see also chapter 2.2.1.

In general surveillance to detect unanticipated effects it is not known at the beginning of the experiment what effects will occur when and where. The test design must thus aim at identifying appropriate parameters that are representative for areas as wide as possible. The chance to detect unanticipated effects is generally rather low and requires a long period of observation.

Case-specific monitoring identifies only selected problem-specific parameters that are very likely to detect even slight impacts of GMOs.

3.6.2.1 Post-marketing monitoring

The terms "post-marketing monitoring" and "cultivation-related monitoring" have been introduced and defined by the Environmental Agency of Germany (FEDERAL ENVIRONMENTAL AGENCY BERLIN; 1999). Both definitions refer to the terminology of the new Directive 2001/18/EC (case-specific and general surveillance).

Post-marketing monitoring refers to the observation of effects of a certain product over a limited period of time. It is based on specific issues in which there are uncertainties with respect to the assessment of a particular suspicion. It is the case-specific monitoring (according to the common position in Directive 2001/18/EC: "case-specific monitoring") that may be imposed on the notifier in the process of granting the consent (FEDERAL ENVIRONMENT AGENCY BERLIN, 1999). After the defined period of time has elapsed, the results may be used for the further consent of the product.

3.6.2.2 Cultivation-related monitoring

Cultivation-related monitoring refers to the observation of effects (weed growth, infestation with pest organisms, use of plant-protection products) of products or product categories (e.g. herbicide-resistant plants and complementary herbicides) in agricultural practice and the agricultural-ecological system. It is in line with the agricultural module of general surveillance according to Directive 2001/18/EC (FEDERAL ENVIRONMENTAL AGENCY BERLIN, 1999).

3.6.2.3 Sections of environmental monitoring

Environmental monitoring includes a variety of aspects that cannot be discussed in detail in this survey.

Among them is for instance the monitoring of **resistance phenomena** or the surveillance of measures of **resistance management**. Both of them are crucial sections of an environmental monitoring of GMOs (development of resistance in weeds or insects).

Another example is **agricultural monitoring**, which identifies data with respect to the agricultural behaviour of transgenic cultivated plants and only marginally addresses ecological issues. It is concerned for instance with the yield of GMOs, customary agricultural practices with respect to the use of GMOs, the effectiveness of herbicides and arising agricultural problems (e.g. in crop rotation).

3.6.3 Direct, indirect, immediate and delayed effects

In environmental risk assessment terms are used that are also relevant in monitoring and must thus be used consistently. The Directive 2001/18/EC (COUNCIL OF THE EUROPEAN UNION, 2001, Annex II) introduces definitions of the terms "direct, indirect, immediate and delayed effects".

"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.

"Indirect effects" refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management (note: e.g. changed use of herbicides or effect of transgenic hybrids).

"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.

"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.

3.6.4 Damage and risk

KÄPPELI & SCHULTE (1998) define these terms as follows:

damage: measure for the magnitude of a danger; the absolute extent of adverse effects

risk (in a narrow sense): measure for the magnitude of a danger, expressed in terms of a function of probability of the event of a damage and the potential consequence of the damage.

AMMANN et al. (1998) have developed a four-tier scale to assess damage:

Tab. 4: Definition of damage according to AMMANN et al. (1998).

degree of damage	definition
severe damage	dramatic changes in population densities, in the composition of populations (displacement of species), loss of ecosystem functions
medium damage	dramatic changes in population densities and in the composition of populations (functional changes).
slight damage	population changes that do not cause loss of function.
negligible damage	individual-based, short-term and reversible effect.

These general definitions of damage are approximate indicators independent of GMOs. In case-specific monitoring these general definitions of damage should be used to establish quantitatively verifiable (measurable) damage thresholds on a case-by-case basis for each GMO.

3.7 Interaction of risk assessment and monitoring

The first step in dealing with a newly developed GMO is always the ecological risk analysis, and not monitoring.

In risk assessment a potential risk is identified on the basis of

- the probability and
- the forecast consequential effect of a feature of the GMO.

In case the potential risk is deemed negligible, the remaining risk and unanticipated effects must be examined by means of monitoring of release tests or after the placing on the market.

The quality of the monitoring depends to a great extent on the quality of the risk analysis and possible results of related research or safety research. Only sufficient knowledge and experience permit to carry out a risk analysis that sets up relevant risk hypotheses for monitoring. Irrelevant or false hypotheses put case-specific monitoring on the wrong track. There can be no hypothesis-based case-specific monitoring without risk analysis.

Monitoring further generates new knowledge and experience on the environmental effects of GMOs. Such newly gathered knowledge becomes part of further risk assessment of GMOs and enables to set up future more effective hypotheses for more efficient monitoring. Monitoring and risk assessment in their interaction keep building up each other towards an ever higher quality level.

3.8 Monitoring in a tiered system from release to placing on the market

New transgenic cultivated plants are to be introduced by way of a tiered system, in line with the current course of action. In each grade safety research, related research and monitoring are implemented with different focuses in an attempt to increase the safety of GMOs. Monitoring must primarily be implemented after the placing on the market of GMOs; to a limited extent it can also be applied in release tests.

The research and monitoring focuses in the tiered system are positioned as follows:

- safety research in **contained systems** (laboratory, greenhouse, climate chamber).
- carrying out **environmental risk assessment** (risk estimate).
- related research and monitoring in **release tests** (studies for a limited period of time in release plots with safety measures and dispersal control).
- related research and monitoring after the **placing on the market** of GMOs (trade with and cultivation of transgenic cultivated plants).

Deliberate release means any intentional introduction into the environment of a GMO for which no specific containment measures are used. It is done by field tests in open environments.

Release tests are controlled field tests in a defined habitat section. The behaviour of GMOs in open environments and the hypotheses from related and safety research (of contained systems) are to be verified. In releases, the ecosystem environment lends itself readily to control. The risk of such tests is thus rather low compared to the placing on the market. The conclusions from the tests carried out allow only limited application to the situation after the placing on the market in an ecosystem. In a field test, issues of biodiversity or invasion biology for instance can hardly be resolved.

The **placing on the market** of GMOs means making GMOs available to third parties, whether in return for payment or free of charge. Transgenic cultivated plants may be grown. Monitoring after placing on the market theoretically includes in its surveillance function the whole area of a member country or, on an EU level, all member countries. In monitoring after placing on the market the limited hypotheses of the field tests must be verified on an empirical basis and unidentified remaining risks must be traced.

Tab. 5: Focuses of monitoring of releases and after placing on the market of GMOs.

monitoring of releases	monitoring after placing on the market
one or few field tests.	several field tests, possibly a nation-wide sampling network.
small observation sites.	vast observation sites.
limited period of time.	long-term monitoring unlimited in time.
test sites include risk-avoiding measures (e.g. surrounding seed) that may change results	observation takes place in normally managed or semi-natural areas.
ecologically valuable habitats are largely excluded from the test site.	focuses on the inclusion of ecologically valuable areas in the observation network.
agricultural conditions are to be adjusted to the test structure of the test site (e.g. small plots).	in test sites the usual agricultural conditions prevail.
results refer only to the situation of the examined release site.	results reflect the nation-wide environmental effects of GMOs after placing them on the market
special attention is given to the examination of potential risk factors (risk parameters)	focuses on the surveillance of ecological effects and adverse effects (damage parameters).
focused examination of particular features and parameters.	even complex ecological reaction may be monitored.
focuses on testing risk hypotheses and the acquisition of knowledge.	focuses on surveillance.

3.8.1 "Thirst for knowledge" versus safety in releases

Prior to placing GMOs on the market without restriction, tiered laboratory tests and controlled field tests in releases are carried out. Thus, the potential risk of GMOs is to be gradually minimized, increasing the safety level for unrestricted consent. Still, every new step in the tiered system holds a new risk to be identified. When the results of laboratory tests are satisfactory, the step into open environments may be taken, taking into account the risks involved (release). Only after the first release tests may it become clearer if the GMO has done any ecological harm in this test. In planning the test the question arises how much risk is to be taken in releases in order to assess potential environmental effects. If for reasons of safety the ecological risk in releases is largely avoided, the pressing ecological questions cannot be clarified. By contrast, if, in an attempt to clarify urgent ecological issues, rather endangered habitats are included in the release site, one possibly runs the risk of an ecological damage as early as in the release phase.

In releases it is often attempted to keep the risk of potential adverse effects as low as possible. According to the Directive 2001/18/EC (Annex III, COUNCIL OF THE EUROPEAN UNION, 2001) precautionary measures must be taken with a view to

- distance(s) from sexually compatible plant species, both wild relatives and crops
- any measures to minimize or prevent dispersal of any reproductive organ of the genetically modified plant (e.g. pollen, seeds, tuber).

The **safety-oriented strategy** attempts to largely prevent critical situations, such as the excessive occurrence of compatible crossing partners or the existence of habitats with a rich variety of species in the proximity of field tests. In release sites, due to the small size of the area, there are hardly any ecologically relevant structures of agroecosystems. This is in line with the ecological awareness that in tests involving potentially high-risk objects the risk of irreversible damage is to be kept as low as possible. Such damage cannot be ruled out in particularly rich types of cultivated land. Still, most ecological issues cannot be resolved by means of tests on a ruderalized strip of arable land with poor biodiversity.

Tests with a high level of safety have the advantage that during the release process unanticipated adverse effects are unlikely to occur, since the sources of risk have largely been excluded. However, the risk is thus minimized only in relation to this particular field test and the identification of the risk is thus switched to the next stage, that is related tests after placing on the market.

In selecting test sites, it is necessary to find a meaningful middle course that enables to clarify ecological issues even given high safety levels. The tiered system is thus to split the risk in a well-balanced manner.

It would be dangerous to shift all ecological tests for reasons of "safety" to the placing on the market in order to thus pretend a "safe" GMO in releases. Potential ecological risks are most difficult to control after the placing on the market and affect much larger areas than in releases.

3.9 Criteria of ecological monitoring

3.9.1 Time lags in testing

Long-term monitoring is a prerequisite for proving unforeseeable effects. The non-appearance of an effect in an experiment does not preclude its appearance at a later stage (TIEDJE et al., 1989).

Short-term tests produce short-term results. Long-term tests produce long-term results. Not even the use of more and more precise monitoring methods in short-term experiments will reduce the time lag (TRAXLER, 1998).

Release experiments have a time limit and can therefore only produce short-term results allowing at best the assumption that the risk of placing a GMO on the market can be estimated as low. To declare a GMO safe at this stage of the investigations is however not justified with respect to long-term effects.

When speaking about ecologically relevant time lags in invasive biology one refers to decades at least if not centuries (see Fig. 6). These time lags have to be accounted for in monitoring. It is entirely possible that the invasive character of GMOs will not be revealed until in 50 years' time.

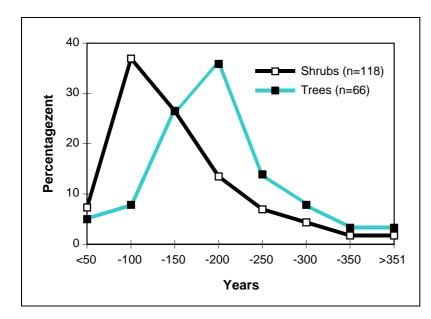


Fig. 6: Time lag between the first introduction and the start of the dispersal of 184 non-native wood species in Berlin and Brandenburg (KOWARIK, 1995). The graphic representation shows the distribution of time lags for 118 shrubs (including wooden liana; mean value: 131 years) and 68 trees (mean value: 170 years). The mean values and many of the individual values are considerably above the calculable life cycles in populationbiological terms of the species and describe the historical dimension of dispersal processes (from KOWARIK, 1998).

3.9.2 Measurability of parameters

There are **easy to measure morphological parameters** that can be determined by direct comparison of transgenic and non-transgenic cultivated plant species. Such easy to measure but time-consuming parameters include for example biomass, height of plant, growth rates, seed production, germination rate, flower morphology and flowering period. These traits are often used as indirect parameters for the interpretation of ecological characteristics of GMOs.

Ecological characteristics that are difficult to measure are for example invasive capacity and competitiveness. Although these ecological characteristics can partly be described with morphological characteristics, they cannot be determined or predicted with certainty. The characteristic "high seed production" may or may not be favourable for invasive species. It turns out that it is hardly possible to deduce certain effects from certain characteristics (TORGER-SEN, 1996).

The measurement of individual characteristics (as carried out in related research and release tests) is therefore suitable when formulating risk hypotheses and risk potential. It is not suitable for making definite statements about the safety of the tested transgenic plant.

The invasive capacity of a plant can therefore be determined only by empirical investigations, that is, by observing whether the transgenic plant can be found as an invasive species outside the arable field.

3.9.3 Comparison of transgenic and traditional crop plants

The direct comparison of the GMO and a comparable traditional cultivated species is a dogma in risk assessment. Related research checks whether the characteristics of the transgenic plant (excluding those modified deliberately) are different from those of the traditional species.

Direct comparison should not be more than an auxiliary method in GMO risk assessment. Risk assessment has to go beyond the level of simply comparing GMOs and traditional plants.

Direct comparison with the traditional species has its limits especially when it comes to analysing the test results. For example, if in the field tests the transgenic plant develops morphological characteristics similar to those of the traditional plant it is often argued that the GMO will display behaviour similar to that of the traditional plant once it has been placed on the market. This is however an assumption whereby general ecological behaviour is deduced from a few selected morphological traits that have been measured.

