ENVIRONMENT AGENCY AUSTRIA umweltbundesamt

Monitoring of genetically modified organisms

A joint policy paper by BfN (Germany), FOEN (Switzerland) and EAA (Austria)

Federal Agency for Nature Conservation

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
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CONTENT

ZUSAMMENFASSUNG

Ein sachgerechtes Monitoring, das den Anbau und die Verwendung von gentechnisch veränderten Pflanzen begleitet, ist ein wesentliches Element der gesetzlichen Regelungen für die Zulassung und Vermarktung von gentechnisch veränderten Kulturpflanzen. Zweck dieses verpflichtenden Monitorings ist es, mögliche schädliche Auswirkungen von GVO auf Natur und Umwelt zu erkennen und frühzeitig Gegenmaßnahmen zu ergreifen. Die Ausgestaltung dieses Monitorings wird derzeit auf nationaler und europäischer Ebene intensiv diskutiert.

Im vorliegenden Grundsatzpapier „Monitoring of genetically modified organisms" werden wesentliche Eckpunkte und Anforderungen formuliert, wie das Monitoring der Umweltauswirkungen von gentechnisch veränderten Pflanzen (GVP) umgesetzt werden sollte. Diese Empfehlungen basieren auf der langjährigen Erfahrung der an der Studie beteiligten Institutionen – des deutschen Bundesamtes für Naturschutz (BfN), des österreichischen Umweltbundesamtes und des schweizerischen Bundesamtes für Umwelt – mit natur- und umweltschutzfachlichen Beobachtungsprogrammen und der Beschäftigung mit der Konzeption für das Monitoring gentechnisch veränderter Pflanzen. Darüber hinaus berücksichtigen die Empfehlungen bislang wenig beachtete Aspekte zu Naturschutzfragen, die aber für ein geeignetes Monitoring der Umweltwirkungen gentechnisch veränderter Pflanzen von großer Bedeutung sind.

Das Grundsatzpapier leistet damit einen Beitrag, einen angemessenen europäischen Standard für das Monitoring von gentechnisch veränderten Pflanzen zu formulieren. Das Papier enthält dazu folgende wichtige Empfehlungen:

1. Das Monitoring der Umweltwirkungen gentechnisch veränderter Pflanzen muss den wissenschaftlichen Mindestanforderungen an eine Umweltbeobachtung genügen um aussagekräftige und belastbare Daten zu gewährleisten. Die Auswahl der Parameter, der Methoden, des Designs, der Beobachtungsorte, sowie des Zeithorizonts für das Monitoring muss so erfolgen, dass potenzielle schädliche Effekte auf die Umwelt über das Monitoring sicher erfasst werden können.
2. Der Anwendungsrahmen für die Fallspezifische Überwachung (CSM) muss gegenüber der derzeitigen Praxis erweitert werden. Da die Umweltrisikoabschätzung sich im wesentlichen auf zeitlich und räumlich begrenzte Untersuchungen bezieht, soll CSM neben dem Monitoring von identifizierten Risikopotentialen vor allem auch die Aussagekraft der vor der Zulassung durchgeführten Risikoabschätzung überprüfen, d. h. die Stimmigkeit von notwendigen Annahmen und von gezogenen Schlüssen untersuchen.
3. Eine strikte konzeptuelle und methodische Trennung zwischen Fallspezifischer und Allgemeiner Überwachung ist für die Umsetzung des Monitorings nicht hilfreich. Die Abstimmung zwischen den beiden Elementen des Monitorings sollte sicherstellen, dass alle relevanten Fragestellungen und Parameter insgesamt durch das Monitoring abgedeckt werden.
4. Die Erfassung der Exposition der Umwelt durch GVP und ihre Produkte muss ein wesentliches Element der Monitoringpläne werden. Erst die Verfügbarkeit derartiger Daten erlaubt einen Rückschluss, ob Umwelteffekte mit dem Anbau oder der Verwendung von GVPs in Zusammenhang stehen.

5. Für die Identifizierung von geeigneten Parametern und Indikatoren für die Erfassung von unvorhergesehenen Effekten im Rahmen der allgemeinen Beobachtung wird die Anwendung verschiedener sich ergänzender methodischer Ansätze vorgeschlagen. Die Evaluierung möglicher Ausbreitungswege von GVP in der Umwelt und die Ableitung von Ursache-Wirkungshypothesen werden durch den Einsatz von Modellierung und geostatistischen Extrapolationen sowie durch die Identifizierung von relevanten Indikatoren für wichtige Schutzgüter ergänzt.
6. Die Eignung von bestehenden Monitoringsystemen muss hinsichtlich ihrer Nutzungsmöglichkeit im Rahmen des GVO-Monitorings besser evaluiert werden. Wenn bestehende Monitoringsysteme nicht geeignet sind, müssen notwendige Anpassungen stattfinden oder aber ergänzende Monitoringmaßnahmen vorgesehen werden.

SUMMARY

The monitoring of environmental effects is an important element of the regulatory framework for genetically modified organisms (GMO) in the European Union and Switzerland. The aim of GMO monitoring is to detect potential adverse effects of GMOs and their use on human health and the environment and – if necessary – to facilitate early and appropriate mitigation action. However, the implementation of GMO monitoring at the national and EU-level, specifically for the cultivation of GM plants, proved to be a challenging issue and is subject to ongoing discussions.

With this policy paper the National Environment Agencies in Austria and Switzerland and the Federal Agency for Nature Conservation in Germany jointly provide substantial input into this discussion and outline necessary elements and requirements for an appropriate GMO monitoring.

The recommendations are based upon the expertise of the three Agencies as competent authorities or advisory bodies with regard to GMO monitoring and their general expertise in environmental monitoring, environmental protection and nature conservation.

Therefore the recommendations specifically take into account interrelated issues of environmental protection and nature conservation, which are of importance for an appropriate environmental monitoring of GMOs.

The policy paper shall contribute to the implementation of an adequate EU-wide standard concerning the environmental monitoring of genetically modified plants (GMPs). Among others the paper contains the following recommendations:

1. The environmental monitoring of GMPs needs to be conducted according to scientifically defined quality criteria to generate data, which are robust and conclusive.
   The choice of parameters, methods, experimental designs, of the locations and the timeframe for monitoring needs to ensure that potential adverse effects of GMP and their use can be detected reliably and as early as possible.
2. The scope for case specific monitoring (CSM) needs to be broadened compared with the existing practice. CSM needs to better address the legal requirement to confirm that the assumptions and conclusions in the environmental risk assessment regarding the occurrence of potential adverse effects are correct, even if the ERA did assess identified risks as negligible.
3. A strict conceptual division between CSM and general surveillance (GS) is not considered helpful with regard to the implementation of monitoring plans for individual GMPs. With a view to the case-specific requirements the overall design should be handled flexible to ensure that all relevant issues and parameters are taken into account.
4. The detection/assessment of exposure of the environment to GMPs, parts of GMPs and transgene products in the environment is considered to be a crucial aspect of GMP monitoring. The comprehensive identification of exposure routes and the level of exposure of the environment is required to facilitate conclusions as regards the causal relationship between unforeseen environmental effects and specific GMPs.

5. Concerning the identification of appropriate parameters and indicators for the monitoring of unanticipated effects the policy paper suggests the use of different complementing approaches: Evaluation of cause-effect hypotheses and of exposition pathways by which a GM crop might impact the environment within and outside the cultivation area, modeling and geo-statistical extrapolation e.g. to address effects on a landscape scale and long-term implications, and the evaluation of safeguard objects and protection goals for biodiversity, water and soil and selection of indicators representing them in the relevant environment.
6. The appropriateness of existing monitoring programs or data for GMP monitoring should be closely evaluated. Adaptations, extensions of the scope or additional surveillance systems may be necessary, if existing systems are found to be inappropriate to address the specific requirements related to GMP monitoring.

1 INTRODUCTION AND BACKGROUND

Since the first discussions concerning the safety of GM technology in the mid seventies most countries of the world have developed biosafety regulations for GM applications concerning the use of genetically modified organisms (GMOs) in contained systems and for environmental release. As a general principle to these regulatory frameworks at the national as well as international level, GMOs have to be assessed with respect to potential risks for humans or the environment before they may be placed on the market or released into the environment.

The regulatory frameworks in the EU and Switzerland with regard to the environmental and health safety of GMOs are based on similar approaches and among other considerations implement the precautionary principle. According to this principle harm or damages to the environment or human health shall be avoided or minimised by appropriate measures, which is specifically important if a risk assessment is associated with high levels of uncertainty. Thus the precautionary principle enables the competent authorities to take measures based on preliminary scientific evidence indicating a potential for harm.

Monitoring of environmental effects of GMOs after placing on the market as it is stipulated in Swiss and EU legislation is an important instrument to implement the precautionary approach in GMO regulation (ZÜGHART et al. 2008). By demanding a post-marketing monitoring for GMOs the EU and Swiss regulations acknowledge that the obligatory pre-release risk assessment of GMOs can possibly not address all questions, possible effects and potential risks associated with the release of GMOs, e.g. due to the complexity of the receiving environment. Monitoring is meant to further address open questions from risk assessment, especially on indirect, delayed and long-term cumulative effects of GMOs and their use on the human health and the environment.

However, while the requirement for monitoring is generally acknowledged its implementation is a matter of ongoing debate among regulators, notifiers, consent holders, scientists and other stakeholders. Issues that are discussed controversially on an European level include the scope and objectives of the monitoring, choice of monitoring parameters and methods, or the geographical areas to be monitored.