In competition tests the GMO is often tested in direct comparison with the traditional plant. In these tests only the relative competitiveness between the two species is determined but not their behaviour towards certain wild herbs.

The ecological behaviour of traditional crop plants is usually well known from years of agricultural practice. During the release period the risk factor of GMOs is higher because of the lack of empirical knowledge about their ecological behaviour. Obtaining the sum total of all GMO characteristics does not mean that ecological behaviour can be predicted with certainty.

Transgenic genetic material also poses an intrinsic GMO risk factor. For organic farming for example, which requires crops guaranteed to be free from genetic engineering, the presence of transgenic genetic material means a higher risk as it can be conveyed onto farmland by dispersal or pollen transfer. Similarly, it is a risk for biodiversity protection as it is stipulated that protected areas be free from genetic engineering.

Summing up, the assessed risk of GMOs is higher because

- no or little experience is available about the environmental effects of a new GMO and
- the GMO means intrinsic damage to organic farming or protected areas.

3.9.4 Risk and damage parameters

In monitoring **risk** and **damage parameters** can be investigated.

Risk parameters are isolated characteristics that may favour an ecological damage to occur in the future. The capacity for outcrossing for example is a risk parameter since outcrossing as such need not (but may) cause ecological damage.

A **damage parameter** must be stipulated beforehand as otherwise ecological damage cannot be clearly defined and measured. If for example the presence of GMOs in nature reserves or national parks is considered a damage because these areas are designed to conserve their natural diversity, the finding of GMOs in these areas will be a **damage parameter**.

GMO monitoring goes one step further with the following specifications of **suspension criteria**, which include the definition of a damage threshold. If this threshold is exceeded the notification for a product should be rejected or its commercialisation stopped.

3.9.5 Suspension criteria

One of the main objectives of the risk assessment is excluding unacceptable ecological risks (SCHULTE & KÄPPELI, 1996). Defining suspension criteria in monitoring can prevent the occurrence of unacceptable effects in most cases. Suspension criteria are measurable test parameters designed to decide over the placing on the market of GMOs or the suspension of their cultivation (AMMANN & VOGEL, 1999).

Currently there is no definition of ecological damage. It is treated by the individual interest groups according to their own subjective interpretation. While the intrusion of GMOs into ruderal habitats is considered a serious ecological damage by some ecologists with respect to biodiversity protection and floral alienation, others regard it as a normal and well-known process in agroecosystems.

Monitoring carried out without stipulated damage parameters and suspension criteria is purely observing the ecological behaviour of GMOs without a baseline for an assessment. Here discussions of the results (sometimes in the form of disputes) take place after the first tests. Then one refers to forthcoming monitoring results and awaits them. What is missing is the flashing warning light and an action plan. For the monitoring of air pollutants it would be unthinkable to measure pollutants first and then deliberate whether the measured concentrations might be regarded as harmful for humans.

A strategy without stipulated damage parameters is a degradation of monitoring. It is then merely an instrument that helps to keep the conscience calm in the absence of a political or social agreement on whether the definition of damage should be economically or ecologically oriented.

The definition of ecological damage by means of suspension criteria provides clarity about the assessment of results to come from the start of the tests and outlines a clearly defined procedure following these results (e.g. specific further tests focusing on certain issues or suspension of tests and notification).

Defining suspension criteria means raising fierce disputes and having to make unpleasant decisions. But it also means adopting a clear point of view regarding specific questions in risk research and thus enabling effective monitoring.

For each new GMO suspension criteria must be agreed in a step-by-step procedure by a group of experts from research, agriculture, industry and ecology. However such an agreement of experts necessary for the definition of suspension criteria seems unlikely at the moment (see Fig.1).

3.9.6 Analysis and interpretation of the results

A basic requirement is that the chosen test design enables a transparent analysis that is also as objective as possible. If test designs, individual stages of the analysis and evaluation criteria have been stipulated in the monitoring plan, subjectivity can largely be avoided. For example, the dispersal of the neophyte *Impatiens parviflora* can be seen as positive or negative in terms of nature conservation, depending on the (subjective) choice of evaluation criteria (increased species diversity or increased ecological interaction) (SCHMITZ, 1999). The original test data (without their analysis) should therefore be accessible for inspection by the competent authority.

The choice of statistical tests may settle the existence of so-called statistically significant differences. It also enables the results to be directed within a certain framework to fit a specific result model previously conceived.

If the significance level of the statistical tests is lowered to 90%, there is a high probability for a "type I error" to occur which means that an undesirable change which does not actually exist is wrongly assumed. If the significance level is raised to about 100%, a "type II error" is

more likely to occur, meaning that undesirable change is not noticed. A general requirement in ecological testing and early warning systems especially is that undesirable changes be recognised in time even if a "type I error" has to be accepted sometimes. Significance levels should therefore not be set too high (TRAXLER, 1998).

Statistically calculated results have to be analysed in ecological terms. Statistically significant changes are not necessarily changes relevant in ecological terms and vice versa.

3.9.7 Harmonisation and advances of monitoring techniques

Many of the methods and parameters currently used in plant-ecological monitoring are described in a manual entitled "Handbuch des Vegetationsökologischen Monitorings" (TRAXLER, 1998) of the Austrian Federal Environment Agency. This manual provides a general survey which helps choosing methods when planning tests in the field of plant ecology and compares the methods in terms of their practical feasibility, precision, significance, result quality, weaknesses, costs, etc.

In principle there is no single method that could do justice to the manifold requirements of ecological issues. Some methods and test parameters however tend to be frequently used. These methods have evolved from what may be called a "methodical evolution" over the last decades determined by two selective factors, namely financial resources and cost-benefit effect. It can be assumed that the range of methods currently used is feasible in financial and practical terms and, apart from a few compromises, produces acceptable results. However it has to be pointed out that better results could be achieved with a more sophisticated test design.

The frequent call for method harmonisation is justified for reasons of comparability. However, it must not hamper advances or improvements of methods. It has to be clear where the harmonisation of methods is essential for a programme to work as a whole or where specifically designed, problem-oriented techniques produce more efficient data.

3.9.8 Interdisciplinary aspects of area selection

Case-specific GMO monitoring should be conducted by groups of people specialising in e.g. plant ecology, soil microbiology, entomology who are selected in the risk assessment as the relevant experts. Each specialist group has its own priorities when choosing the best test areas. Release sites however should be selected under an interdisciplinary aspect. If possible, each specialist group should be working on the same site to allow for a more comprehensive interpretation of the results. In the case of placing GMOs on the market this is a requirement for case-specific monitoring only.

General surveillance is usually based on existing surveillance programmes used by each group of specialists. These programmes are not harmonised. The harmonisation of these programmes (e.g. through national environmental surveillance) should be aimed for.

3.9.9 Test networks in international co-operation

In principle, a European network of release sites (using the same methods to deal with the same issues) makes sense. Such European networks have been established by many initiatives in ecological research to identify regional aspects. New test sites confirm the results of existing ones and/or, if the results are contradictory, bring to the surface conclusions that cannot be generalised. However, investigations revealing only a few regional aspects should be subject to a cost-benefit analysis.

The question is where to strike the balance between higher costs and greater accuracy. The same question applies to the number of repeats required at monitoring plots where costs rise exorbitantly above a certain sample size while confidence levels hardly improve (see Fig. 7).

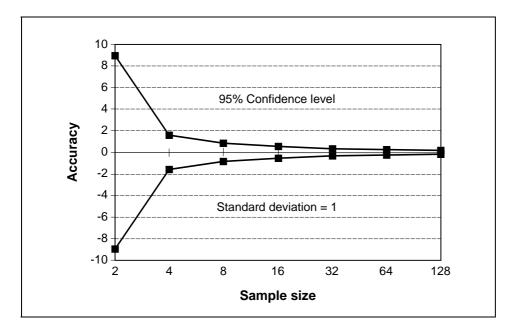


Fig. 7:
At a standard
deviation of one
and a confidence
level of 95%,
accuracy increases
only marginally for
sample sizes over
16 even when
doubling the effort
(according to
USHER, 1991).

International co-operation and the development of accessible databases providing detailed information on test parameters and current problems can help in the sensible use of the financial resources for monitoring and in avoiding unnecessary duplicate research (BRANDT, 1998).

3.10 Higher risk factors

3.10.1 Habitat of the area under cultivation

The habitat into which the GMO is released is crucial when deciding how intense the tests for the monitoring should be and for the test design. The test programme must be tailored to suit the habitat in question. Is the area under cultivation

- a field
- grassland (meadow)
- woodland
- wetland
- · a habitat influenced by man
- a near-natural habitat
- or else?

This study focuses on GMOs in agroecosystems. The risk in agroecosystems may be considered lower than on grassland because agricultural ecosystems created by farming are completely independent. If transgenic grasses are used on grassland, entirely different safety measures will have to be taken because man-influenced grassland resembles semi-natural grasslands (many ecological protection targets) in structural and coenological terms. Monitoring here would have to cover much larger areas. Transgenic woods also require a specific test design with the long life cycle of trees requiring a prolonged test duration.

3.10.2 Dispersal of GMOs into distant areas

The capacity for dispersal of GMOs is an essential criterion in the planning of the monitoring system. If species disperse by themselves, the test area will no longer be limited to the field area but include many other (semi-natural) habitats that may be at a considerable distance from the area under cultivation (see figures 9 and 10). Here GMOs and their ecological effects are no longer verifiable. At best they can be traced by sampling with a high level of uncertainty.

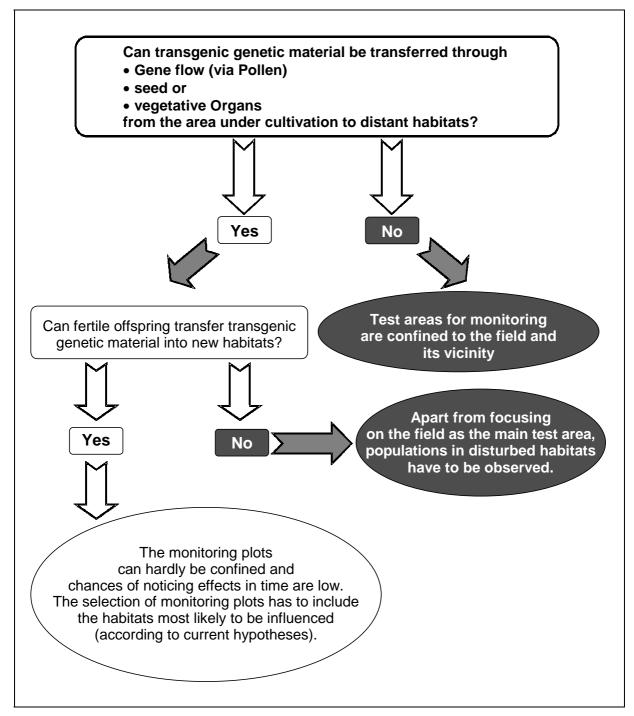


Fig. 8: Key questions relating to GMO dispersal capacity that are used for defining the monitoring strategy.

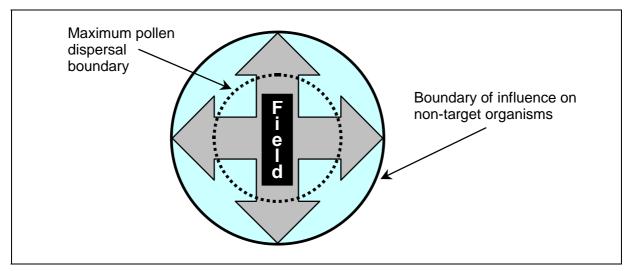


Fig. 9: Bt maize cannot establish itself permanently in habitats at a distance from the field. Effects beyond the field boundary are produced e.g. by pollen and concern above all nontarget organisms whose habitat is near the field. The shaded area shows the test area for monitoring.

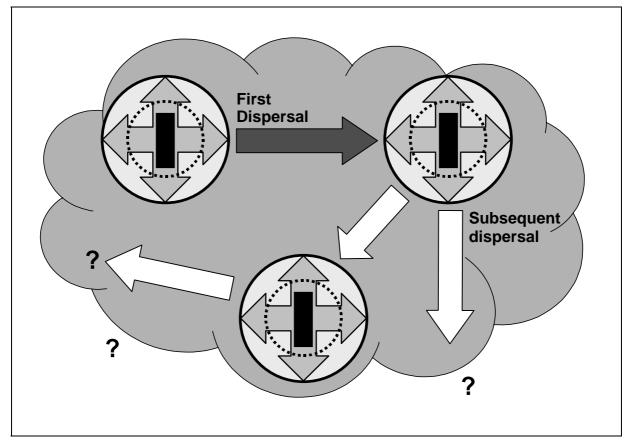


Fig. 10: PGS hybrid rape. Permanent establishment in habitats at a distance from the field cannot be excluded due to invasiveness, loss of seeds and outcrossing. Ecological effects beyond the field boundary are produced by the GMO itself, by its cross products, pollen and by herbicide drift. The shaded cloud with question marks indicates an unconfined potential test area that might have to be considered when monitoring these ecological effects.

In the risk evaluation, one should critically assess those potential ecological effects of transgenic organisms that are hardly verifiable in monitoring (e.g. potential introgression). Lack of predictability and insufficient verifiability are therefore categories of risk evaluation that require re-assessment.