This paper shall contribute to the ongoing discussion on GMO monitoring from the point of view of the National Environment Agencies in Austria and Switzerland and the Federal Agency for Nature Conservation in Germany, concerned with environmental protection and nature conservation issues. The publishing agencies are either agencies with sole or shared responsibilities for environmental release of GMOs, or advisory bodies in the approval process of GMOs on national and EU level. They are thus involved in the evaluation of monitoring plans and monitoring reports delivered by applicants as well as the development of concepts of environmental monitoring of GMOs (SUKOPP & SUKOPP 1997, TRAXLER et al. 2005, HEISSENBERGER et al. 2003 & 2004, ZÜGHART et al. 2003–2008, GRAEF et al. 2004–2006, HILBECK et al. 2008a, KOWARIK et al. 2008, MEIER et al. 2005, OEHEN et al. 2008) and are involved in ongoing research projects as well as in discussions on the subject at the EU-level. Experts delegated by the respective Agencies also participated to the EU “Working group on guidance notes supplementing Annex VII of Directive 2001/18/EC” of DG Environment and contribute to the creation of checklists for selected GM crops and other papers (EU-MWG 2008a).

It is of great concern to the contributing Agencies that the framework and design of present and future GMO-monitoring systems in Europe will be comparable and generate good quality data to support further assessment and decision making. The aim is to ensure that these monitoring systems will be appropriate to detect environmental effects of GMOs and their use as early as possible and support the implementation of adequate management and mitigation measures.

In the following chapters we discuss the legal requirements and scientific basis of monitoring of GMOs from our point of view. As monitoring measures are based on the results of the pre-release environmental risk assessment (ERA) of GMOs, we will briefly outline the requirements and the basis of the ERA (chapter 2). The legal basis and the scope of the ERA as well as the basic principles, e.g. the case-by-case and the step-by-step principle, are presented and the interrelationship between the ERA and the monitoring of GMOs is discussed.

In the following the basic requirements for the monitoring of GMOs are described (chapter 3). The scope of case specific monitoring (CSM) and how CSM and ERA are interrelated is discussed next (chapter 4), followed by an outline on the scope of general surveillance (GS) as well as the interplay of CSM and GS (chapter 5). Here we discuss different types of unanticipated effects that should be covered by GS, explain the approach of GS, and briefly evaluate the role and usefulness of existing monitoring programs and farmer questionnaires.

Subsequently we address the necessity for the monitoring of the presence of GMOs or parts of it and of transgene products in the environment. We also outline suggestions for methodological approaches to cover this aspect of GMO monitoring (chapter 6). Next concepts for the identification of monitoring objects and parameters are proposed (chapter 7) and the relevance of establishing standardised methods for environmental monitoring of GMOs is addressed (chapter 8).

Finally the role of further risk assessment studies (chapter 9), the current state of monitoring (plans) in the EU (chapter 10) and overall conclusions are outlined (chapter 11).

2 MONITORING IS BASED ON THE ENVIRONMENTAL RISK ASSESSMENT OF GMOS

2.1 Introduction

GMO monitoring is highly interconnected with the environmental risk assessment (ERA) for GMO applications according to the Swiss, the EU or EU-Member States Biosafety regulation frameworks.

As stated by the legal requirements for ERA a case-by-case environmental risk assessment needs to be carried out prior to an environmental release of a GMO, taking into account direct and indirect, as well as immediate and long-term effects (for reference see e.g. Dir. 2001/18/EC). The applicant is required to submit a notification for release or placing on the market of a specific GMO containing a full environmental risk assessment and a monitoring plan, which have to be evaluated by the respective competent authorities. The authorities consider the results and conclusions of the ERA in their decision making while taking into account associated uncertainties to enact adequate risk management and monitoring measures. Risk management and monitoring measures are carried out by the applicant after authorisation is granted.

Monitoring is thus partially based on the ERA as conducted before authorization. It is described by the applicant in a monitoring plan which is part of the notification. Monitoring is conducted after approval; its conditions and its duration are specified in the decision for authorization.

The approval process for deliberate release and placing on the market of GMOs is outlined in Fig. 1, indicating requirements for ERA and monitoring in the EU.

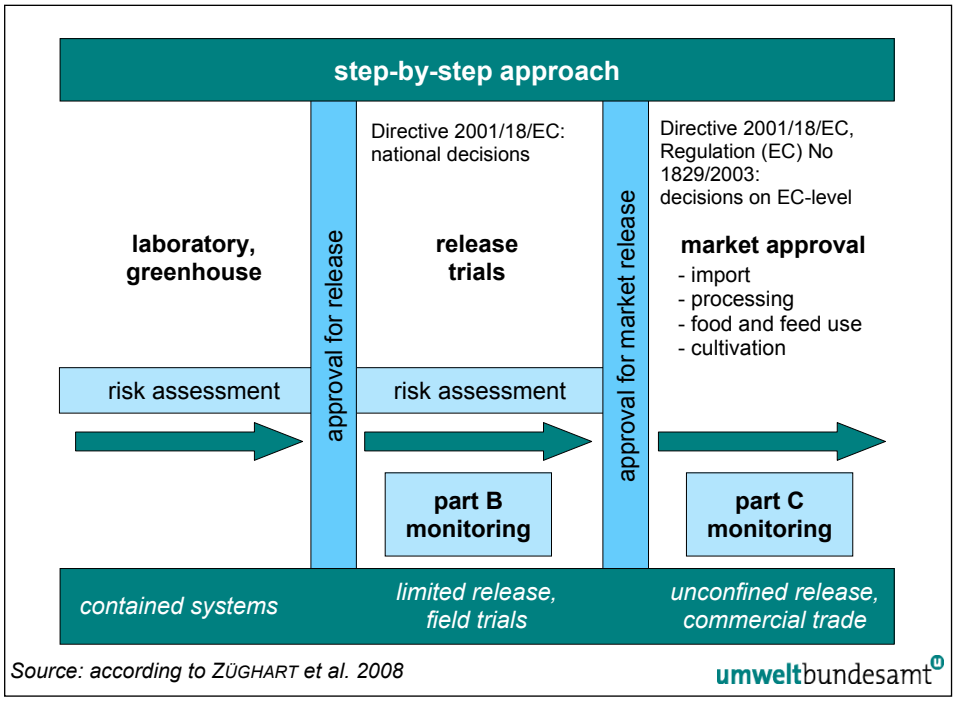

Figure 1: Overview of requirements for environmental release of GMOs with regard to ERA and monitoring.

2.2 The Environmental Risk Assessment of GMOs – Scope and Definitions

Applicants are required to conduct an Environmental Risk Assessment (ERA) when a GMO notification is submitted under Directive 2001/18/EC, Regulation (EC) No 1829/2003 (for EU member states) or under the Swiss Ordinance on the deliberate release of organisms into the environment (Release Ordinance RO; SR 814.911). A risk assessment always has to be carried out prior to a release (Directive 2001/18/EC, preamble, point 19; Art. 19 Abs. 1 and Art. 4, 7, 19 & 28 RO). The ERA covers notifications for deliberate release (part B according to Dir 2001/18/EC) or placing on the market (part C according to Dir. 2001/18/EC).

The general provisions of Directive 2001/18/EC define the environmental risk assessment (ERA) as "*the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose and carried out in accordance with Annex II*" (Article 2).

According to Annex II of Directive 2001/18/EC the objective of the ERA is "*on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have*". Furthermore *"A general principle of the ERA is also that an analysis of the cumulative long term effects relevant to the release and the placing on the market is to be carried out".*

In the Swiss framework Release Ordinance SR 814.911 states in Appendix 4: "*The purpose of determining the risk is to determine and assess the consequences of the real case of handling organisms in the environment, for … human beings, animals or the environment and biological biodiversity and the sustainable use thereof. … The risk assessment must evaluate the justifiability of the risk.*"

The steps of the ERA comprise the identification of the characteristics which may cause an adverse effect, the evaluation of the consequences of a potential adverse effect and the likelihood of its occurrence as well as the risk estimation and the application of an appropriate management strategy. In all these steps the precautionary principle should be applied, e.g. by considering possible areas of uncertainty.

Both, the European (Directive 2001/18/EC, Annexes II and IIIB) and the Swiss legislative provisions (Swiss Release Ordinance, SR 814.911) require assessments of specific environmental effects when a GMO is intended to be placed on the market. Although the potential adverse effects outlined are comparable, in several cases, the Swiss Ordinance further specifies the risk assessment requirements by formulating scenarios which should be evaluated at a minimum (according to Appendix 4 RO, SR 814.911):

- The potential establishment and spread of the GMO
- The possibility for gene transfer of the GMO (e.g. outcrossing) and the potential selective advantages conferred to the GMO or GM-wild plant hybrids
- Potential changes in the interactions of the GMO with non-target organisms

- Potential effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling
- Mechanisms of interaction with and effects of the GMO on target organisms as well as the potential for the development of resistance in target organisms and the consequences thereof
- Potential interactions with the abiotic environment
- Potential changes in management (agricultural) practices associated with the GMO

A detailed outline of the risk assessment strategy for GMOs in the EU as well as guidance for ERA is given in the EFSA guidance documents for risk assessment. The general guidance (EFSA 2006a) is supplemented by specific guidance documents targeted to various issues of risk assessment. With regard to ERA of GM plants the EFSA GMO panel published a draft document "Guidance on the environmental risk assessment of genetically modified plants" for public consultation in March 2010 (EFSA 2010). The draft is regarded in most comments e.g. from Member States authorities as a major step forward to specify detailed guidance for ERA issues. EFSA currently takes into account the suggestions for further improvement of the document ahead of publication of the finalized guidance document.

In the draft document the above mentioned risk assessment strategy is proposed and detailed for specific ERA issues as mentioned above and relevant crosscutting considerations, concerning the comparative assessment, the receiving environment with regard to GMO releases, general principles for data analysis and the assessment of long-term effects and of stacked events.