3.10.3 Introgression of transgenic genetic material into related species

The ecological behaviour of a hybrid between the GMO and a closely related wild species (which has received transgenic genetic material by introgression) is unpredictable. The potential for introgression of GMOs is thus a factor of high uncertainty since the results of GMO release tests cannot be applied to the new hybrid.

The risk of GMO introgression can be assessed for each individual case by means of Dispersal Codes (according to DE VRIES, 1996). These codes will be developed for the whole of Europe.

Another high risk factor is the persistence of GMOs (e.g. seed persistence).

3.11 Experimental requirements for test sites during the release and placing on the market of GMOs

3.11.1 Test design on release sites

Release test sites are plots of farmland (sizes < 1 hectare up to several hectares) where initial field investigations are carried out according to the safety requirements.

The release test site is divided into small plots for cultivation with buffer zones between them (see Fig. 11). On one plot a specific species is cultivated and managed according to specified measures. This experiment is usually replicated on several other plots. From the individual plots samples are taken which are designed to satisfy the statistical criteria of data analysis. From one test plot samples are usually taken for several working groups, often by using destructive methods, which means that these areas will not be available in the future because they have undergone "experimental" changes for testing purposes.

Around the test sites there is a safety zone where it is not allowed to cultivate the traditional variety of the transgenic species being tested. Here samples are taken to examine the dispersal problem (GMO pollen and seeds).

At the Roggenstein test station of the Munich University of Technology a test site of the size of 60 x 114m (0.7 hectares) was established for the release of maize and winter rape. Around the test site there is a surrounding zone twice 3m wide with traditional plants with intercepted pollen production (ERNST et al., 1998; FISCHBECK, 1998). Plots where transgenic plants were cultivated were replicated three times, plots with non-transgenic varieties six times. The individual sub-plots are small-sized areas (about 15 x 6m).

Within a radius of 600m it was not allowed to cultivate maize or rape. In this zone plants were placed to receive the pollen.

With the test plots of GMOs and those of the comparable traditional plants being so close to one another, the test design of the Roggenstein site is hardly suitable for monitoring birds and insects. This requires larger areas under cultivation and greater distances between the area with the transgenic plant and that of the comparable traditional plant (mobility and habitat size of animals!).

For ecological issues the structural elements of agroecosystems are also important (e.g. field boundaries, balks, fallow land).

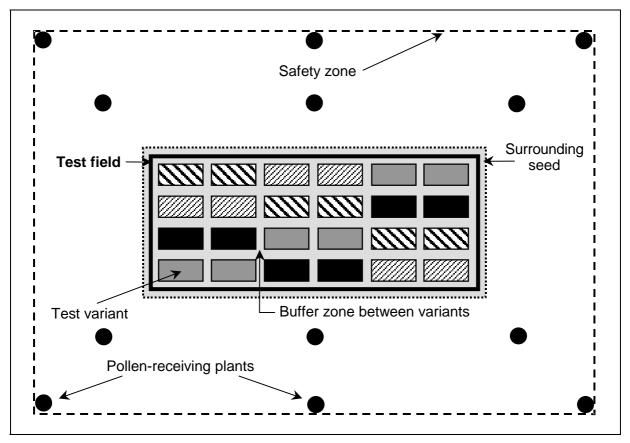


Fig. 11: Schematic design of a test site for GMO releases. In the test field 4 variants are tested six times. The striped variants represent GMOs, the solid shaded variants the comparable traditional plants (changed according to ERNST et al., 1998).

3.11.2 Test field size

Release test sites usually cover a small area. For the cultivation of all test variants (including buffer zones) often less than 1 hectare is available. A field size of 5 hectares (as in the case of the release of Liberty Rape by AgrEvo in France (AGREVO, 1999) is considered large. The actual test area however goes beyond the field size and includes the safety zone that surrounds the release site. The dimensions of the large test areas of bird monitoring are however hardly ever reached with GMO releases. For ecological issues the presence of the structural elements of agroecosystems is necessary in the test field or in the vicinity.

3.11.3 Basic floral survey of the release site

Detailed preliminary ecological investigations (species and habitats) at the prospective release site are necessary for safety reasons (potential cross partners, protected areas) and for the test approach itself.

The specifications for the monitoring of the release of GMOs should be accompanied by a complete list of the species in the surroundings of the release site. There should also be separate lists of the species in all neighbouring quadrants of the site.

There must be a table giving the categories of threat for the individual plant species according to the Red List of Endangered Plants.

Species protected by ordinance under the relevant nature conservation act or mentioned in Annex II of the **Flora-Fauna-Habitat Directive** must be listed.

The list of species should be updated and completed directly on the release site and within a radius of 1 km by specific mappings with particular attention being paid to the wild herb flora of the field and potential crossing partners of the GMO.

3.11.4 Homogeneity criteria

The planning of the test design requires a complete survey to clarify the criteria of homogeneity before the start of the test.

One usually assumes that the area within a test site is relatively homogeneous. This can be clarified by investigations of the vegetation or soil samples. There are no areas that are fully homogeneous but the relevant measurements alone will be useful for the assessment of future test results (transparency requirement in preliminary testing). At inhomogeneous test sites, there have to be more repeats than at homogeneous sites to obtain the same statistical significance. The number of repeats required can be determined (with certain restrictions) with statistical tests before the start of the experiment. One has to assume that the test parameters are distributed over the time scale in the same way (same variance) as in the preliminary survey. This is more likely to apply to the more stable parameters such as certain soil properties than to the parameters of vegetation which are more fluctuating. It often makes sense to include special places such as wet field depressions in a test site. They can be tested separately by way of "stratified sampling", constituting a different test variant.

The area of the test site and its individual test variants is usually too small. This causes a number of methodical problems. Usually only a few questions can be addressed in a few repeats.

3.11.5 Test design, spatial replications

The number of repeats (spatial replications) of a test variant is usually restricted due to financial limitations. This is always a problem with scientific work. The less often an experiment is repeated, the less reliable the results are and the more likely they are to be subject to the whim of chance (see also Fig. 7).

3.11.6 Destructive methods and disturbance effects of test plots

Destructive methods are procedures whereby the test area is disturbed as a result of sampling. This may lead to experimentally distorted results. The destructive harvesting method used for the assessment of biomass is one example. Taking away the vegetation means that more light falls onto the surface, causing an accumulation of weeds. These weeds can then renew their pool of seeds there but nowhere else on the test field. Over several years this chain of consequences gives an example of how results can be distorted unintentionally. Where destructive methods are used for testing the test plots have to be large enough so that areas where destructive sampling has taken place can be marked and excluded from further testing.

On agricultural field plots the taking away of biomass at harvesting time does not have a destructive effect because the whole plot is managed in the same site-specific way.

Other artificial disturbances of test sites are the "trampling effects" caused by scientists investigating the test areas. Often the sampling point cannot be reached from the edge of the plot. By treading on the ground the flora of the plot is pressed down or damp soil is compressed.

With interdisciplinary projects involving several groups of specialists working in the same place, disturbances between these groups are likely to occur. In these cases, a site plan of all areas under observation may help as well as a visual guidance system for the investigations. String of different colours on the ground can be used to indicate the paths and closed areas of the individual groups. It is also helpful to keep an interdisciplinary work diary where the test areas are entered and the times specified when the individual groups intend to work there as well as the times when disturbances should absolutely be avoided (TRAXLER, 1998).

Natural disturbances of an experiment caused by herbivorous insects, snails or mammals (rabbits) and infestation with fungi can have a considerable influence on the test results (BAKKER, 1998; HANLEY et al., 1995; SILVA & TERESA, 1992). Taking specific protective measures often prevents this. Detailed notes should be made of undesirable disturbances as they may lead to the wrong conclusions in the data analysis.

4 MONITORING PARAMETERS AND TEST METHODS

The abbreviated English version of this study includes only a brief outline of the monitoring methods. A detailed description can be found in the full German version by TRAXLER et al. (2000).

The relevant investigations for the monitoring of GMOs include tests examining the invasive potential of GMOs, their outcrossing rate and outcrossing frequency as well as competition tests and investigations of diaspore bank and diaspore fall as well as germination rate and germination ecology.

4.1 Standard parameters and methods of plant ecology

For the monitoring of transgenic plants the vegetation has to be of key importance since it has a vital function for many animal groups as a food resource (e.g. insects, flower-visitors) or as a structural factor (e.g. birds).

A detailed description of the methods and survey parameters used in plant ecological monitoring can be found in the manual entitled "Handbuch des Vegetationsökologischen Monitorings" (TRAXLER, 1998) of the Austrian Federal Environment Agency. These methods and parameters will be mentioned here only by way of example. The methods currently used were developed for the testing of (natural) plant populations over a time scale. In GMO monitoring they are suited particularly to the observation and surveillance at phytocoenosis level (e.g. wild herb populations). For more specific questions relating to crop plants or individual traits the specific methods of population biology and agricultural technology have to be applied.

Frequent test parameters and methods:

- cover values
- numbers of individuals (density)
- biomass
- frequency
- · total numbers of species
- phenology
- vegetation structure (horizontal and vertical).

Plant ecological methods:

· vegetation cover

- o visual cover estimation
- line-intercept method
- o point-line method
- point-quadrat method
- o point-centred-quarter method
- o planimetering of cover values by photography.

• numbers of individuals

o counting.

vegetation structure and biomass

- harvesting method
- o height measurements for phytomass estimation
- o estimation methods
- o counting methods
- o light methods
- o picture analysis methods.

phenology

- o phenological survey according to DIERSCHKE (1972, 1989, 1994)
- o phenological survey of generative development (WEBER & PFADENHAUER, 1987).

frequency

- o determination of frequency according to Raunkiaer
- point-quadrat method (point-touch method)
- o nested plots
- o frequency-score method
- o importance-score method.

• Other methods:

- o photo-monitoring
- o mapping
- o remote sensing
- o retrospective monitoring.

4.2 Biochemical monitoring methods

Tests focusing on the running wild of genetically modified plants and outcrossing with related species should be part of every monitoring programme. Genotypic methods may be used to identify the modified genetic substance as well as methods to identify the phenotypic effect of the genetic modification.

Test focuses:

- running wild
- · outcrossing
- phenotype of GMO (ELISA method)
- genotype (PCR or Southern hybridization).

4.3 Ornithological monitoring methods

Agroecosystems are habitats for a large number of (threatened) bird species. In view of the conservation of species diversity, the protection of habitats of special importance in ornithological and other terms has been formulated as a priority protection target. The purpose of ornithological monitoring is to investigate the effects of GMO cultivation on the avifauna. The focus of the monitoring is on indirect effects via the food chain.

In general, birds are suitable indicators. There are however methodical problems. Ornithological monitoring only makes sense if the area under GMO cultivation is larger than 10 hectares (bird mobility). With smaller areas ornithological questions can only be dealt with to a limited extent.

Methods of ornithological monitoring

- point taxation
- · line taxation.

Ornithological monitoring parameters

The following test parameters shall be recorded under standardised conditions:

- · bird species
- their sex (male, female, young bird) and
- abundance (number of individuals)
- classification in behavioural categories (breeding, song, feeding, resting) and
- food-ecological parameters for animals in search of food (stratum used, food, etc.).

Where applicable, the following additional parameters may be included in related research:

- · conspicuous behaviour of birds
- · finding of dead birds
- orphaned nests (sterile eggs).

Priority issues of ornithological monitoring

The investigations should focus on GMOs that might have an effect on the food chain. These are essentially plants which

- might cause changes in insecticide and herbicide use,
- · might have toxic effects on birds,
- become less attractive as a food source for birds due to modified ingredients and
- might cause structural changes on the area under cultivation and on non-target areas.

Contextual aspects

- 1. The relative abundance of individual species on the GMO field is compared to the year before the cultivation of transgenic plants and to previous years.
- 2. The changes in the relative abundance on the GMO field are compared to the reference area.
- 3. Population change at breeding time are compared to the results of the monitoring in general. Do these developments reflect a general (national) trend in population fluctuations or are they confined to the GMO cultivation area?

Additional parameters for related research

- · veterinary-medical examinations of dead birds found
- · biochemical examination of eggs found
- · reproduction-toxic investigations
- animals with conspicuous behaviour
- · breeding-biological investigations
- density of skylark (Alauda arvensis) as indicator type
- dispersal of GMOs through birds.

4.4 Entomological monitoring methods

The monitoring methods described here shall help to determine the potential effects of the cultivation of transgenic plants on the entomological fauna of agroecosystems. With various methods the numbers of species and individuals on the test field (area cultivated with transgenic plants) are determined as well as on representative comparable and neighbouring areas. As the monitoring of insects requires considerable effort, it is advisable to restrict the survey to character and indicator species that are typical of the field fauna. Ground beetles, butterflies, grasshoppers and flower-visiting insects are suggested as suitable indicator groups. Infestation with pests and their natural predators ("beneficial animals") constitute another aspect of monitoring.

Although most insects are small and inconspicuous they play an important part in the ecosystem as a whole due to their large numbers of species and individuals. Because they have complex habitat requirements many insect species are suitable bioindicators for the assessment of certain habitat conditions and biotope qualities on cultivated land. They are well suited to biotope investigations and assessments. However, the basic requirement for these investigations is a sound knowledge of the taxonomy, geographic range, ecological requirements, abundance and the degree of threat of the relevant groups and species.

4.4.1 Entomological methods and parameters

Selection of representative insect groups

Because of the species and individual richness of insects it is not possible to survey and verify the entire insect fauna. For the monitoring investigations representative insect groups therefore have to be selected.

According to SOULE & KOHM (1989) species of ecological relevance for monitoring and management should be selected from the following three categories:

- keystone species whose disappearance entails the extinction of many other species
- mobile link species constituting important functional components between several food chains or animal-plant associations
- indicator species serving a particular interest in environmental monitoring or management measures.

The selection of the animal groups should be made according to the relevant habitat.

In agroecosystems (fields, field boundaries and meadow habitats), MÜHLENBERG (1993) and FINCK et al. (1992) suggest the following groups of anthropods for investigations being **relevant for nature conservation**:

- spiders (Araneae),
- butterflies (Rhopalocera, Hesperidae, Zygaenidae),
- ground beetles (Carabidae),
- grasshoppers (Caelifera, Ensifera)
- and maybe also:
- hoverflies (Syrphidae) and
- some aculeate Hymenoptera.

Any other groups have to be taken into consideration according to the issue at hand.

Since the use of pesticides and pest-resistent GMOs on the arable field is designed to reduce pest infestation, their effect on the target organism (but also on non-target organisms) is of key importance. In this context the following insect groups also have to be taken into consideration:

- Crop-feeding insects ("pests"): phytophagous insects (e.g. aphids, leaf beetles, weevils, blossom beetles). The groups most relevant for the crop under investigation have to be determined.
- Natural enemies of pests ("beneficials"): predators and parasites (e.g. parasitic wasps, lacewings, ladybirds, hoverfly larvae).
- Flower-visitors (dipterans and hymenopterans such as different bee species, hoverflies, blossom beetles) on the field under cultivation and adjacent areas.

Entomological survey parameters:

- number of species
- · number of individuals
- spatial and temporal distribution of species and insect groups
- degree of crop infestation or abundance of pests on the crop
- dissemination of transgenic pollen by insects.

Methods for selected insect groups:

- · ground beetles: pitfall traps
- butterflies (visual observation along transects and of flowers)
- grasshoppers (counting, nets, acoustic population survey)
- hoverflies (nets, flower visit observations, malaise traps, maybe larval survey)

To identify crop infestation on the field under GMO cultivation, the methods common in agriculture are also applied:

- counting (visual check) flowers, buds, tips of shoots, leaves and fruit after egg deposition, larvae or imagines or after visual damage
- catching pests with traps (yellow traps, nets)

Apart from restricting animal groups (insect groups) to a few well-known and significant groups (\rightarrow indicator groups and species), it is important to:

- optimise the method selection (e.g. reduce trap numbers to a minimum)
- target the times of investigations (e.g. investigations carried out only during the main active time of the relevant animal group).

4.5 Soil analyses

The function of soils is determined above all by the activity of soil organisms. Soil microorganisms (bacteria and fungi) have a key position because they decompose organic matter and thus influence the nutrient cycle. They depend on the activity of the soil fauna (e.g. collembolans) which decomposes litter and plays an important role in structuring the soil. Harm of soil micro-organisms caused by changes in the use of herbicides or of soil arthropods by using Bt plants may mean that important soil functions are lost.

The analysis of soil micro-organisms requires a high effort due to their heterogeneous distribution. Most monitoring programmes do therefore not include comprehensive analyses of soil

micro-organisms or soil-functions. The recommended procedure for the Austrian long-term soil observation (BLUM et al., 1996) for example stipulates only two parameters (microbial biomass and nitrogen mineralisation) in its basic programme. Analyses relating to the aspect of diversity are not even mentioned in the supplementary programme. It is often difficult to interpret the results of these analyses because distribution and activity of soil micro-organisms are subject to considerable temporal and spatial fluctuations. Also, there is a continuous development of new methods that are applied in this field, which makes it difficult to develop of a standardised procedure.

The function of the soil as a habitat for animals and as a site of vegetation is largely determined by microbiological processes (KENNEDY & SMITH, 1995). Micro-organisms are in close interaction with the soil fauna (decomposition and mixing of litter, transport) and the roots of vegetation (nutrients, symbioses, root exudates). If this complex system is disturbed, important functions may be lost and crop yields reduced.

Soil analysis is especially important where genetically modified micro-organisms are released because little is known about the behaviour of particular micro-organisms. Horizontal gene transfer (much more likely to occur among bacteria than between bacteria and plants) may transfer new characteristics. Introducing a competition-enhancing characteristic may result in the elimination of species. The possibility of alterations of whole ecosystems due to the introduction of bacteria changing the nutrient cycle should also be considered. Nitrogen-fixating bacteria may enter soils poor in nutrients changing the vegetation by enhancing the nitrogen availability. Contrary to the common opinion, bacteria may spread over a wide area by transport by water (rain) or the wind (TEBBE, pers. comm.).

When developing monitoring plans, the following protection targets need to be considered:

- conservation of the function of the soil with respect to its habitat functions,
- · conservation of soil fauna diversity and
- conservation of soil micro-organism diversity.

Methodical approaches for the monitoring of soil organisms in connection with transgenic plants are described in detail by HEISSENBERGER et al. (1999).

4.5.1 Soil microbiology/soil function

4.5.1.1 Parameters

The following parameters should be assessed under standardised conditions as part of a monitoring programme:

- basic survey of soil parameters
- biomass
- nitrogen fixation
- soil respiration
- soil enzymology/metabolic acitivity
- diversity of soil micro-organisms
- indicator organisms.

4.5.1.2 Methods of basic soil analyses

- soil profile
- soil type
- · skeleton content
- soil colour
- colour pattern and concretion
- carbonates
- soil structure (soil fabric)
- porosity
- · root content in the soil
- biological mixing
- humus.

For agricultural areas,

- farming management and plot data
- crop type and yield quantity
- soil management (depth and type)
- fertilisation (quantity and type)
- use of pesticide (quantity and type)

should also be assessed.

The methods that should be applied have been described in BLUM et al. (1996) and in the literature referred to therein.

4.5.1.3 Soil function

Soil function depends to a large extent on the abundance and activity of the micro-organisms living in the soil. To monitor soil function, the assessment of basic soil-microbiological parameters is therefore essential.

- **Biomass** (viable cell counts or quantification of microbial cell components)
- Nitrogen mineralisation
- **Soil respiration** (CO₂ production, oxygen intake or heat output (ALEF & KLEINER, 1989) or adenosine triphosphate (ATP) content
- Soil enzymology/metabolic activity.

The enzymes that are analysed most often are:

- proteases: determination of protein and peptide decomposition
- ureases: measurement of hydrolysis of urea, important parameter when urea containing fertilisers are used
- phosphatases: cleavage of phosphate from nucleic acids or glycerol phosphate
- *cellulase:* cellulose decomposition, one of the most important mineralisation processes in the soil
- xylanases: used mostly in agricultural used soils because of their low cellulase activity The methods to be used can be found in ALEF (1991), SCHINNER et al. (1995) and SINSA-BAUGH et al. (1991).

BIOLOG microtiter plates can also be used to measure the potential decomposition.

4.5.1.4 Diversity analyses

For a long time the analysis of microbial communities had been limited to the analysis of cultivable species. Characteristics of pure bacterial cultures in the laboratory however tell us little about their behaviour in natural ecosystems. The methods of molecular biology have shown that the diversity of micro-organisms in the soil is much higher than revealed by cultivation-dependent methods (TORSVIK et al., 1990). Diversity analyses of bacterial communities are usually carried out by identifying variations in the 16S-rRNA coding gene (rDNA). Similar to the 16S-rDNA of bacteria, 18S-rRNA genes can be used for the analysis of fungi.

For cultivation-independent analyses of microbial populations, fatty acid profiles of microorganism communities can be made from the phospholipid components of cellular microbial membranes (LECHEVALIER & LECHEVALIER, 1989).

Identification of changes in the number or behaviour of indicator organisms

For monitoring purposes, the exemplary surveillance of a few microbial species or groups that are typical of an ecosystem makes sense. These bacteria and fungi should either be especially abundant or play a key role in the biological activity of the soil because of their metabolic activities.

Cultivable micro-organisms can be characterised after cultivation in selective substrates, by analysis of the colonies using phenotypic (e.g. Gram staining, BIOLOG system) or genotypic traits (RFLP analysis of the 16S- rRNA genes).

The number of selected soil bacteria can be determined by means of immunochemical identification and quantification (SCHLOTER et al., 1993). The *in-situ* hybridization of bacteria cells with fluorescence-marked oligonucleotides is a more recent molecular technique.

4.5.1.5 Zoological soil investigations

The soil is inhabited by a large number of animals of different types and sizes. They play an important role in the mineralisation processes and in structuring the soil. To classify the organisms in the soil by their functions, their size and way of nutrition are often more relevant than the taxonomy (SCHINNER et al., 1995).

For monitoring purposes at least a rough **taxonomic classification** and an investigation of the density, i.e. of the **biomass** should be carried out. The analysis of the micro-fauna is done from soil suspensions directly under the microscope. The analysis of the meso-fauna and macro-fauna is carried out from soil samples after extraction using a temperature, moisture and light gradients.

5 ECOLOGICAL PROTECTION TARGETS IN AUSTRIA

Risk analysis is always embedded in a framework of values. The sites, organisms and ecosystems that are deemed worthy of protection must be specified (MÜLLER & LINDENTHAL, 1999). In this chapter a few ecological protection targets will be suggested for Austria. Ecological protection targets have to be stipulated by each individual Member State.

GMO risk analyses are concerned with the as yet "unknown" transgenic plant. The fact that we do not know enough about the ecological protection targets that might be affected by GMOs is often not considered. Here the results of national research in nature conservation and basic research provide information. LATOUR & REILING (1994) propose the following basic aspects for risk analyses in the environment ("comparative threat analysis"): description of the area, use of land, protective status, etc. This chapter lists the basic ideas of nature conservation research that may be used for GMO risk analysis at national level. They include ecological protection targets such as Red List species, endangered biotope types, plant populations and cultivated areas deemed worthy of protection, biodiversity centres and organisms and habitats that are protected by law. Particular attention is paid to protection targets of agroecosystems which are currently most likely to be affected by GMOs. Protection targets on grassland that might be seriously affected by the potential use of transgenic grasses are not considered here.

The relevant test objects (species, habitats, species diversity, plant populations, indicator groups) are chosen in line with the concept of ecological protection targets, providing the basis for the ecological monitoring of environmental effects of GMOs. For it is not the main objective of general monitoring to gain knowledge (this is the aim of research), but to protect areas, species and biotic communities of ecological significance.

The ecological protection categories presented in this chapter are not necessarily under legal protection but are regarded by ecologists as valuable habitats or groups of organisms. The protection targets mentioned here are endangered or declining irrespective of the use of GMOs. The relevant protection targets should be stipulated in the monitoring guidelines of the directive 2001/18/EC.

5.1 Habitats of agroecosystems

Biotopes in agroecosystems (geographic vicinity) or biotopes offering favourable conditions for the establishments of new plants (e.g. wood-free areas, ruderal areas) are at a higher risk of GMO invasion. Although GMOs may in theory influence all habitats the focus is here on habitats situated in agroecosystems or on habitats that are most likely to be influenced (seminatural habitats with characteristics similar to fields). These are fields, agrotopes, ruderal biotopes and dynamic wetland areas.

5.1.1 Man-influenced pioneer biotopes

5.1.1.1 Fields

The primary goal is the conservation of extreme forms of arable soils such as

- sandy soils
- calcareaous soils with a tendency to dryness
- · acid soils poor in nutrients
- upland fields in dry inner-Alpine valleys
- extremely wet heavy soils (wet depressions).

Entomologic aspects of agroecosystems

Agroecosystems are characterisized by short-lived crops of one type (monocultures) and a low diversity (of flora and fauna).

Apart from typical pests, such as aphids, leaf beetles, weevils, sawflies, gall midges and grass fly species which are characteristic for all types of crops and which occur in high abundances, "indifferent" species and "beneficials" are present (see table 6).

Table 6: Examples of beneficials (Arthropoda) in agroecosystems.

Family	Species
wolf spiders (Lycosidae)	Pardosa spp.
orb-weavers (Araneidae)	Argiope bruennichi Araneus spp.
sheetweb-weavers (Linyphiidae)	Oedothorax spp. Erigone spp.
ground beetles (Carabidae)	Poecilus cupreus Pterostichus melanarius Harpalus rufipes Bembidion lampros Platynus dorsalis
rove beetles (Staphylinidae)	Xantholinus longiventris Lathrobium longulum Tachyporus hypnorum Philonthus sp.
ladybirds (Coccinellidae)	Coccinella septem-punctata Adalia bipunctata Propylea 14-punctata
Lacewings (Chrysopidae)	Chrysopa carnea Chrysopa perla
aphidiids (Aphidiidae)	Aphidius spp.
platygasterids (Platygasteridae)	Prosactogaster sp.
aphelinids (Aphelinidae)	Aphelinus sp.
trichogrammatids (Trichogrammatidae)	Trichogramma sp.
hoverflies (Syrphidae)	Episyrphus balteatus Sphaerophoria scripta Melanostoma mellinum Eupeodes corollae

5.1.2 Agrotopes

As part of field borders and ridges, agrotopes are defined in structural rather than biological terms (e.g. transitional zone between field and grassland) (STEIDL & RINGLER, 1997). Structural elements of agroecosystems are field and meadow balks, tendrils, terraced balks, paths and pathside verges, loess walls, narrow passes, stone formations and dry stone walls.