In both, the EU and the Swiss legislation on the basis of the risk assessment safety measures or management strategies for risks should be determined. A decision on risk management measures is a prerequisite to determine the overall risk for a GMO (Directive 2001/18/EC, Annex II C2.6). The Swiss provisions (Art.19 par. 2d, RO; SR 814.911), specifically require an assessment of the overall risk of the deliberate release of a GMO according to the type, severity and probability of possible damage, taking into account the proposed safety measures. When considering the acceptability of the conclusions (justification) the precautionary principle should be taken into account.

2.3 Basic requirements for the environmental risk assessment with relevance for monitoring

Annex II of Directive 2001/18/EC specifies the requirements which have to be taken into account during the ERA of GMOs. These requirements also influence the scope and structure of the monitoring plan.

Due to the broad range of individual characteristics of different organisms, their possible genetic modifications and the resulting characteristics of the GMO and due to different environments the ERA should be carried out on a **case-by-case** basis.

This approach should ensure that for any notification

- the specific GMO with its introduced or modified traits (the 'event'),
- its intended use and potential exposure routes (due to cultivation or through import and processing of GMO products) and,
- the respective receiving environments

are taken into account during the risk assessment.

The fact that the environmental effects of a GMO or its use may be different in different receiving environments is recognized in Directive 2001/18/EC. The directive refers to the differences in geographic distribution of wild relatives of certain GM plants within Europe as an example to illustrate the implications of the specifics of regional environments for the ERA. Therefore data for the ERA should be generated by field trials in relevant and representative regions, where the GMO is intended to be released. Such a **site-by-site** evaluation is needed to consider variations in environmental effects, in particular for the assessment of potential effects on biodiversity in general, on non-target organisms, and on ecological processes and functions (e.g. soil functions) in which these organisms are involved. The difficulties associated with this approach are apparent e.g. for the assessment of effects on non-target organisms: To conduct the assessment a few test species have to be selected as non-target surrogate taxa. This selection of species however should be representative for all receiving environments (SCHOLTE & DICKE 2005; DUTTON et al. 2003; HILBECK & ANDOW 2004; HILBECK et al. 2006; ANDOW et al. 2008). Monitoring is considered a means to assess whether the assumptions underlying the risk assessment strategy and the conclusion drawn from the ERA were valid.

According to the **step-by-step** approach outlined in Directive 2001/18/EC testing of a GMO should start under contained conditions and proceeds with stepwise release into the environment, according to the gathered knowledge concerning biosafety issues. Releases are progressing from small scale trials with strict containment measures to avoid spread of the GMO to larger scale trials with fewer control and containment measures until sufficient data have been collected to conclude on the environmental safety of a GMO. This sequential environmental release of a GMO into its receiving environment is crucial to identify potential adverse effects as soon as possible and to be able to stop the release into the environment if risks are considered unacceptable or not manageable by risk management measures. This step-by-step approach should be conducted in parallel with the collection of relevant data from representative receiving environments (Annex II of Directive 2001/18/EC). The information and data gained during this step-wise release of the GMO, in particular results from part B monitoring obtained during experimental releases (part B notifications according to Directive 2001/18/EC), are of considerable importance for the ERA and the requirements on the monitoring of the GMO and its use after its market approval. These data can be helpful for the formulation of adverse effect hypotheses and for choosing relevant monitoring parameters for the observation of the GMO in its receiving environment during commercial cultivation.

The use of **scientific and technical data**, generated by adequate **scientific methods** is crucial in order to achieve scientifically sound and robust results concerning effects of a GMO on the environment. The determination of risks must be carried out according to scientific criteria and methods and be based on available scientific and technical data.

An assessment of **exposure** of specific elements of the environment is an additional step in the ERA. The evaluation of those species or processes potentially affected by the GMO in a specific environment is a prerequisite for any assessment of potential adverse effects, e.g. on non-target organisms. In combination with an effect assessment the exposure assessment allows the evaluation of species which may be at risk. Exposure assessment likewise is an important issue for GMO monitoring, to assess whether relevant parameters, e.g. certain non-target species, have to be investigated during monitoring. In the revised guidance document on risk assessment of genetically modified plants EFSA also foresees an explicit exposure characterization, which is especially important when evaluating non-target effects (EFSA 2010).

Data provided by the notifier during the risk assessment procedure should reflect the current **state of the art** of scientific knowledge.

In the ERA, areas of **uncertainty** should be clearly identified. Uncertainty may result from two areas: measurement uncertainties as a characteristic of the scientific method used for generating specific data or uncertainties due to a lack of data. If no data are available this should be clearly stated in the ERA. The extent of uncertainty in the ERA should also influence the decision on whether Case Specific Monitoring (CSM) will be carried out and in which extend (see also Chapter 4.2).

Interpretation of the ERA

A principle of the ERA is that the data for risk assessment submitted in notifications should be taken into account together with additional available information (Directive 2001/18/EC; Annex II). The potential environmental risk of the GMO should be evaluated on the basis of data collected in laboratory assessments, data from part B trials conducted under different (relevant) environmental conditions and data from other sources (e.g. published studies on the environmental characteristics and effects of a GMO).

It is important that conclusions and interpretations drawn from ERA results are carefully evaluated with regard to the potential adverse effects and the derived risk hypotheses identified. In principle, evaluations of potential adverse effects should be based on scientific data. The ERA may not always be fully conclusive because of uncertainties or lack of data. Furthermore disagreement may arise concerning the level of detail, the methodology or the interpretation of results. In these cases either the ERA needs to be refined or adequate risk management measures have to be applied. At any rate Post-release monitoring should not be a substitute for a proper pre-release risk evaluation.

Shortcomings associated with practical implementation of regulation

The analysis of the current regulatory practice indicates that the requirements for ERAs as outlined above are not implemented satisfactorily and that a number of shortcomings can be identified, e.g.:

- Studies not conducted according to the scientific state of the art or according to applicable standards (e.g. OECD guidelines, etc.)
- Data generated in trials conducted at locations which cannot be considered representative for European ecosystems (e.g. data from trials at different continents)

- No meaningful data available from monitoring of commercial application in non-European countries or from part B monitoring measures
- Uncertainties concerning the significance of the results of risk assessment studies tend to be underestimated for drawing conclusions with regard to determination of overall risk

Such shortcomings need to be addressed further to achieve the required standards for ERA. In addition any remaining uncertainties in the ERA will have to be considered when implementing CSM.

3 BASIC REQUIREMENTS FOR THE MONITORING OF GMOS (CSM AND GS)

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

In general, monitoring of GMOs should be subject to general standards and requirements related to the objective that GMO monitoring aims to identify environmental changes related to GMOs as early as possible. While in this chapter general aspects concerning the monitoring of GMOs will be discussed, the intrinsic differences between CSM and GS will be specifically addressed in the following chapters (4 and 5).

The design process of the monitoring of GMOs should start with the identification of the potential adverse effects of a certain GMOs on the environment. A main tool for the identification of adverse effects is the formulation of cause-effect hypotheses derived from the ERA, biosafety research results as well as from existing knowledge of ecology and ecosystem theory. As research experiments are usually limited in scope (e.g. time or space) additional tools are needed such as modeling and geo-statistical extrapolation to extrapolate the results of the ERA to larger spatial scales or over longer periods. The monitoring should be able to address the most relevant effects of the respective GMO and its use (ZÜGHART 2008).

The next step is to prioritise the identified effects and to select the relevant indicators, parameters or monitoring objects that are appropriate to address these effects or relevant protection targets. Suggestions how to select the monitoring parameters are outlined in chapter 8.

Also for the monitoring of GMOs a step-by-step approach has to be applied (Directive 2001/18/EC, Annex VII; see also Fig. 1). Experience, data and results gained from part B monitoring of experimental releases or large-scale field trials should be used for the design of the post-marketing monitoring (SUKOPP & WEDDELING 2007). As part B monitoring is obligatory according to Article 6 of Directive 2001/18/EC, the methodology and the results thereof should be presented in part C notifications together with the implications for post-marketing monitoring taking into consideration the scope of the notification.

In the following, additional requirements that should be fulfilled for GMO monitoring are listed:

- Monitoring should deliver comprehensible results which are comparable across sites, regions or even countries. One tool to achieve comparability is the application of standardised methods (for details see Chapter 9).
- The question whether any causal relationship between an observed environmental change and the placing on the market of one or several GMOs exists, can only be addressed if a relevant **baseline** for comparison is established. Such a baseline can be a reference status of an environmental variable in

time (e.g. before GMO cultivation) or in space (e.g. in areas without GMO cultivation; see Council Decision 2002/811/EC). The assessment of the baseline should be carried out with scientifically sound methods and focus on specific environmental parameters (e.g. the status of a certain bird species population or specific weed species abundance). Descriptive observations of general nature (like the status of e.g. "wildlife") neither take into consideration the natural variability nor individual species responses. They are thus of very limited value. Although the use of "historical or existing knowledge" of e.g. farmers can provide a useful, additional source of information when establishing baseline values, this information cannot substitute investigation by scientific methods. Baselines must also consider spatial heterogeneity and thus be established on the relevant spatial scale.