10% of the elements of a semi-natural landscape have to be present to meet the ecological requirements for areas under agricultural use.

In terms of species diversity conservation, agrotopes are

- refugia for relict species whose habitats have disappeared,
- temporary alternative and asylum habitats for farmland organisms,
- partial habitats for animals from different parts of the countryside.

5.1.3 Ruderal biotopes

Ruderal biotopes are man-made areas (excluding agricultural areas) such as landfills, manure heaps, ruins of buildings, hillocks, stone and silt places, pathside verges, rail tracks and areas next to buildings. Ruderal vegetation is highly varied and many neophytes and wild cultural plants can be found (HOLZNER, 1989). While long naturalised archeophytes can now be found in the Red Lists, neophytes are rated negatively in terms of nature conservation as unwanted flora-adulterating intruders.

Neophytes may use ruderal sites as dispersal areas to spread into other biotopes.

This increased capacity for invasion renders ruderal biotopes so important for GMO monitoring as it can be expected that GMOs with a tendency to run wild or products of outcrossing will be found there first.

5.1.4 Fallow fields, grassland and vineyards

5.1.4.1 Fallow fields (complete fallows)

Fallow fields are agricultural areas that are no longer used. Initially many annual weeds and ruderal plants establish themselves on the cleared patches of ground. Species that are in the sperm bank have a competitive advantage (dormancy effect) over immigrating species (dispersal usually possible only over short distances). Long-term fallow land rich in nutrients usually becomes impoverished in the course of succession and turns into ruderal land with tall perennial herbs. Soils less rich in nutrients (e.g. acid sandy soils) may produce valuable plant populations in terms of nature conservation in the long term. Nutrient-rich fallow stages however are valuable for nature conservation in zoological terms.

5.1.4.2 Fallow grassland

Unused nutrient-rich grassland tends to become covered with tall perennial herbs and to be prone to eutrophication. The populations found here are usually poor in species and dominated by a few competitive species. From the point of view of plant ecology, dry nutrient poor habitats facing south are particularly valuable as they may gradually turn into species-rich dry grasslands. Nutrient-rich fallow stages nevertheless are valuable for nature conservation in zoological terms.

5.1.4.3 Fallow vineyards

Under favourable conditions (sandy, south-facing soils, poor in nutrients), fallow stages may develop into dry grassland.

5.1.4.4 Entomologic aspects of fallow land

Many species are unable to survive on intensively used agricultural land and retire to fallow areas. Similar to the arable field coenosis, the fauna of fallow land includes many endangered or rare species. Many species depending on dry grassland habitats for example find suitable conditions on sandy, south-facing patches of fallow land. Many pollinators (e.g. Syrphidae, Lepidoptera) also find a reasonable number of flowers to visit in fallow land.

5.1.5 Gravel, sand and clay pits, quarries (closed-down mining areas)

Mining areas on cultivated land are habitats where invasive GMOs primarily establish themselves. The lack of a humus layer is characteristic of these habitats. Secondary succession is therefore slow. Populations are usually patchy. According to HOLZNER (1989) this biotope type is highly endangered.

Gravel, sand and clay pits are habitats of segetal and ruderal species because habitat-specific features (open ground, vegetation dynamics) enable these species to survive at least in the short term. It is therefore likely that GMOs or their crossing products will also be found in these habitats.

On these "disturbed areas" with large patches of bare ground ruderal and segetal plant communities are dominant in the early stages. They are important as areas where weed from arable fields can retire. According to RINGLER et al. (1995), typical plant communities include annual or biennial weed communities.

5.1.5.1 Open mining areas (sand and gravel, dumps)

These areas are habitats for annuals, perennial pioneers and persistent species of nutrient poor or dry meadows.

5.1.5.2 Open mining areas with heavy soils (clay, loamy and muddy soils)

Due to spreading by birds, halophytic communities and dwarf sedges (both habitats listed in Annex I of the Fauna-Flora-Habitat Directive) can be found here with species such as *Lotus maritimus*, *Juncus gerardii* and *Bolboschoenus maritimus*.

Of the riparian and macrophyt vegetation relevant for nature conservation, the plant communities of intermittently damp areas (e.g. dwarf sedges) are most likely to be influenced by GMO invasion.

On dry alkaline substrate rich in lime valuable dry and semi-dry grasses may develop.

5.1.5.3 Entomologic aspects of sand, gravel and clay pits

On closed-down mining sites of quarries and gravel and sand pits a surprisingly high species diversity may be found especially with highly mobile animals on the surface such as grass-hopper species of *Sphingonotus* and tiger beetles (Cicindelidae). Ponds in mining sites may be suitable larval habitats for dragonflies which are also highly mobile and even for some threatened dragonfly species such as *Coenagrion scitulum* and *Libellula quadrimaculata* as there is no competition from predators (such as fishes). Sunny mining sites being poor in vegetation are used as breeding habitats by many solitary bee species such as the *Andrena* and *Halictus* species, bumble bees, digger wasps and others. Mining sites have become important habitats for ground beetles as they are largely free from insecticides (RINGLER et al., 1995). Mobile ground beetles that are able to fly (*Bembidion* spp. and *Agonum* spp.) are typical species of pioneer sites on mining areas.

Sand, gravel and loam pits are important "islands" on cultivated land due to the opportunities they offer for nesting and food. The re-establishment of the natural status of gravel, sand and clay pits poor in vegetation helps conserve more than 259 species of *Hymenoptera* (i.e. more than 50% of the species found in southern Germany).

5.1.6 Semi-natural or natural habitats

5.1.6.1 Alluvial soils of river streams and riparian areas

With flooding, mud, silt and sand will be deposited in the river bed. First these natural pioneer habitats are free from vegetation and available for plants invasion. Depending on the height and substrate of the alluvial deposit, the habitats can be wet or dry. Erosion and more flooding lead to further shifting whereby succession is interrupted.

On alluvial deposits, ruderal plants can be found or sometimes wild growing cultivated plants such as rape (observed at the River *Wienfluss*, Vienna, 1999).

Alluvial soils and dynamic riparian areas of rivers and standing waters are important protection targets.

5.1.7 The soil as a habitat

The occurrence of certain animal and plant species is usually determined by the climate and is connected to specific habitats. In the soil different habitats can be found within a small area, often within a few millimetres. The soil micro-organisms and the organisms grazing on them are distributed accordingly. Analyses have shown that micro-organisms are distributed in the soil neither randomly nor evenly (SCHINNER & SONNLEITNER, 1996) and that their occurrence is determined by the availability of organic matter, pores, water and oxygen.

These distribution patterns result in a high spatial and temporal heterogeneity. One can assume that the microbial community that establishes itself in the root area of a plant will be different from communities in areas where there are no roots and therefore a different nutrient supply (GRAYSTON et al., 1997). With environmental changes such as the desiccation or compaction of soil (i.e. changes in the water and oxygen supply) the microbial community may change completely within a relatively short period of time as the generation time of bacteria is relatively short (1-3 hours, BROCK et al., 1994). Their high density and their large number of species as well as the fact that they go through non-culturable stages under less favourable conditions (COLWELL et al., 1985) enable short-time changes in the distribution of species under changing environmental conditions.

5.1.7.1 Soil protection

While nature conservation often means the protection of certain species or habitats, soil protection is defined as the protection of the soil function, which means the conservation of its function as a habitat for man and nature.

According to AUERSWALD (1998) the functions of the soil are as follows:

Transformer function

Meaning the conversion of energy and matter through biotic and abiotic factors.

Storage function

Energy is stored in form of heat (balance of fluctuations during the day) and in form of chemical compounds (products of photosynthesis). Because of this storage and release of nutrients, nutrients can be made available for plants when they are needed.

Habitat function

Apart from containing the roots of plants, soils are a habitat to many animals and soil microorganisms (protozoa, algae, fungi, bacteria). The soil organisms themselves have an important role in the function of the soil.

Archive function

Meaning the "gene-bank" of many organisms that remain as yet unknown. Some characteristics transferred to genetically modified organisms (antibiotic resistance genes) are derived from soil micro-organisms.

Productive function

Soil productivity is the basis of agricultural production and forestry and thus of man's food supply. For a long time, the productive function therefore was the most important soil function.

Raw material function

The soil provides a large number of raw materials such as sand or clay. Mining usually leads to the total destruction of the soil.

Site function

This is actually a function of the surface area rather than of the soil. When e.g. roads are built the surface area remains but the soil is destroyed.

The definitions stipulated in the German Soil Protection Law (LAW CONCERNING THE PROTECTION OF THE SOIL, 1998) according to RÜCK (1998) are derived from the functions mentioned above:

Natural functions as

- basis of life and habitat for humans, animals, plants and soil organisms
- part of the balance of nature, in particular of its water and nutrient cycles
- a decomposing, balancing and restoring medium for material effects due to its filter, buffer and metabolic properties especially for the purpose of groundwater protection.

Functions as an archive of natural and cultural history

Functions of use such as

- raw material deposit
- settlement and recreation area
- site for use in agriculture and forestry
- site for other economic and public uses, transport, supply and disposal.

From the functions described above, potential targets for the conservation of the soil quality can be derived. These targets may relate to functions or uses and have been formulated as follows (RÜCK, 1998):

- · precautionary protection of the soil
- · sustainable use of the soil
- · conservation of the soil functions
- · conservation of the soil as a resource
- prevention and avoidance of harmful soil changes.

5.1.7.2 Significance of soil organisms for the soil function

Soil fauna

The soil fauna consists of unicellular protozoa and multicellular metazoa. Depending on their size they live in different habitats.

Protozoa feed on dissolved organic matter, organic particles and as predatory animals on other organisms. For ciliates bacteria are the most important food source (ENGLAND et al., 1993). By continuous grazing the bacteria population is kept in a physiologically juvenile stage, thus speeding up the decomposition of organic matter (PAUL & CLARK, 1996).

Metazoa have many functions in the soil (FÖRSTER, 1998):

- · feeding on bacteria and fungus hyphae
- substrate decomposition and surface enlargement through detritus eaters
- input and dispersal of micro-organisms (body surface, faeces)
- nutrient release (nitrogen compounds, low-molecular organic compounds) through excretion.

Although metazoa play a minor role in the mineralisation process they contribute to the decomposition processes by breaking down organic matter and by bioturbation (substrate mixing) (LABES et al., 1999). Nematodes, annelids, collembolans, beetles (and their larvae) and mites are only a few examples of the wide variety of animals in the soil. More details on their biology can be found in DUNGER & FIEDLER, 1989.

Soil micro-organisms

The term soil micro-organisms includes bacteria, fungi and algae. Their proportion of the live biomass is usually 75-90%, their total mass is 1.5 up to 15 t/ha (FRIEDEL & VON LÜTZOW, 1998).

Analyses should start with functional analyses and move on to population dynamics and investigations of the biochemical regulation of these processes (TIEDJE et al., 1999). Diversity investigations should be carried out always considering that the classification of bacteria into "species" is difficult because of their high genetic flexibility and their capacity for genetic exchange.

Apart from bacteria, fungi are important for structuring the soil due to hyphae growth and production of exopolysaccharides. These usually multicellular eukaryotic organisms often form a widespread mycelium, which is important for the solidification of the soil. They are also important for the decomposition of cellulose and lignin.

5.2 Ornithological protection targets in agroecosystems

5.2.1 Conservation of species diversity

In Central Europe the growing industrialisation of agriculture is the primary cause of lost species diversity (BAUER & THIELKE, 1982). The Austrian Red List also includes many bird species whose acute threat results from lost structures, insecticide use, eutrophication and other effects of intensive agriculture. The impoverishment of agricultural land in terms of species composition shows that the conservation of the present species diversity must be a protection target. According to the requirements of AMMANN & VOGEL (1999), long-term monitoring should be designed as an instrument for the promotion of sustainable agriculture. The survival of characteristic species of agroecosystems can only be ensured if the interests

of nature conservation are integrated in the management of all cultivated land. Not even protected areas on a large scale are suitable habitats for self-preserving populations of these widespread species. In this respect agricultural land must not be regarded purely as a productive area but also as a habitat of particular importance.

The following species of Annex I of the EU Birds Directive and of the Red Lists for Austria (BAUER, 1994), Lower Austria (BERG, 1995) and Styria (SACKL & SAMWALD, 1997) have their main distribution or partial habitats in agroecosystems. Species listed in Annex I of the EU Birds Directive "should be the subject of special conservation measures concerning their habitats in order to ensure their survival and reproduction in their area of distribution;" (Council Directive 79/409/EEC of 2nd April 1979 on the conservation of wild birds). Because they are highly sensitive to environmental changes, these species often are important indicators. Their frequent absence on arable land that is used intensively is a considerable methodical problem. From their habitat requirements, protection targets for structural elements and partial habitats in agroecosystems can be derived. The dramatically reduced populations of the skylark and yellow-hammer in some places however show that to preserve species diversity even abundant characteristic species have to be included in the list of ecological protection targets.

5.2.2 List of endangered breeding birds characteristic of agroecosystems

For the species listed their protection status and degree of threat is given according to Annex I of the Birds Directive and of the Red Lists for Austria (BAUER, 1994), Lower Austria (BERG, 1997) and Styria (SACKL & SAMWALD, 1997).

Grey Partridge (Perdix perdix) Red List Austria: 3

Quail (Coturnix coturnix) Red List Austria: 3

Great Bustard (Otis tarda) Birds Directive, Red List Austria: 3

Skylark (Alauda arvensis) Red List Styria: 4

Red-backed Shrike (Lanius collurio) Birds Directive, Red List Styria: 4

5.2.3 List of endangered food and winter guests in agroecosystems

Saker (Falco cherrug) Red List Austria: 1

Stock Dove (Columba oenas) Red List Austria: 4

Great Grey Shrike (*Lanius excubitor*) Red List Austria: 1 **Jackdaw** (*Corvus monedula*) Red List Lower Austria: 3

5.2.4 Conservation of habitats of particular ornithological significance in agroecosystems

Species conservation now focuses on the preservation of species communities through protection of their habitats. The significance of habitats in agroecosystems from an ornithological point of view is emphasised by a few exemplary bird species. Usually these habitats are essential partial habitats or habitat structures for the target species. For some species under acute threat these habitats constitute the main areas of their `regional distribution.

5.2.4.1 Sandy soils

Crested Lark (Galerida cristata) Red List Austria: 2

5.2.4.2 Acid soils poor in nutrients

Great Grey Shrike (Lanius excubitor) Red List Austria: 1

5.2.4.3 Wet and heavy soils

Limicolae regularly to be found in field depressions are for example Ruff (Philomachus pugnax) and Common Snipe (Gallinago gallinago).

The following selection of some highly endangered breeding bird species living in wetland habitats shows how important these habitats are.

White Stork (Ciconia ciconia) Birds Directive, Red List Austria: 3

Lapwing (Vanellus vanellus) Red List Lower Austria: 3

Curlew (Numenius arguata) Red List Austria: 1

Blue-headed Wagtail (Motacilla flava flava) Red List Austria: 2

5.2.4.4 Upland fields in inner-Alpine valleys

Upland fields in inner-Alpine valleys are refugia for species that have disappeared from areas with fast advancing intensification. The smaller plots and the more structured cultivated land are favourable for the avifauna. As a habitat for highly endangered bird species this cultivated agricultural area is a protection target of particular importance.

Ortolan Bunting (Emberiza hortulana) Red List Austria: 1

Whinchat (Saxicola rubetra) Red List Austria: 4

5.2.4.5 Gravel, sand and clay pits

Gravel, sand and clay pits are valuable substitute habitats for many bird species under acute threat. They are particularly important for species that once lived in the sand and gravel areas of unchannelised rivers. In this respect the early succession stages with bare ground poor in vegetation are particularly valuable:

Stone Curlew (Burhinus oedicnemus) Birds Directive, Red List Austria: 1

Tawny Pipit (Anthus campestris) Birds Directive, Red List Austria: 1

Wheatear (Oenanthe oenanthe) Red List Lower Austria: 5

Little Ringed Plover (Charadrius dubius) Red List Austria: 3

5.2.4.6 Agrotopes

Agrotopes are small-scale borders and ridges constituting important special structures and refugia. Examples are the field stone formations mentioned before. Because they have disappeared, the wheatear has largely lost its habitats (see chapter 5.2.4.5). Narrow passes, loess walls and ruderal areas (e.g. rail tracks) are also important habitat elements for some species.

Bee-eater (Merops apiaster) Red List Austria: 3

Barn Owl (Tyto alba) Red List Austria: 1

Corn Bunting (Miliaria calandra) Red List Austria: 3

5.2.4.7 Agricultural areas under organic farming

Agricultural areas under organic farming are characterised by a much higher species diversity than fields managed with conventional methods (RÖSLER & WEINS, 1995) and by much higher population densities of characteristic field birds.

In England the population density of the skylark on organic farmland is more than twice as high as on conventional farmland (BTO, 1995).

Many Red List species depend on historical forms of land use or extremely extensive forms of agricultural management. For them not even areas under ecological farming provide suitable substitute habitats.

5.2.4.8 Fallow areas

Fallow areas are an important habitat element or at least enhance the habitat quality for nearly the full range of field bird species. Fallow areas are preferred as breeding places by many species (e.g. grey partridge). They also seem to have a favourable effect on the food supply.

Stonechat (*Saxicola torquata*) Red List Austria: 4 **Whitethroat** (*Sylvia communis*) Red List Styria: 3

5.2.4.9 Gravel areas (along river streams)

Gravel areas (along river streams) do not constitute special habitats of agroecosystems but they are at a higher risk of GMO invasion (see chapter 5.1). The typical populations of gravel banks are under threat due to the loss of these habitats (channelisation, impoundment, regulation). Relicts of Little Ringed Plover (Charadrius dubius) and Common sandpiper (Actitis hypoleucos) can be found at natural rivers with relatively natural dynamics (e.g. Pielach, March, Traun, Lech rivers).

Common Tern (Sterna hirundo) Birds Directive, Red List Austria: 1,

Red List Lower Austria: 0

5.2.5 Protection of Important Bird Areas

Birds areas in Austria that are of particular ornithological importance have been summarised by Bird Life Austria under the term Important Bird Areas (IBAs) (DVORAK & KARNER, 1995). These areas are the so-called "hot spots" of the avifauna. According to the precautionary principle the cultivation of GMOs should be generally banned in these areas. In accordance with the EU Birds Directive special protection areas (SPAs) and also IBAs should remain free from GMOs until scientific work shows that adverse effects of habitat qualities by transgenic organisms can largely be ruled out.

AMMANN & VOGEL (1999) demand to know whether "cultivated transgenic refugees can be tolerated in nature reserves". To rule out an adverse effect of Important Bird Areas by GMOs at least in the medium term, a buffer zone of several kilometres should be established around all IBA and NATURA 2000 sites.

5.2.6 Protection targets in habitats outside of agroecosystems

Habitats of ornithological importance such as hay meadows, forests and orchards may be influenced in the long term by the release or placing on the market of transgenic grasses, forest and fruit trees.

5.2.6.1 Protection targets in orchards

The main areas of the distribution of some highly endangered species such as Scops Owl (*Otus scops*), Little Owl (*Athene noctua*), Hoopoe (*Upupa epos*), Wryneck (*Jynx torquilla*), Green Woodpecker (*Picus viridis*), Middle Spotted Woodpecker (*Picoides medius*) and Redstart (*Phoenicurus phoenicurus*) can be found in orchards.

5.3 Protection targets according to the Fauna-Flora-Habitat-Directive

On 21st May 1992 the European Union adopted the Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora (in short: FFH-Directive) with the aim to protect and promote biological diversity. To restore or preserve a favourable condition of natural habitats and species of Community interest, special areas of conservation have to be identified to form a coherent European ecological network. This network is called "Natura 2000" and contains also special protection areas for birds designated according to the Directive 79/409/EEC (Birds Directive).

The Annexes I and II of the FFH-Directive list habitats and species that have to be protected through the NATURA 2000 network. Among the species and habitats of Community interest there are "priority natural habitat types" and "priority species". These are habitats or species on the territory of the Member States threatened with extinction and for which the Community has a special responsibility. In the Annexes these habitats and species are marked with an asterisk (*) (from ELLMAUER et al., 1998; 1999).

5.3.1 Plant species and habitats according to Annex I and II of the Fauna-Flora-Habitat-Directive

In Austria 18 vascular plant species can be found that are mentioned in Annex II of the FFH-Directive. Three species are listed as priority species and 15 as non-priority species. Of the latter, three species are treated as extinct according to the Red List (*Aldrovanda vesiculosa*, *Coleanthus subtilis*, *Saxifraga hirculus*) (NIKLFELD & SCHRATT-EHRENDORFER, 1999).

Of the habitats protected under the FFH-Directive, 22 priority and 43 non-priority habitat types can be found in Austria (from TRAXLER & ELLMAUER, 1999).

Although most NATURA 2000-sites in Austria cover natural or semi-natural habitats, some of them also include cultivated and agricultural land. Habitats of the FFH-Directive situated there are also under the relevant legal protection.

In the following tables (7-10) habitats of the FFH-Directive are given that can be found in agricultural areas as well as semi-natural habitats where increased invasiveness seems likely due to their specific habitat characteristics. According to the results of neophyte research, alien species could establish themselves in even more habitats.

Tab. 7: Habitats of the Flora-Fauna-Habitat Directive in agroecosystems (from TRAXLER & ELLMAUER, 1999).

Code	habitat	sites		
Priority p	Priority protection habitats			
1530	Halophytic pannonic habitats	Community fragments in mining pits with heavy soils and as salt patches on fields and grassland; Ex.: Baumgarten, Zwingendorf.		
6210	Dry grassland on calcareous substrates	South-facing embankments, balks		
6250	Dry grassland on loess	Loess embankments and balks		
Non-priority habitats				
3132	Dwarf sedges communities	Damp fields and wet field depressions		

Tab. 8: Habitats of the FFH-Directive on managed grassland areas (from TRAXLER & ELLMAUER, 1999).

Code	habitat	sites		
Non-prio	Non-priority habitats			
6410	Molinia meadows	Extensively managed meadows at planar to montane levels, dominated by Molinia, on intermittently moist to wet soils poor in nutrients with a high degree of humus or peat		
6440	Cnidion floodplain meadows	Regularly flooded meadows of large river valleys of the continental-subcontinental climatic areas on alluvial soils		
6510	Lowland hay meadows	Extensive, species-rich dry-hay meadows at planar to montane levels (up to appr. 1,000m altitude) with little or moderate use of fertilisers and cutting once or twice a year (after the grass flowering period)		
6520	Mountain hay meadows	Extensive, species-rich dry-hay meadows at montane to sub-alpine levels (above appr. 1,000m altitude) with little or moderate use of fertilisers and cutting once or twice a year		

Tab. 9: Semi-natural habitats of the flora-fauna-habitat-Directive with increased capacity for invasion (from TRAXLER & ELLMAUER, 1999).

Code	habitat	sites	
Non-priority habitats			
3270	Chenopodion and Bidention of muddy banks	Muddy banks of rivers and standing waters	
6431	Eutrophic tall herbs	Nitrophilous edge communities rich in herbaceous perennials along ditches, streams, rivers or riparian forests at montane to sub-alpine levels	

5.3.2 Insects in agroecosystems according to Annex II of the FFH-Directive

In Austria 66 animal species are listed in Annex II of the FFH-Directive (PAAR et al., 1998) (of which 21 are insect species). Four species (of which two are insect species) are extinct or treated as disappeared.

These species and their populations vary in the individual Federal Provinces. Priority species however can be found in each of the Provinces. The following two priority species can even be found all over Austria: *Callimorpha quadripunctaria* and *Osmoderma eremita*. Four dragonfly species are also mentioned in Annex II of the FFH-Directive: *Coenagrion mercuriale*, *Leucorrhinia pectoralis*, *Ophiogomphus cecilia* and *Coenagrion hylas*. Since dragonflies are important bioindicators for water streams and other wetlands (RAAB & CHWALA, 1997), agricultural habitats are not directly relevant for their populations.

Table 10 lists only insects mentioned in the FFH-Directive that are relevant for agricultural habitats on account of their populations and ecological requirements.

Table 10: Insects of Annex II of the FFH-Directive (from PAAR et al., 1998) for which agricultural habitats are important.

FFH-No.	Scientific Species Name	Red List Austria	Biogeograph. Region	Ecological Requirements
1060	Lycaena dispar	2	С	damp meadows with hygrophilous <i>Rumex</i> species as caterpillar food
1061	Maculinea nausithous	2	C, A	damp meadows with Sanguisorba officinalis and Myrmica sp.
1059	Maculinea telejus	2	C, A	damp meadows with Sanguisorba officinalis and Myrmica sp.
1052	Hypodryasmaturna	3	C, A	damp forest meadows

Abbreviations: A = alpine region; C = continental region

5.4 Plant communities

In Austria there are 813 phytosociological associations and unranked communities that are described in the "Pflanzengesellschaften Österreichs" (Plant Communities of Austria) (GRAB-HERR et al., 1993). The advantage of plant communities over individual species is that they express the habitat quality more comprehensively. Communities poor in characteristic species indicate early stages of changing habitats or transitions although valuable species may still be found.

The following sub-chapters briefly describe only plant communities of cultivated land under agricultural use and of related pioneer biotopes that are relevant in terms of nature conservation.

Grassland communities are not described here although they would be highly relevant in the case of a release of transgenic grasses.

5.4.1 Segetal communities (wild field herbs)

5.4.1.1 Stellarietea mediae

CENTAUREETALIA CYANI

Caucalidion lappulae

Caucalido daucoidis-Scandicetum pecten-veneris

Camelino microcarpae-Anthemidetum austriacae

Euphorbio exiguae-Melandrietum noctiflori

Adonido-Delphinietum consolidae

Veronico-Euphorbion

Geranio rotundifolii-Allietum

CHENOPODIETALIA ALBI

Arnoseridion minimae

Sclerantho annui-Arnoseridetum minimae

Scleranthion annui

Papaveretum argemones

Anthemido ruthenicae-Sperguletum arvensis

Vicio pseudovillosae-Legousietum

Spergulo-Oxalidion

Panico-Setarion

Stachyo annui-Setarietum pumilae

ERAGROSTIETALIA

Salsolion ruthenicae

Setario-Plantaginetum indicae

Chenopodietum botryos

Euphorbion prostratae

Chamaesyco humifusae-Oxalidetum corniculatae

Matricario chamomillae-Chenopodion albi

Matricario chamomillae-Atriplicetum littoralis

5.4.2 Ruderal habitats

5.4.2.1 Polygono arenastri-Poetea annuae

Typical habitats can be found at pathside verges, between driving lanes of field and forest tracks, on sports grounds and playgrounds.