- The **monitoring period** will depend on the specific monitoring parameter and method chosen. In any case it must be ensured that the evaluation of relevant direct, indirect, immediate, long-term, cumulative and unexpected effects is possible. For example, the monitoring of potential adverse effects resulting from gene transfer of a GMO must be extended beyond the authorisation period of a particular GMO, if hybrids with wild relatives carrying the transgenes of that particular GMO are present in the environment. The monitoring period shall also take the natural variability of the monitored parameter into consideration. It is thus clear that the monitoring period in most cases will be longer than the time of consent for a specific GMO. It can be assumed that GS will most likely result in longer monitoring periods than CSM.
- Monitoring should take place in representative **areas/environments** where the GMO is intended for environmental release or – if only import and processing of the GMO is envisaged - where environmental exposure is expected. Any reference or control areas and samples must be representative in terms of the environmental conditions where the GMO will be cultivated or used. The selection of monitoring areas must also consider the specific characteristics of the GMOs, such as the crop and its ecological characteristics as well as the introduced GM trait. Monitoring may be restricted to selected areas or regions, if considered representative for the specific hypothesis/parameter to be monitored. GMO monitoring should ideally take place where exposition or effects of the GMO or its use are to be expected (SCHRÖDER & HOFFMANN 2008). However also areas in which exposure or effects are considered unlikely at the current state of knowledge may be included (e.g. in GS). Special consideration has to be given to either nationally or EU-wide protected areas (e.g. according to Directives 92/43/EEC or 79/409/EEG; Art. 8 RO) or ecologically sensitive areas with specific nature protection goals. Irrespective if this is done during the ERA of a particular GMO (see e.g. STELZER et al. 2003, WINTER 2006) or after the authorisation, specific monitoring actions need to be defined with regard to the specific protection goals set forth for these areas. This may include intensive monitoring efforts in buffer or external zones of protected areas (e.g. national parks) in order to detect invasions (e.g. in case of GM oilseed rape) or other unexpected effects in time (UMWELTBUNDESAMT et al. 2007).

Monitoring needs an **adaptable and dynamic concept** (ZÜGHART et al. 2008). It should be designed as an iterative process, using feedback from reporting to enable improvements and/or amendments as appropriate (ACRE 2004).

Council Decision 2002/811/EC specifies that monitoring plans and the associated methodology is updated or adapted as necessary and may include adjustment of methods, monitoring goals or the program (EC 2002). This may be the case if reviews of monitoring plans show that the effectiveness and efficiency of applied monitoring measures are not sufficient in addressing the monitoring goals or to evaluate ERA conclusions (EC 2002). It may also be necessary to redesign models, depending on the results of the validation based on the data collected during monitoring. Also the time periods for monitoring may have to be amended in the light of the monitoring results. Another need for adaptation may derive from new developments in sampling and analytic techniques (EC 2002).

The basis for the adaptation of the monitoring plan and the associated methodology is the review of the monitoring results at appropriate intervals (EFSA 2006b). In detail adaptation may be necessary:

- if unexpected effects on the environment are detected during monitoring which require an adaptation of the monitoring itself, e.g. in order to include relevant new parameters or indicators in the monitoring plan.
- if results from monitoring, biosafety research or other new scientific results indicate that the ERA of the GMO needs to be re-addressed or updated which in turn affects the hypothesis tested in the monitoring plan (e.g. CSM).
- if practical difficulties are identified during the implementation of the monitoring plan (e.g. lack of access to monitoring sites etc.).
- if results of monitoring show that adaptation of monitoring parameters, objects or the monitoring frequency is necessary in order to achieve better results.
- if practical experience shows that certain GMO monitoring actions cannot be integrated into existing networks/programs as foreseen in a monitoring plan after the GMO has been authorized.

4 CASE SPECIFIC MONITORING (CSM)

4.1 Scope of CSM

The objective of Case Specific Monitoring (CSM) is "*to confirm that any assumption regarding the occurrence of potential adverse effects of the GMO or its use in the e.r.a. are correct*" (Annex VII of Directive 2001/18/EC).

The Swiss Release Ordinance (SR 814.911, Art. 19, par. 2e) does not explicitly specify a CSM but in analogy demands from the notifier a "*monitoring plan to show how the applicant will examine whether the assumptions of the risk determination and assessment in accordance with Appendix 4 are correct and whether the measures to adhere to the requirements of Art. 7 par. 1 & 2 and Art. 6 GTL (Gene Technology Law, SR 814.91) are sufficient*" (SR 814.911, Art. 19, par. 2e).

The guidance notes to Annex VII of Directive 2001/18/EC further states that CSM "*should […] focus on potential effects arising from the placing on the market of a GMO that have been highlighted as a result of the conclusions and assumptions of the ERA*" (EC 2002, B.). "*CSM serves to confirm that scientifically sound assumptions in the ERA regarding potential adverse effects arising from the GMO and its use are correct*" (EC 2002, C.). The guidance notes to Annex VII further specify that the approach "*should focus on all the potential effects on human health and the environment identified in the risk assessment, taking into account i.e. different locations, soil types, climatic conditions […]* " (EC 2002, C.).

4.2 Interplay between the ERA and CSM

CSM is currently only established for one application (Amflora GM potato) and implemented in few monitoring plans of pending applications. The overall risk assessment submitted by the notifier usually concludes that there is only negligible risk for most of the identified hazards. The only notable exception is the identified risk of resistance development in target organisms due to the cultivation of insect resistant GM crops, specifically GM maize lines (see also Chapter Present state of monitoring plans). In the notifiers' views as well as in the view of EFSA (EFSA 2006b) a potential effect would only be monitored in CSM when the ERA indicates that a risk is evident. The following examples show the practice of implementation and the different ways how the ERA is interpreted (see also chapter 11).

In the notification of GM potato EH92-527-1 (notification C/SE/96/3501 according to Directive 2001/18/EC) the notifier proposed a monitoring plan which is related to molecular parameters (stable insertion of genes, lack of expression of ORF4), plant performance (amylase/amylopectin ratio, glycoalkaloid levels in tubers, several plant characteristics, susceptibility to diseases and pests, feed quality parameters) and ecological parameters (persistence, volunteer management inside and outside the managed field) although the notifier stated that no particular concern was identified in the ERA that required specific CSM. Ir-

respective whether this monitoring is regarded to be CSM or GS as indicated by the notifier, the measure aims to verify the assumptions of the ERA over a prolonged period.

Another example is the risk assessment practice of *Bt*-maize (e.g. notifications of GM maize lines MON810, MON863, MON88017, 59122, 1507, Bt11). In general, in these notifications, the likelihood of occurrence of e.g. direct toxicity of *Bt*-maize to non-target organisms, indirect population effects, or adverse effects on the nutrient cycles in the soil, is considered negligible. Thus neither risk management measures nor CSM are proposed although EFSA states in its Scientific Opinion on the renewal of authorization of MON810 maize, that, "*the potential lethal and sublethal effects of pollen from maize MON810 represent a potential hazard to non-target European lepidoptera"* (EFSA 2009). However in order to cover the risk of development of resistance in the target organisms, an insect resistance management (IRM) plan is usually proposed for *Bt*-maize cultivation, although the risk is also considered negligible in the ERA. Some notifiers classify the proposed IRM plans as a risk management measure and as CSM (e.g. GM maize Bt11, 1507, 1507xNK603, 59122) while others consider it only CSM (e.g. GM maize MON810, maize MON810xNK603).

In general the ERA is subject to different limitations, especially with regard to variability and uncertainties such as:

- The **scale**: results of the ERA that are derived from contained systems or field release experiments may not be representative for the large scale cultivation of a GM crop. Especially long-term and indirect effects may not become visible. The potential risks associated with the increased scale and duration of use should be addressed in the ERA and have also to be considered within the CSM (see ACRE 2004).
- The **species** used: the results of the ERA are established by tests conducted with a limited number of test species e.g. organisms representing flag species (e.g. *Chrysoperla*, *Coccinella*) or species easy to handle (e.g. *Daphnia*, *Eisenia*). These may not necessarily represent the most exposed or the most susceptible species in the field which however are the ones which are most likely at risk. It may well be that species which are actually affected adversely in the field have not been considered in the ERA. This is generally not accounted for in the ERA of GMOs (see e.g. HILBECK et al. 2008b; DOLEZEL et al. 2009, SCHMITZ et al. 2003).
- The **exposure model** considered: extrapolations including the exposure time (short-term versus long-term) and space (one versus different sites) or consideration of different pathways of exposure are generally not accounted for in the ERA. Additionally, cumulative effects caused by the interaction of different plant/trait combinations or co-exposures to different GMOs are not considered in an ERA for a single event.
- The experimental **methods** used: outdated or inadequate experimental designs may limit the significance of a risk characterisation (overview in DOLEZEL et al., 2009).

Additionally, ERA methods must be adequate to address risks due to specific transgenic traits incorporated in a GMO and the characteristics of the receiving environments (SSC 2000). The increasing complexity of the assessment of GMOs containing a combination of different traits, e.g. as present in stacked events, adds further complexity to the ERA process. Associated uncertainties of all types should be taken into consideration for conclusions of the ERA, and identified in a consistent way (UMWELTBUNDESAMT et al. 2009, AHTEG 2010).

Considering the above mentioned limitations in the ERA a certain possible adverse effect may have to be monitored by CSM even if the ERA shows no or a negligible risk. The Supplementing Guidance Notes to Annex VII (Council Decision 2002/811/EC; EC 2002) state that "*CSM serves to confirm **that scientifically sound assumptions** in the ERA regarding potential adverse effects arising from a GMO and its use **are correct***". These assumptions also comprise the evidence of no risk. This becomes very clear later on in the Decision: "*Where the conclusion of the risk assessment identifies an absence of risk or negligible risk, however, then CSM **may** not be required*". This requires, that 1) **all** assumptions should be considered including those resulting in a negligible risk and 2) that for each adverse effect identified it has to be decided individually whether it should be monitored or not. This has also been emphasized by ACRE stating that "*even if the ERA did not identify risks, its fundamental assumptions still need to be evaluated by CSM"* (ACRE 2004).