Scelerochloo-Polygonetum arenastri

Rumici acetosellae-Spergularietum rubrae

5.4.2.2 Stellarietea mediae (therophyte-rich synanthropic communities) SISYMBRIETALIA

Sisymbrion officinalis

Sisymbrietum altissimi

Lactuco-Diplotaxietum tenuifoliae

Atriplicion nitentis

Atriplicetum roseae

Kochietum densiflorae

Malvion neglectae

Hyoscyamo nigri-Malvetum neglectae

Malvetum pusillae

Malvo neglectae-Chenopodietum vulvariae

ARTEMISIETEA VULGARIS

Euro-Siberian ruderal mugwort and thistle communities and dry semi-ruderal pioneer grasslands.

This class is characterised by nitrophilous and less nitrophilous communities of biennial and perennial plants with a dominating C-R-strategy. These communities prefer typical ruderal habitats with moderate and low disturbance rates such as wasteland, former dumps, balks, road and rail embankments. Grasses are important in these ruderal communities.

ONOPORTETALIA ACANTHII

Onopordion acanthii

Onopordetum acanthii

Lappulo heteracanthae-Onopordetum acanthii

Potentillo argenteae-Artemisietum absinthii

Salvio-Marrubietum peregrini

Cirsietum eriophori

Lappulo echinatae-Cynoglossetum

Erysimo wittmannii-Hackelion

Hackelio deflexae-Chenopodietum foliosi

Cynoglosso-Chenopodietum boni-henrici

Arction lappae

Arctietum lappae

Hyoscyamo-Conietum maculati

Balloto-Marrubietum vulgaris

Urtico urentis-Chenopodietum boni-henrici

AGROPYRETALIA REPENTIS

Convolvulo-Agropyrion repentis (semi-dry ruderal grasslands)

Diplotaxidi tenuifoliae-Agropyretum repentis

Convolvulo-Brometum inermis

Melico transsilvanicae-Agropyretum repentis

Poo compressae-Anthemidetum tinctoriae

Elymo repentis-Seselietum libanotis

Agropyro-Kochion

Agropyro cristati-Kochietum prostratae

5.4.3 Seminatural habitats

Galio-Urticetea (nitrophilous borders, riparian herbaceous perennial vegetation, disturbed woody plant communities)

The cultivated land of today includes a number of small habitats containing many linear structures such as hedgerows, woodland edges, balks and banks of streams and waters. These habitats are usually rich in basic nutrients and are suitable growing places for demanding tall perennial herbs that establish so-called nitrophilous edge communities.

At the edges of waters of the planar up to the montane levels typical zonation systems can often be found which sometimes include natural edge communities (Convolvuletalia sepium). In lowland areas they have suffered the influence of man and in many places they have been modified by neophytes.

LAMIO ALBI-CHENOPODIETALIA BONI-HENRICI

Galio-Alliarion

Sambucetum ebuli

Conio-Chaerophylletum bulbosi

Anthriscetum trichospermi

Anthrisco-Asperugetum procumbentis

Impatienti noli-tangere-Stachyion sylvaticae

Aegopodion podagrariae

Sisymbrietum strictissimi

Elymus caninus community

CONVOLVULETALIA SEPIUM

Senecionion fluviatilis

Senecionetum fluviatilis

Artemisia verlotiorum-Gesellschaft

Petasition officinalis

Chaerophyllo-Petasitetum officinalis

Arunco-Petasitetum albi

Equisetum telmateia-Gesellschaft

5.4.3.1 Epilobietea angustifolii

The structure and dynamics of clearings and clear-cut areas are influenced and controlled by disturbance. Dying trees and natural catastrophes (large fires, insect pests and windbreaks) cause vegetation gaps in the forest. Light, soil moisture and humus decomposition regimes all undergo dramatic changes, thus creating new ecological opportunities for groups of vegetation that are boosted by these disturbances.

Clear-cut areas boost the mass dispersal of species with a ruderal and competitive ruderal strategy in particular so that a thick layer of grass and herbs soon develops with *Calamagrostis epigejos* (on soils poor in nutrients) or *Sambucus ebulus*, *Arctium nemorosum* and *Eupatorium cannabinum* (on soils rich in nutrients). The growing of trees is hampered by competition from tall perennial herbs.

The communities are not discussed in detail here.

Trifolio-Geranietea sanguinei

(Thermophilic and sub-thermophilic border communities)

This class includes primary and secondary thermophilic edge communities which can mostly be found at the edges of bushes and woodlands. The edge communities are either adjacent to a forest or separated by a protective zone. They can also be found at the boundaries of meadows (under mesic conditions) or dry grassland (under xeric conditions). The most colourful and species-richest edge communities are the *Quercus pubescens* relict exclaves of Central Europe. Here they are joined by the different Prunetalia and Quercetalia pubescentis communities to form complexes of vegetation that are deemed worthy of protection.

ORIGANETALIA VULGARIS

Geranion sanguinei

Geranio-Dictamnetum

Arabidi turritae-Laserpitietum asperi

Peucedanetum cervariae

Geranio-Anemonetum sylvestris

Rosetum gallicae

Geranio-Trifolietum alpestris

Campanulo bononiensis-Vicietum tenuifoliae

Trifolion medii

Trifolio-Laserpitietum

Ranunculetum nemorosi

Trifolio medii-Agrimonietum

Trifolio medii-Melampyretum nemorosi

Vicietum sylvaticae

Agrimonio-Vicietum cassubicae

Knautietum dipsacifoliae

Genista sagittalis-(Trifolion medii)-community

MELAMPYRO-HOLCETALIA

Melampyrion pratensis
Teucrio scorodoniae-Polygonatetum odorati
Lathyro montani-Melampyretum pratensis

5.4.3.2 Calluno-Ulicetea (Dwarf heaths)

Communities of the class of Calluno-Ulicetea grow on acid soils that are rich in humus and poor in nutrients, often podsolised and sometimes wet (podsols, pseudo-gleys). They are forest community substitutes growing on clearings and areas cleared by fires and kept free from trees through anthropo-zoogenic measures (fire, mowing and grazing). The flora of these communities is not endowed with a rich variety.

The individual communities are not discussed in detail here.

5.4.3.3 Koelerio-Corynephoretea

This class includes simply structured plant communities with small grasses or dwarf therophytes. These communities can be found in one or two layers and there are usually many gaps.

The habitats of Koelerio-Corynephoretea are extreme in terms of climate and soil. They include exposed rocks, rock ridges, humps, but also asphalt layers and roofs as secondary habitats.

The habitats are sunny and dry up quickly because of their thin soil-layer. On vegetation-free surfaces or dark-coloured rocks temperatures rise to 50 to 60 °C under the sun causing extreme conditions.

The dominant species determining the communities have eco-physiological, morphological and population-biological adaptive mechanisms enabling them to cope with extreme and fluctuating habitat conditions (extreme daily and seasonal climatic fluctuations, thin, dry soil often poor in nutrients). These species can be divided into four functional groups: (1) short-lived Therophytes, (2) succulent Chamaephytes, (3) hemikryptophytic Graminoids and (4) poikilohydrous mosses and lichens.

The existence of these communities depends on disturbances that include regular climatic fluctuations and irregular and hardly predictable zoo-anthropogenic disturbances.

The individual communities are not discussed in detail here.

5.4.3.4 Isoeto Nanojuncetea (dwarf-sedges)

This class includes short-lived and ephemeral communities on open and intermittently wet soils. Typical habitats include open grounds of fish ponds, pond edges, river banks, old river arms, muddy puddles, wet tracks, drainage ditches, wet pastures, tank tracks and rice fields in plains, hills and mountains. These communities develop in places of wounded vegetation and on plant-free areas.

An association on arable fields that is highly endangered is the Centunculo-Anthocerotetum punctati. This community can be found in wet, loamy-clayish fields and fallows poor in lime and often situated on the floodplains of rivers. In Austria, fragmentary formations of this community have been observed in the south of the Burgenland at the river Lafnitz, in the Waldviertel and in the Alpenvorland.

Other communities occuring in fields and fallows include the Veronico anagalloidis-Lythretum hyssopifoliae (wet depressions, slightly saline wet fallows in the Pannonic climatic province of Austria) and the Cerastio-Ranunculetum sardoi (micro-depressions on fields with cereal crops, recent fallow east of Baumgarten in Lower Austria).

5.4.4 Natural or semi-natural habitats with a high capacity for invasion

5.4.4.1 Bidentetea tripartiti

They are natural or semi-natural communities of summer therophytes. They are short-lived, usually poor in species and hardly permanent. They can be found on the bare grounds of dried-up drainage basins, on river banks and on ammonia-rich sites near dung heaps and manure pits.

Most of these communities are deemed worthy of protection and contain a number of Red List species.

Bidenti-Polygonetum hydropiperis
Rumicetum maritimi
Rumici-Alopecuretum aequalis
Catabroso-Polygonetum hydropiperi
Chenopodietum rubri
Bidenti-Atriplicetum prostratae
Chenopodio rubri-Polygonetum brittingeri

5.5 Red Lists of endangered plants in Austria

Although the Red List does not mean that the species it includes are automatically protected by law it is an important and generally accepted instrument in nature conservation policy. Nature conservation laws may then stipulate protected species by way of ordinances. These ordinances are usually based on the degrees of threat mentioned in the Red Lists, but other criteria are also applied by which a plant may be deemed worthy of protection (e.g. orchids which are often picked because of their attractiveness).

The Red List species are ecological protection targets designed to ensure the conservation of biodiversity. The Red Lists are important assessment criteria in GMO monitoring when threshold values, ecological damage or suspension criteria are defined.

Arable fields are home to many Red List species. Adverse effects on these species by the cultivation of certain transgenic plants cannot be ruled out. KNAUER (1994) states that in North Rhine-Westphalia 31% of field species, 32% of moist and wet meadow species and 16% of fresh meadow and pasture species are threatened. These conditions probably also apply to Austria.

5.6 Red Lists of endangered animals in Austria

In the latest version of the Austrian Red Lists of endangered animals (GEPP, 1994) 20 insect groups with a total of 10.042 insect species (of Orthoptera, Vespidae, Sphecidae, Coleoptera, Neuroptera, Mecoptera, Trichoptera, Thysanoptera and Lepidoptera) have been assessed. Of these, 2,278 species are listed in the categories of threat 0-4. Many endangered species find suitable refugium habitats on field boundaries such as field and meadow balks or in ecologically managed fallows (see also chapter 5.1.2).

In the following the main causes for threats to species are listed, with agriculture playing an important part:

- destruction and alterations of habitats
- chemical pressures
- consequences of technological advancement
- · direct persecution by man
- · natural fluctuations in abundance.

5.7 Biodiversity and ecosystem protection

Biodiversity is a scientific work concept describing the diversity of biotic units in a certain area at a certain time. To describe biodiversity, species are often used, in which case species diversity is described. Other units such as life-forms ("plant functional types") or plant communities can also be used to describe different aspects of biodiversity (BEIERKUHNLEIN, 1999). Biodiversity helps maintaining the stability of ecosystems and also has a value of its own (intrinsic value) (DICK & TIEFENBACH, 1996; and preamble of the Convention on Biological Diversity).

Biodiversity research (including the different definitions of the term biodiversity) is in its early days. At this stage it makes sense to focus on the diversity of species, plant communities and habitats in monitoring programmes because here the preliminary work has been done and the relevant knowledge has been acquired.

At the UN Environment Conference in Rio de Janeiro (1992), Austria and 103 other countries signed the international "Convention on Biological Diversity". Later on Austria ratified this convention. The reasons for the protection of biological diversity are ethical responsibility, the aesthetic value of nature and economic benefit (ELLMAUER, 1995). The Biodiversity Convention does not merely express a will. It means that the signatory states undertake the obligation to identify the biodiversity prevailing in their countries and to monitor its developments (BEIERKUHNLEIN, 1999).

At the UN Conference in Trondheim (1996) the effects of alien species were considered the second-important problem worldwide for the conservation and utilisation of biological diversity (SANDLUND et al., 1996, cited by KOWARIK, 1998). Since the dispersal of neophytes (exotic species model) is often compared to the dispersal of GMOs in the risk assessment, the protection of biodiversity should be seen as an important issue of monitoring.

6 REGIONAL ASPECTS IN AUSTRIA

Dividing Austria into biogeographical regions is important for choosing release sites. Biogeographical units enable abstractions from a number of ecological factors and thus comparability at the level of the larger biogeographical areas. A release site is therefore representative of the relevant biogeographical region.

Current GMO risk assessments are usually case-by-case procedures involving the individual assessment of every new transgenic crop plant and every transgenic trait. Investigations have shown however that a follow-up region-by-region procedure would also be useful. An ecological risk such as the capacity for outcrossing can only take effect if potential crossing partners or particular habitats are actually present. Austria for example has Pannonic habitats (FFH-directive) unique in the EU for which a risk evaluation or monitoring is not possible in any other country.

Field tests carried out so far show that different results have been achieved with the same test plants on different test sites. A transgenic Bt potato species was tested for its capacity for overwintering on three test sites in the USA. On two sites the plants did not last over the winter whereas in Oregon 65% survived (PARKER & KAREIVA 1996). Results obtained on one test site are not valid in general. A monitoring network has to cover all biogeographical regions of Austria in order to identify at least the different climate-related effects.