In the sense of Directive 2001/18/EC and its annexes, the following criteria might be used to decide whether an identified risk should lead to CSM or not:

- the level of uncertainty (e.g. issues from the ERA that are subject to a degree of uncertainty; see EC (2002), 1.1.)
- the amount and quality of data available for a specific risk characterisation
- the level of release (large versus small scale; EC (2002), 1.1.)
- the consequence of a potential adverse effect
- the level of (ir)reversibility of a potential adverse effect.

In addition, there may be adverse effects, which are identifiable based on cause-effects relationships, but which were not assessed in the ERA. Those adverse effects comprise for instance indirect effects or food-chain-effects, e.g. impact of the use of herbicide tolerant crops on weeds and the associated fauna. Such gaps in the ERA may also be covered by CSM. This has also been the view of the Spanish Competent Authority which evaluated the ERA of GM maize NK603 (notification EFSA/GMO/NL/2005/22 according to Regulation (EC) No 1829/2003) and which requested the inclusion of monitoring effects of the GMO on weed communities and resulting effects on biodiversity as CSM in the respective monitoring plan.

In this context it should also be noted that an ERA may be re-addressed or updated in case new information on the GMO and its adverse effects on human health or the environment become available, e.g. during monitoring of the GMO, during further assessment or due to additional scientific information available for a specific GMO.

This could be the case if effects were observed or detected which were not expected to happen based on the outcome of the ERA. This could be due to:

- the detection of new characteristics of a GMO which cause a potential adverse effect (e.g. higher expression level under certain conditions),
- the change of consequences of an adverse effect,
- the change of the likelihood of occurrence of an adverse effect (e.g. outcrossing to a wild relative),
- the detection of unexpected adverse effects.

4.3 The CSM approach: Matching the objectives and implementing adequate monitoring tools

The overall aim of the CSM is to validate the results of the ERA or parts of it and to determine whether the ERA adequately addressed the potential risks. It represents a kind of quality control of the ERA which is subject to different limitations for instance small sets of test organisms, short time periods, small scale etc. (see above). CSM also aims to verify whether the results of the ERA are valid under the conditions of large-scale cultivation. Finally CSM aims to further investigate whether any adverse effects identified by the ERA as relevant occur under conditions of authorized use and to cover any gaps in the ERA, due to the uncertainties associated with the ERA, or a lack of comprehensive data, e.g. for all receiving environments.

The content and parameters of the CSM have to be selected on a case-by-case basis taking into account the criteria mentioned above like the data available and the level of uncertainty, the level of release etc. The risks/adverse effects identified to be monitored by CSM could in principle be direct, indirect or immediate as well as indirect, delayed or long term cumulative.

The selection of monitoring methods, time period, scope, etc. depend on the risk/adverse effect to be monitored. Dependent on the specific issue to be investigated, different methods may be suitable, from small scale and short term observations to long term and large scale surveys. With regard to the latter the boundary to GS gets more and more blurred. For example, a suitable CSM approach for the monitoring of effects on non-target organisms could be to monitor the effects of a specific GMO variation on non-target organisms, e.g. the comparison of population dynamics in large paired fields and in the surrounding natural habitats in a number of locations. By this approach it would be possible to examine population trends in non-target organisms that would be impossible to examine at a smaller, spatial and temporal scale. In contrast this approach would be insufficient for examining organisms that move long distances. Thus for these organisms a different approach would be necessary, e.g. the analysis of relationships between the intensity of planting of a specific crop variety in a locality and the population dynamics of these non-target organisms. At this level a grey area exists between CSM and GS (NATIONAL ACADEMY OF SCIENCE 2002). Thus care should to be taken to avoid potential gaps in the overall monitoring strategy.

Stringent application of the principles of the Directive would result in implementation of more environmental focused CSM measures compared to the current situation. This in turn would broaden the database for any subsequent risk assessment which needs to be conducted for any renewal of authorizations. The current experience with several applications for renewal including e.g. GM maize MON810, which is cultivated in EU Member States, shows that data gaps still exist for complex issues like the assessment of effects on non-target organisms and other long-term cumulative effects. Appropriate CSM requirements could be a means to establish missing data and thus to preempt concerns, which are based on the associated assessment uncertainties.

5 GENERAL SURVEILLANCE (GS)

5.1 Scope of GS

The aim of General Surveillance according to Directive 2001/18/EC (Annex VII) is "… *to identify the occurrence of adverse effects of the GMO or its use on human health and the environment which were not anticipated in the e.r.a."*. In addition, Council Decision 2002/811/EC (EC 2002) specifies another aim: "… *to identify and record any indirect, delayed and/or cumulative adverse effects that have not been anticipated in the risk assessment*."

The Swiss Release Ordinance does not explicitly specify general surveillance, but in analogy states that "*The Federal Office for the Environment (FOEN) shall ensure the establishment of a monitoring system for the early recognition of possible hazards to the environment and impairments of biological diversity by genetically modified organisms and their genetic material …*" (SR 814.911, Art. 51 par 1).

According to the above mentioned aims, GS is mainly focused on indirect, delayed and/or long term effects as well as cumulative effects. Additionally, it covers direct and immediate effects as far as they were not anticipated in the ERA.

GS should focus on the influence of the GMO on and interactions of the GMO with possibly affected organisms and ecosystems including "*effects on ecological functions; dispersal, establishment and persistence of GMOs in non-target environments or ecosystems; out-crossing with wild relatives in natural populations; unintended changes in the basic behavior of the organisms and changes in biodiversity"* (Council Decision 2002/811/EC; EC 2002).

5.2 General surveillance: case-by-case and beyond

According to Directive 2001/18/EC GS plans should consider the specific characteristics of the GMO, e.g. the potential lifespan (e.g. annual or perennial crops and trees), the modified or introduced traits (herbicide-tolerance, insecticide resistance, altered composition parameters, etc.), the intended use of the GMO (import and processing only or cultivation) as well as the range of relevant environmental conditions where the GMO is expected to be released (Annex VII of Directive 2001/18/EC, general principles). Hence, also GS should be developed on a case-by-case basis.

The respective monitoring period and area of GS will thus have to be established according to the GM plant, the trait and the receiving environment but in general it can be assumed that GS should be carried out over a longer time period and possibly a wider area than CSM (EC 2002).

General surveillance can also extend beyond case-specific aspects of a specific GM application. This may be the case if GS actions are designed and used for several, different GMOs with different characteristics. An example may be the monitoring of different types of GM oilseed rape grown adjacent to a protected area or ecologically sensitive habitat. In this habitat GS could monitor the occurrence or spread of GM oilseed rape in general without case-specific provisions for each GM event.

5.3 Interplay between CSM and GS

Directive 2001/18/EC and Council Decision 2002/811/EC (EC 2002) provide very general definitions of GS, thus leaving room for interpretation. According to EFSA (2006a) potential effects should be monitored under CSM if they have been clearly identified in the ERA as a risk, or under GS if they are absolutely unanticipated. However, potential effects may be identified, for which the likelihood of occurrence cannot be specified, the consequences are not predictable or which were not investigated in the ERA. These situations are not covered in detail by EFSA (2006a). On the other hand there may be effects that arise due to the cultivation of several GMOs and for which the risk cannot be assessed in a single GMO notification (e.g. risks due to gene stacking caused by cross-pollination).

In addition to anticipated and unanticipated effects the British Advisory Committee on Releases to the Environment (ACRE) considered a third category of adverse effects of GMOs that should be monitored (ACRE 2004). The three categories are summarized below:

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

Category II: *Interactive or cumulative effects, which are difficult or impossible to predict*. E.g. effects that might arise as a result of an increase of the scale of cultivation or potential effects arising as a result of interaction between the GM crop in question and other varieties (GM and non-GM) during the timeframe of consent. Such effects are difficult to predict or assess comprehensively in the framework of the ERA for a single notification.

Category III: *Unanticipated effects*. Potential effects not identified in the ERA, which can only be addressed by general surveillance.

According to ACRE (2004), interactive or cumulative effects are considered as unanticipated because "*within the ERA of an individual dossier it may be difficult to predict what effects might arise due to an increase in the scale of cultivation, or the full effects of environmental interactions*". Therefore, effects of this category should be monitored preferably within the scope of GS.

There are gradual differences in the predictability among effects and therefore gradual transitions between CSM and GS. It is therefore necessary to include the option of investigating similar parameters in CSM, in GS, or in both simultaneously. This has to be decided on a case-by-case basis. In general, the border between CSM and GS should be handled in a flexible way and reconsidered if doubts arise. Various criteria might be considered to support the decision whether a parameter is monitored under CSM or GS, e. g. the kind of effect, which should be monitored; the kind of indicator; the scale of monitoring; or the safeguard objects chosen. These criteria still have to be elaborated in detail.

5.4 Types of effects to be covered by GS

It is possible to distinguish between different categories or types of adverse effects which should be covered by GS:

- Effects which have not been identified in the ERA of an individual GMO notification (so called unanticipated effects).
- Effects which have been identified in the ERA, but which are difficult to predict or assess, i.e. effects
  - which are difficult to assess with regard to either the likelihood of exposure (e.g. cumulative effects by releasing different types of GMOs with the same transgenic traits, like herbicide tolerance genes or Cry-toxins), or with regard to the consequences (e.g. effects resulting from increasing the scale of cultivation in a wide area and for a long time period).
  - for which the assessment of likelihood of consequences of the effect is associated with considerable uncertainty in the ERA.
- Effects which are difficult to assess because of their complexity (e.g. impacts on ecological functions, food-chain effects).
- Effects that occur rarely, but may have large environmental implications, e.g. effects on soil functions due to horizontal gene transfer.

5.5 The GS approach: Identification of potential adverse effects and selection of appropriate monitoring parameters

It is generally accepted that it is not possible to monitor all possible effects of GMOs in all environmental compartments (e.g. air, water, soil, biota) and at all ecological scales (species/populations, ecosystems, landscapes). The challenge is to identify parameters and key environmental indicators that are appropriate to address adverse effects of GMOs on the environment and provide robust datasets on these (SUKOPP 2004, DEFRA 2007).

GS should include both a general observation not focused on a particular GMO which covers a range of indicators demonstrating the state and trends of the environment where the GMO is grown or released, and also more specific parameters related to the GMO/GM trait and the scope of its use leading to a more GMO-focused monitoring.

Hence, different complementary approaches to identify monitoring parameters can be appropriate:

- Consideration of adverse effect scenarios identified in the ERA, but not covered by CSM. Such scenarios are based on cause-effect hypotheses established by biosafety research, knowledge about the GMO and its trait as well as general ecological knowledge (ZÜGHART & BRECKLING 2003).
- Evaluation of pathways by which a GM crop might have an impact on the environment including changes within and outside the cultivation area. Relevant pathways should be considered when identifying indicators and monitoring parameters for GS (HUGO et al. 2007). Such parameters may also be derived from the assumptions formulated in the ERA and thus may be covered also

by CSM. For each of these pathways indicators/parameters have to be identified which can indicate an unexpected effect due to the release of a GM crop upon comparison with the baseline data.

- Modelling and geo-statistical extrapolation: Effects on the landscape and regional scale as well as long-term implications of commercial use can be assessed only to a limited extend through local approaches. Based on small-scale and short-term results an appropriate upscaling procedure can help to indicate potential long-term, delayed and combinatory effects respectively indicators and monitoring parameters (BRECKLING et al. in press).
- Evaluation of safeguard objects and/or protection goals for biodiversity, water and soil and selection of indicators representing those objects in the relevant environment. The selection of safeguard objects (e. g. specific protected arthropod species occurring in or near maize fields) ensures that the observation within a complex environment in which the GMO is cultivated is focused to specific organisms and functions which are of specific conservation concern or represent important ecosystem services. (UMWELTBUNDESAMT 2001, TRAXLER et al. 2005, KOWARIK et al. 2008, BARTZ et al. 2009, MEIER et al. 2009).

5.6 Stepwise development of a GS plan

GS should be developed stepwise. The first step is to identify relevant monitoring objectives, indicators or parameters of GS as described above. When parameters have been determined, the next step is to develop the appropriate methodology to observe these parameters.

In case existing networks and environmental schemes shall be involved, their scope with regard to primary objectives, parameters, methods, design, monitoring location etc. has to be examined (see chapter 5.7). It has to be verified in detail whether data from such networks or programs are applicable for general surveillance of GM crops, and whether an adaptation of the existing monitoring schemes is possible and appropriate.

If current monitoring systems and networks collecting environmental data are not able to provide relevant data or if significant data gaps are identified it is obvious that as a next step further monitoring tools have to be developed and/or established, which are appropriate to fulfill the requirements of Directive 2001/18/EC (EFSA 2006a).

In case of monitoring data being collected by persons or institutions other than the applicant, binding agreements/contracts with third parties are required which clearly determine what kind of data can be provided and how these data are made available (EC 2002, B.1.3).

5.7 Existing monitoring schemes and networks

The Swiss regulation stipulates that "For the monitoring it [*the FOEN*] shall use, as far as possible, data from existing monitoring systems in the environmental and agricultural sector, and shall also examine particular observations of third parties" (SR 814.911, Art. 51 par. 3).

The European legal provisions for GMO authorizations enable existing monitoring schemes to be used for monitoring of GMOs, specifically for GS. The guidance notes to Annex VII of Directive 2001/18/EC state that *"GS could, where compatible, make use of established routine surveillance practices such as monitoring of agricultural crops, plant protection, veterinary and medical products as well as ecological monitoring, environmental observation and nature conservation programs"'* (EC 2002, C. 1.3.2). *"If established routine surveillance practice is used in the general surveillance, this practice should be described as well as the changes in the practice needed to fulfill a relevant general surveillance."* (EC 2002; ibid.).

Currently predominantly monitoring plans for GM plants for food and feed uses, import and processing are implemented. Surveillance networks established by the European Association of Bioindustries (EuropaBio) play a key role in the general surveillance of these applications.

As described in detail in chapter 11, mainly three European Trade Associations (COCERAL, FEDIOL, UNISTOCK) which are coordinated by EuropaBIO are involved in GS for food and feed uses, import and processing. However current monitoring plans as well as the annual monitoring reports provided by the applicants do not specify which members or companies took an active part in the monitoring. No information is given on responsibilities, monitoring parameters, methods, locations or detailed monitoring results. Therefore, the monitoring results cannot be verified by the competent authorities.

A different monitoring strategy is implemented in case of applications concerning the import of GM carnations. As stated in the GS plan occasionally services of different experts like botanists, breeders and importers are involved. Breeders and botanists with interests in Dianthus biology were asked to alert the consent holder to any unusual hybrids identified during routine work or surveys. Again it remains unclear, how data are collected. Even though a small number of breeders and botanists are listed in the monitoring plan, no agreements were established to commit the experts. Results therefore depend on chance findings by the experts (ZÜGHART 2010).

Pending notifications for cultivation (see chapter 11) contain monitoring plans which propose, among other methods, the analysis of information collected by currently implemented environmental observation programs. However, neither the involved programs or networks nor the monitoring objectives or methods are specified.

GM maize MON810 was the first GM-crop to be cultivated in the European Union (see chapter 11). The German authority in 2008 requested from the consent holder to establish a general surveillance plan which was based on the analysis of publicly available reports of selected monitoring networks. This first trial to use existing monitoring networks in the context of cultivation failed because e.g. no agreement concerning the access to data was settled beforehand and the suitability of the selected programs to detect adverse effects of MON810 was not ensured.

These examples show that several prerequisites have to be fulfilled before existing monitoring networks and schemes can be used for general surveillance appropriately.

Prerequisites for the involvement of existing programs or networks include:

- the monitoring objects, indicators and parameters as well as methods, time, frequency and scope of data collection are relevant and appropriate
- the monitoring programs and networks provide robust data for general surveillance
- the monitoring schemes or networks are flexible concerning their potential for extensions/adaptations: e.g. indicator or parameter sets, intervals and sites of data collection
- the spatial range of the programs and networks fits with the geographical area, where the GMO is used
- agreements with institutions/representatives of monitoring schemes and networks to collect and provide data for general surveillance are established
- access to data for further analysis is ensured
- long-term funding for gathering relevant data should be ensured
- if European Associations are involved: all members and companies included should be listed and their ability to cover the scope of general surveillance be demonstrated.

Currently a lot of different networks and environmental monitoring schemes are established on regional or national level in the European Union and in Switzerland. The primary objectives for collecting these data are different and none of the monitoring systems is currently designed specifically for monitoring of GMO releases (DEFRA 2007, EFSA 2006a). In some countries evaluations have been conducted to identify monitoring schemes or networks which could potentially feed into general surveillance of GMOs (DEFRA 2007, HINTERMANN & WEBER 2003, MIDDELHOFF et al. 2006, ZÜGHART et al. 2003). Additionally the European Commission conducted in 2005/2006 a survey asking the Member States' competent authorities to provide information on existing national environmental monitoring programs suitable for GS of GMOs (EU-MWG 2008a, General surveillance Appendix 1).

A detailed and systematic investigation of monitoring schemes and networks in question is essential in order to check the suitability for the specific GS objectives. Especially, the kind of parameters, the methods of sampling, the monitoring design, the time frame and scale and the data established have to be feasible for the identification and evaluation of relevant effects associated with the GMO and its use.

In case significant data gaps are identified when using existing monitoring programs or networks additional surveillance methods need to be established.

5.8 Farmer Questionnaires

Farmer questionnaires may be a valuable tool to collect data on management practices of a GM crop as they consider mostly data on agronomic issues like occurrence of pests, application of pesticides or the occurrence of weeds. This refers to parameters which sometimes have to be also reported for other obligations (e.g. in the context of the Austrian program for rural development, BMLFUW 2009). These surveys not only provide useful feedback on product quality to the consent holder, but in certain cases may also be helpful for the interpretation of the results of CSM and GS.

Experiences and observations made by farmers may give useful hints on the occurrence of unexpected effects of the GMO onto the agricultural environment. However, such observations need confirmation using science-based methods and measurements (NATIONAL RESEARCH COUNCIL 2002). Farmer questionnaires supplement a science-based monitoring, but shall not replace sound investigation of environmental effects of GMOs on a broader environmental scale.

6 MONITORING OF THE PRESENCE OF GMOS, PARTS OF GMOS AND TRANSGENE-PRODUCTS IN THE ENVIRONMENT

GMOs are able to reproduce, spread and persist in the environment (MENZEL 2005, WARTRUD et al. 2004, ZAPIOLA 2008). The possibility of long-term persistence in the environment and the potential uncontrolled spread over long distances harbours the potential for unforeseen or unpredictable environmental impacts (LETOURNEAU et al. 2009, SNOW et al. 2003, WARWICK et al. 2009, WILKINSON et al. 2009).

Parts of GMOs (e.g. pollen, plant residues) and transgene products (e.g. Bt-toxins), are not able to reproduce themselves, yet they can persist and accumulate in the environment as well. They can be detected in the air (pollen), in soil, water or water sediments, in food (honey), compost, manure, sewage sludge, contents of stomachs or intestines and feces from domestic or wild living animals. Accumulation of parts of GMOs and transgene products at specific locations therefore may lead as well to unpredictable or unforeseen exposure scenarios and environmental impacts (DOUVILLE et al. 2007, HARWOOD et al. 2005, 2007, LANDESUMWELTAMT BRANDENBURG 2007, 2008, LUTZ et al. 2005, ROSI-MARSHALL et al. 2007, SAXENA et al. 2002).