The bracken (*Pteridium aquilinum*) is a striking example of the variable success of the invasion of a plant species in different biogeographical regions. In England (Atlantic region) the bracken is a serious problem for nature conservation in bogs and mires. It is managed with herbicides applied even in nature reserves. In Austria however problems exist only locally on nutrient poor hay meadows and pastures.

6.1 Biogeographical regions

Applications for the placing on the market of GMOs have to include a description of the geographical regions and environmental areas where the product is intended to be used within the Community (pr Directive 2001/18/EC Annex IV; Council of the European Union, 2001). In the following a detailed division of Austria into biogeographical regions is given, which corresponds to the division of Europe into European regions.

Biogeographical regions are units defined by climatic, vegetational and geological aspects. The division of countries into biogeographical regions is crucial for choosing the test areas for a GMO monitoring programme. Since a monitoring programme cannot cover the whole area of Austria, regions have to be defined that are regarded as homogenous in terms of some specific aspects. The test areas are then regarded as representative of the whole region. The characterisation of the test fields by means of climatic, soil and ecological parameters is regarded as an important decision aid for the planning of the monitoring (OECD, 1994).

On the basis of former vegetational divisions, SAUBERER & GRABHERR (1995) divided Austria into nine biogeographical regions, similar to ELLMAUER et al. (1993). According to the FFH-Directive Europe was divided into much larger biogeographical regions, of which the Alpine and the Continental regions are represented in Austria.

A representative monitoring system should be a stratified test design and include test areas in all biogeographical regions.

6.2 Description of regional aspects using potential crossing partners of oilseed rape

In this chapter Austrian distribution maps are given of selected potential crossing partners of rape. These examples show how widespread some of these crossing partners are whereas others can be found only in a few isolated cases as "rare refugees".

The gene flow from transgenic rape to related wild or cultivated species is most likely to happen with *Brassica napus* (wild or cultivated plants), *Brassica rapa, Raphanus raphanistrum* and *Sinapis arvensis*. This is a result of abundance and the potential for hybridization under field conditions. The species mentioned are very common in Austria (*Brassica napus* only scarce) and their distribution ranges include the main rape cultivation area and beyond. Irrespective of the region the potential risk of outcrossing can therefore be ranked high.

Related rare and sparse species of rape have distinct regional aspects, however with little or no hybridization success (can usually be produced experimentally only). It is only the rare *Hirschfeldia incana* that can form spontaneous hybrids with rape (EBER et al., 1994). Introgression of transgenic genetic material into the rare species is not likely and may be dismissed. Summary tables of hybridization, dispersal and the risk of outcrossing for transgenic cultivated plants with related wild species or wild growing cultivated species can be found in GERDEMANN-KNÖRCK & TEGEDER (1997), PASCHER & GOLLMANN (1997 and 1999) and SCHEFFLER & DALE (1994). Information on the hybridization of *Brassica rapa* can be found in LANDBO & JORGENSEN (1997) and MIKKELSEN et al. (1996), of *Raphanus raphanistrum* and *Brassica adpressa* in EBER et al. (1994).

The mapping data for the following distribution maps have been taken mainly from the "Floristische Kartierung Österreichs" (Floral mapping of Austria; NIKLFELD et al., unpublished) and supplemented with data on Salzburg (WITTMANN et al., 1987), Carinthia (HARTL et al., 1992), Styria (ZIMMERMANN et al., 1989) and North Tyrol, East Tyrol and Vorarlberg (POLATSCHEK et al., 1998; distorted quadrant allocations!).

The site details of the floral mapping largely reflect those of 1986.

Signatures of site details:

+ = extinct s = synanthropic

a = distributed by human u = unsteady

n = naturalised W = spontaneously unsteady

i = indigenat x = no further details

c = cultivated d = doubt as to whether native

o = normal status

Tab. 11: Occurrence of some potential crossing partners of rape in the biogeographical regions of Austria (- rare, + sparse, ++ common, +++ abundant; Gene fl = likelihood of gene flow from rape to closely related wild growing or cultivated plants).

Species B	Bohem.	Pann.	SE-A.	LA.Alp.	Klag.B.	NorthAl CentrAl	CentrAl	S.Alp	Remarks	Gene fl
Brassica juncea		1		ı	ı		ı		Rarely unsteady	Low
Brassica napus	‡	‡	‡	‡	‡	+	+	1	Often running wild, mostly unsteady	High
Brassica nigra	I	I	+	+	I	I	I		Unsteady running wild, river banks, dumps, fields	Low
Brassica oleracea	I	ı			I	I	I		Rarely running wild	Low
Brassica rapa	‡	+	+ + +	‡	+ + +	+ + +	‡	‡	Became much rarer 30 years ago (when rape almost ceased to be cultivated). Today: abundant, running wild on dumps and fields	High
Diplotaxis muralis	+	‡ ‡	‡	+	‡	ı	ı	I	Loamy fields, ruderal areas, walls; sparse; naturalised (?)	Medium
Diplotaxis tenuifolia	+	+ + +	‡	+	‡	+	+	+	Dry ruderal areas, pathside verges, embankments, pavement cracks; abundant; naturalised?	Low
Erucastrum gallicum	+	‡	+	‡	‡	I	I	1	Unsteady and naturalised (recently); rare and sparse; ruderal areas, pathside verges, fields, river banks	Low?
Erucastrum nasturtifolium	I	+	I	I	I	I	I		Recently naturalised (?), sparse; fresh ruderal areas, floodplains, banks	Low?
Hirschfeldia incana	I	I							Syn.: Brassica adpressa; unsteady	Low
Raphanus raphanistrum	† †	+ + +	+ + +	+ + +	‡ ‡	‡	‡	+	Abundant, mostly in cooler climates on acidic substrate: fields, ruderal areas	High
Sinapis alba	I	+	I			ı	ı		Occasionally unsteady and running wild. Fields, pathside verges, dumps.	Low
Sinapis arvensis	+ + +	† † +	+ + +	+ + +	+	+	+	+	Abundant on hills and mountains; fields, pathside verges, dumps. In continental climates substrate-independent; in cooler climates dependent on calcareous soils.	High

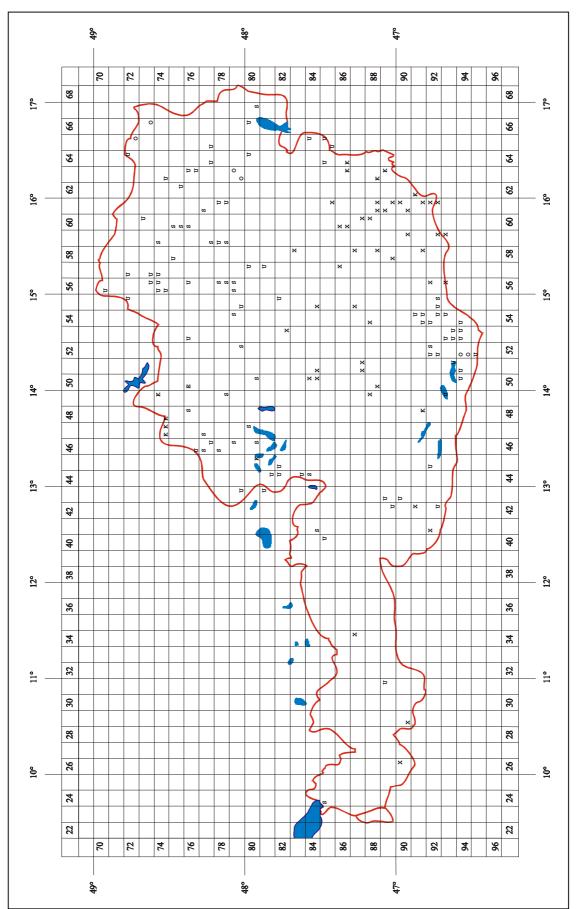


Fig. 12: Distribution of Brassica napus in Austria. Mapping data until 1986 with supplements (NIKLFELD & ENGLISCH, orig.).

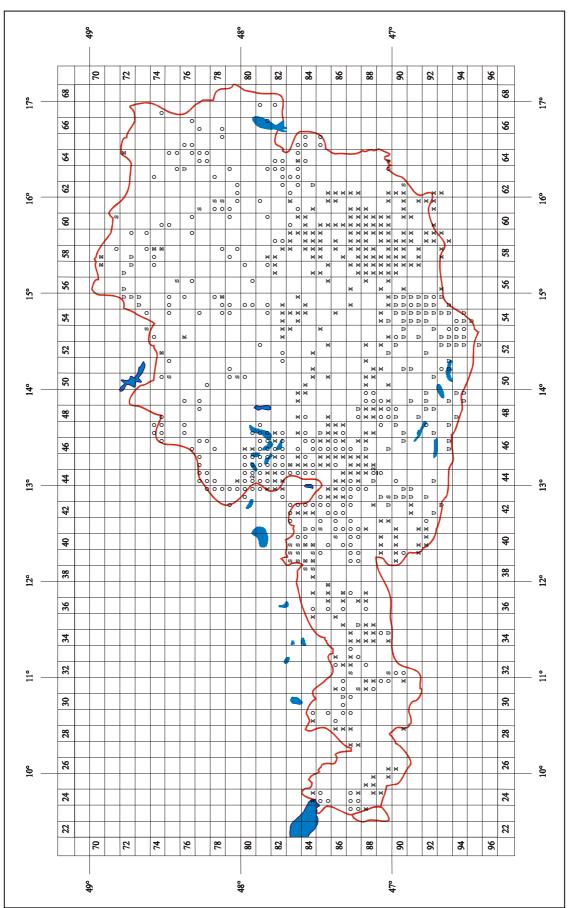
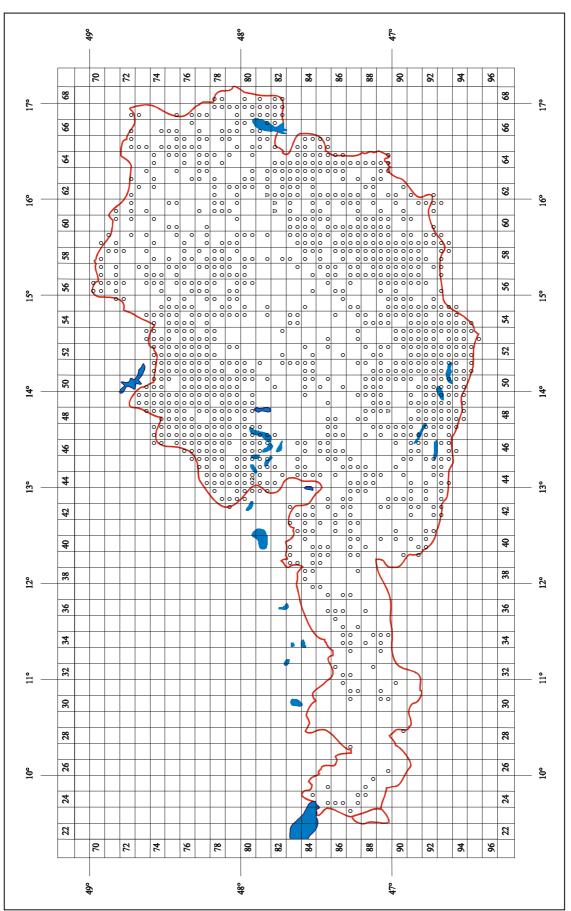
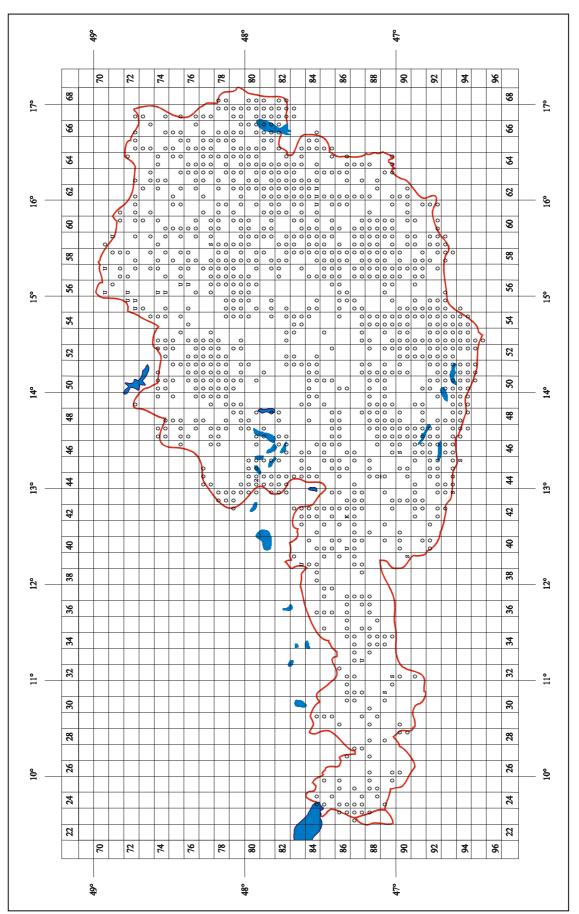


Fig. 13: Distribution of Brassica rapa in Austria. Mapping data until 1986 with supplements (NIKLFELD & ENGLISCH, orig.).



14: Distribution of Raphanus raphanistrum s. str. in Austria. Mapping data until 1986 with supplements (NIKLFELD & ENGLISCH, orig.). Fig.



Distribution of Sinapis arvensis in Austria. Mapping data until 1986 with supplements (NIKLFELD & ENGLISCH, orig.). 15:1 Fig.

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