In Switzerland, the federal law relating to non-human gene technology (Gene Technololgy Law, GTL; SR 814.91) specifies that "*GMOs may be released for experimental purposes if …according to the current state of knowledge, the dispersal of these organisms and their new traits can be excluded…"* (SR 814.91, Art. 6 par. 2e) and further "*GMOs intended for the use in the environment may only be marketed if experiments in contained systems or field trials have shown that they do not disperse, or their traits do not spread in an undesired way*" (SR 814.91, Art. 6 par. 3e). Thus, under Swiss law the spread of GMOs into the environment is already considered as an adverse effect. By contrast EFSA (2006a) considers the establishment, persistence and spread of a GMO as well as dispersal of pollen or seeds and gene flow per se not as environmental hazards.

There is considerable debate whether the exposure of the environment to GMOs or parts of it or to transgene products shall be subject to monitoring. According to EFSA (2006a) "the focus of GS should be on recording unanticipated consequences of the cultivation of a GM plant, such as unforeseen weediness, invasiveness or changes in plant population dynamics or populations of biota associated with the GM plants". This is not entirely in line with Council Decision 2002/811/EC whereupon non-specific elements like dispersal, establishment and persistence into non-target environments or ecosystems and out-crossing/breeding with sexually compatible wild relatives in natural populations may also need to be considered as part of the monitoring plan. In addition, EFSA states also that unanticipated adverse effects may most likely occur where the level of environmental exposure is highest (EFSA 2006a) thereby highlighting the importance of knowing where the GMOs or parts of GMOs are in the environment. Thus an evaluation of how and where the GMO will be grown and the associated environmental exposure is a good starting point in any general surveillance plan.

Identifying environmental exposure routes and recording dispersal, persistence and accumulation of GMOs, parts of GMOs and transgene products in the environment are crucial aspects of the monitoring. Information on the fate of GMOs and GMO products in the environment is a necessary prerequisite for selecting relevant monitoring sites and parameters to assess unforeseen or unpredictable consequences. Moreover the information gained from monitoring the environmental exposure of GMOs, parts of GMOs or transgene products represents an important basis for drawing conclusions on interrelationships between unforeseen environmental effects either occurring immediately or with a time-lag after the environmental release of a GMO. Data on the presence of GMOs, parts of GMOs and transgene products in the environment will provide basic information which may be relevant not only for GS, but also for the ERA as such and consequently may have implications for CSM. Thus according to a precautionary approach the detection of environmental exposure of GMOs and transgene products in different environmental compartments as well as in highly sensitive or protected areas, is an essential element of GMO monitoring.

7 GMO REGISTERS

The knowledge of the location of the cultivated GMOs in the environment is crucial for the choice of monitoring sites (both for CSM and GS), for the interpretation of the results of the monitoring, and for the design of further studies if unexpected effects are observed. For these purposes, the specific locations of GMOs need to be registered and accessed.

Directive 2001/18/EC (Art. 31, 3.) foresees that member states shall establish public registers in which the locations of the release of GMOs under part B and part C are recorded. Several EU member states are currently setting up GMO registers, the implementation and effectiveness, however, differs among member states.

The German GMO Location Register was established in 2005 by the Federal Office of Consumer Protection and Food Safety (BVL). With regard to the German Genetic Engineering Act experimental releases or commercial cultivations of GMOs have to be notified to the register three days ahead of release or planting for cultivation. Via internet, information like cadastral data, field size, notification date and the GMO trait are publicly available (BVL 2009). Additionally, the GMO sites are graphically depicted on the level of community area, whereas the specific location of the field/site can't be identified. Person-related data of the farmers in general are not publicly accessible. Their use is restricted to authorised stakeholders only. This authorisation is granted by the BVL and requires a written application with verification of plausible interest.

In Austria the Austrian Gene Technology Act and the GMO Register Ordinance require the establishment of a GMO register in which information on the location of the cultivation of GMOs authorized for deliberate release or placing on the market has to be included. This register is open to public access and has to be accessible via the Internet. The cultivation registers are implemented by the precautionary laws of the Austrian provinces. At national level the register contains data on GMO releases or commercial cultivation only at an aggregated level (area per municipality, crop and GM variety, unique identifier for the GMO, indication of authority which makes available further details). Details on the owner/user of the fields, requirements by authorities and the exact locations of agricultural plots where GMOs are grown are contained in the register at the level of the provinces. Access to the register can be given to any person. As there is currently no GMO cultivation in Austria, the cultivation register is not yet effective. Therefore its use and practicability for monitoring purposes can currently not be assessed.

According to the Swiss Release Ordinance (SR. 814.911, Art. 56) a register is maintained, which is based on information notified by applicants to the Federal Office for the Environment (FOEN). The submitted information comprises the type of use and release, the timeframe (beginning and end of release) and the site(s) of the release. The information on GMO releases shall be public, if no private or public protectable interests predominate. In each case, the name of the responsible persons as well as the sites, i.e. municipality where GMOs are released – among others – shall be made public.

From an environmental point of view the following aspects need to be considered in the context of GMO registers:

- It is crucial that persons involved in monitoring actions can identify the agricultural fields/plots with GMO cultivation. This should be possible either via direct access to relevant data in the GMO register or via the Competent Authority.
- Persons involved in monitoring need not only the access to the relevant information, but also need to be allowed to enter the fields where GMOs are grown. Hence, they need to be entitled for access by the owner of the field, if they are not in an official inspection capacity. This can only be achieved if the owner is identifiable via the GMO register or via the Competent Authority.
- The planting dates and management measures on the field (e.g. irrigation, herbicide or pesticide applications) need to be known for certain monitoring actions. This information is generally not contained in the registers and needs to be obtained from the owner. This can only be achieved if the owner is identifiable via the GMO register or via Competent Authority.
- The specific GMO/event and variety grown needs to be identifiable via the GMO register. Only with this information the hypotheses formulated in the monitoring plan can be tested or unexpected environmental effects of a certain GMO/groups of GMOs monitored.
- Long-term storage of the data is essential for the assessment of long-term, cumulative and unanticipated effects of GMOs. Data should be available via direct access to the GMO register or via the Competent Authority.
- The information notified to the register have to be validated to ensure the reliability of the data.
- Locations which were notified in the GMO register but where cultivation didn't occur have to be labeled in the register for transparency.
- Using a geografic information system, the data should be further analysed geoanalytically and their geografic position determined.
- Information on locations/fields where unintended releases of GMOs took place should be registered too.

8 CONCEPTS FOR IDENTIFYING MONITORING OBJECTS AND INDICATORS

The question which ecological entities, either organisms or ecological functions should be subject to a specific monitoring program is fundamental and one of the most controversially discussed issues of GMO monitoring. So far, only few monitoring concepts have addressed how to specifically select monitoring objects either for CSM or GS and what criteria shall be applied. Here we outline approaches for selection of monitoring objects based on scientific methods. The following approaches predominantly focus on protection goals and targets.

8.1 The role of hypotheses in the selection of indicators

The selection of monitoring objects or indicators has to be based on the hypothesis formulated for the specific monitoring action. A hypothesis will ensure that a certain monitoring action is conducted with a specific aim and a relevant sample size capable to detect a certain effect of a certain size. The hypothesis may be specifically formulated for an individual GMO or several GMOs or a certain potential adverse effect or process that may be predicted (e.g. the GMO outcrosses to a certain wild relative). However, other hypotheses for GMO monitoring may focus on protection goals and targets, especially in case of the monitoring for unanticipated effects (see also Chapter on GS). The question whether the cause-effect relationship formulated in the hypothesis can be verified will be resolved by the statistical evaluation of the established data.

8.2 Risk-analysis driven identification of indicator species

The identification of cause-effect-chains of potential environmental impacts by a risk analysis tool such as event tree analysis can be the starting point for the selection of indicator species (MEIER & HILBECK 2005). The event tree approach allows to model potential risks of GM crops and to identify relevant species that might be affected (HILBECK et al. 2008a). For example for the estimation of possible adverse effects of herbicide tolerant plants, the identification of weed species that occur within maize crop fields resulted in a first step in 257 weed species from 40 vascular plant families for agro-ecosystems in Germany. In another two steps these species were ranked according to their sensitivity towards the respective non-selective herbicides and their strengths of association with certain biotope types. Thereby 55 high-risk weed species were identified which are considered closely associated with the arable field and the agro-ecosystem and which exhibit a high sensitivity to non-selective herbicides. In another step weed-associated arthropods, among others Lepidoptera, were classified according to their feeding preferences. Monophagous and oligophagous species were considered at high risk, resulting in e.g. 21 Lepidoptera species highly dependent on 11 weed species. These 21 Lepidoptera species and 11 weed species were proposed for monitoring purposes.

8.3 Linking protection targets, subjects of protection and GMOs

The identification of relevant protection targets can also be useful when setting up a GS plan. This concept has been originally outlined for GMO monitoring by UMWELTBUNDESAMT et al. (2001), and was then tested in a follow-up study in Austria (HEISSENBERGER et al. 2003). The focus of this concept is on the agricultural landscape where effects due to GMO cultivation are expected to occur first. The monitoring objects are either represented by organisms or habitats of a certain protection status according to expert knowledge or due to general vulnerability or decline, independent on the stressor which may affect them. Specific cause-effect hypotheses may be applied for the selection of the indicator groups (e.g. insect orders), as they may help in reducing the number of taxa or habitats to be monitored when drafting the monitoring program.
To implement this approach for crops like maize and oilseed rape, the following steps may be taken. By the use of aerial photographs of representative growing areas of oilseed rape and maize, relevant non-target habitats were identified and classified according to the Red List of Biotope Types. These habitats were then further selected for a more detailed investigation including an assessment of insect taxa. Based on the criteria habitat specificity (e.g. stenoecious species), conservation status/rareness (according to national or regional Red Lists) and biogeographic criteria (e.g. species which occur at specific sites only), taxa were chosen as monitoring objects within these habitats.

In a further step, for the identified monitoring objects a specific monitoring plan can then be set up. This approach enables to concentrate monitoring efforts on those areas and habitats in which any effects are most likely to occur due to the spatio-temporal vicinity to the GMO cultivation areas. In addition the value for nature conservation and sensitivity of the organisms/habitats towards any effects by the GMO itself or any related management practices is taken into consideration.

The concept of starting with the identification of monitoring objects which underlie a protection status and which may be affected by GMO cultivation due to their spatial situation has been further developed in another study (TRAXLER et al. 2005). 'Biodiversity hotspots' were identified within the agricultural landscape reflecting those agricultural areas with the highest biodiversity of plant (weed) and lepidopteran species. Existing data on distribution, status of endangerment and ecology of relevant plants, biotopes and lepidoptera were sorted and processed using a GIS-supported database. Indices for biodiversity in agricultural landscapes were created based on the parameters endangerment, relative frequency, species richness and habitat preference, separately for plant and lepidopteran species. Areas where the highest diversity index-value was identified were classified as 'hotspots' of biodiversity. Within agricultural landscapes, these represent areas of high importance for the conservation of national diversity of both plants and agro-associated lepidoptera and may therefore be of high risk if GMOs are commercially cultivated in these areas. Based on their value for nature conservation an 'adverse effect' or 'damage' may be defined.

The risk analysis tools 'event-tree analysis' mentioned above can also be used to link hypotheses on the effect chain of the GMO with legal protection targets relevant for potential environmental effects of GMOs (MEIER et al., 2009). Analysing relevant legislation the authors identified protection targets: habitats, par-

ticularly sensitive habitats (e.g. protected), soil, biodiversity, animals, organic farming, and their respective protection goals which they used as a starting point for the identification of indicators for GMO monitoring. For the protection target 'biodiversity' an event-tree analysis was performed to simulate causal effect chains which might affect biodiversity. This procedure enabled the identification of indicators and in particular indicators covering several protection targets.

9 STANDARDISATION OF METHODS FOR MONITORING EFFECTS OF GMOS IN THE ENVIRONMENT

According to Council Decision 2002/811/EC (point 2.4) the methodology to monitor indicators and parameters/elements should be clearly identified and outlined by the applicant, including techniques for sampling and analysis.

Thus monitoring data collected by different parties from different regions or EU Member States should be established using comparable and sufficiently documented approaches. Therefore, preferably standardised methods "such as the European CEN Standards and OECD-methods for monitoring organisms in the environment" should be applied where appropriate (Council Decision 2002/811/EC). By using standardized methodology for monitoring the compliance with fundamental quality criteria such as correctness, comparability and reproducibility is ensured (VDI 4330 2006).

On a national level, the Association of German Engineers (VDI) together with the scientific experts elaborates standards for the monitoring of environmental effects of GMOs and specific monitoring methods (FINK et al. 2006). These methods are published as VDI guidelines. They represent an accepted technical standard and a common approach in one member state and may be useful for further standardisation efforts at the EU-level. The published guidelines are revised every five years to guarantee the validity of the described methods. The VDI guidelines are published in the series VDI 4330 and 4331 and are consolidated in the VDI manual Biotechnology Volume 1: Monitoring (VDI 2009). The guidelines are published bilingually in German and English. An overview of already finalized guidelines and guidelines still under discussion is presented in Tables 1 and 2.

In addition, a key objective in the field of GMO monitoring is to establish cooperation among EU member states at an early stage and enable consensus on issues and test procedures. The Working Group on Monitoring of the European Commission for example recommended in their checklists relevant methods for the GMO-monitoring. The VDI guidelines are included in these lists (EU-MWG 2008a).

To facilitate a standardised methodology on European level, the European Organisation for Standardisation CEN/TC 264 "Air Quality" set up a Working Group WG 29 "Ambient Air – Monitoring of Genetically Modified Organisms (GMO)". As a first task the WG compiles technical specifications based on existing VDI guidelines on exposure monitoring.

Monitoring conducted by applicants will need to be coordinated with the activities of publicly sponsored monitoring schemes and networks, e.g. for monitoring of biodiversity and monitoring of protection objects according to the Habitats, Birds and Water Framework Directives. The recommendations of the EU-MWG specifically indicated a need for harmonisation (with regard to methodology, data format and data analysis), integration of data established at the national level and discussion concerning extension and adaptation of the current designs of monitoring networks and programs with a view to the requirements of GMO monitoring (EU-MWG 2008a).

Table 1: Standard methods for the environmental monitoring of genetically modified organisms (finalised).

Guideline series VDI 4330	Short title
Part 1	Monitoring the ecological effects of genetically modified organisms; Genetically modified plants; Basic principles and strategies
Part 3	Pollen monitoring; Pollen sampling using pollen mass filters (PMF) and Sigma-2 samplers
Part 4	Biological sampling of pollen; Bee hives as biological pollen samplers
Part 5	Guidelines for the collection and preparation of plant samples for meolecular biological analysis
Part 7	Qualitative methods for the detection of genetically engineered nucleic acids in the environment
Part 9	Assessment of the diversity of ferns and flowering plants; Vegetation survey
Part 11	Immunochemical detection of insecticide Bt proteins from genetically modified crops in soil samples and plant residues
Part 13	Standardised monitoring of butterflies and moths (Lepidoptera); Transect method, light trap, and recording of larvae

Table 2: Standard methods for the environmental monitoring of genetically modified organisms (in progress).

Guideline series	Short title
VDI 4330	
Part 2	Sampling for pollen monitoring
Part 10	Floristic mapping
VDI 4331	
Part 1	Effects of GMO on soil organisms
Part 2	Macroarthropods
Part 3	Microarthropods
Part 4	Lumbricina
Part 5	Enchytraeus
Part 6	Nematodes
Part 7	Microbial communities
VDI 4332	**Wild bees**
VDI 4333	**Amphibians**

On the one hand EU requirements for reporting data (e.g. by INSPIRE) need some further specification with regard to data sets relevant to GMO monitoring, on the other hand some existing national monitoring systems will need to be adapted to be useful for GMO monitoring. The ongoing development of additional national monitoring systems (e.g. for biodiversity monitoring) should take into consideration specific requirements as regards GMO monitoring (see e.g. PASCHER 2008 & 2010).

10 ADDITIONAL RISK ASSESSMENT STUDIES BASED ON MONITORING RESULTS

The results of the monitoring of a particular GMO – submitted regularly by way of monitoring reports to the Competent Authorities – should be presented in accordance with the layout and design of the monitoring plan (ACRE 2004). The reports should also contain a scientifically rigorous analysis of the monitoring results (ACRE 2004). Interpretation of data and all conclusions should be considered in the light of existing environmental conditions and activities (ACRE 2004). The reports should also contain any conclusions with regard to the need for further monitoring but also further assessments where changes in the environment are observed. These further assessments should establish whether these changes are a consequence of the GMO or its use, or of other factors (ACRE 2004).

The legislative requirements in the EU specify that "*where unexpected changes in the environment are observed, further risk assessment may need to be considered to establish whether they have arisen as a consequence of the placing on the market of the GMO or as a result of other factors"* (Council Decision 2002/811/EC).

The Swiss Release Ordinance (RO; SR 814.911) states: "*should analysis of data and observations produce indications of damage or impairment, the FOEN shall investigate scientifically whether a causal connection could exist between these damages or impairments and the presence of GMO or their transgenes"* (Art. 51, par. 5a). Accordingly EFSA guidelines state that '*if unusual effects on human health or the environment are reported, more focused in-depth studies should be carried out in order to determine cause and relationship with GM plants*' (EFSA 2006a). Hence, the monitoring reports submitted by notifiers presenting the results of the monitoring actions should indicate whether unusual effects or changes in the environment have been observed. Therefore the knowledge of the baseline status or the baseline variability of the environmental parameters assessed in the monitoring plan is essential. Further it has to be evaluated whether the observed 'unusual effects or changes' may be due to the placing on the market of the GMO. Further studies or assessments may include laboratory, greenhouse or field experiments or a combination.

EFSA considers such additional studies as CSM studies based on the argumentation that they require an experimental approach to confirm the hypothesis that an observed effect is associated with the GM plant (EFSA 2006a). In our opinion such studies neither belong to CSM or GS, but represent a further category, as follow-up studies are based on the results of the monitoring itself. Dependent on the outcome of these studies the ERA conclusions and/or the plan for further monitoring (CSM or GS) may be revised or amended. And if the ERA is to be revised additional risk management measures might be implemented. Finally, if cumulative effects were detected further studies could also comprise the review of the ERAs of several GM crops.

For GMOs already placed on the market in the EU no such further studies were required so far. However this conclusion was based on the yearly monitoring reports of several GMOs that have been submitted by the notifiers in recent years (e.g. maize NK603, maize MON810, maize 1507 etc.), which were deemed insufficient with respect to their contents and format by several member states.

Further open questions relate to what triggers further risk assessment studies, and to the specific criteria for evaluation of observed changes in an environmental parameter. Monitoring concepts or monitoring plans submitted so far do not contain such criteria or thresholds. In this context the baseline status or the baseline variability of the environmental parameters assessed in the monitoring plan need to be known. Therefore the collection of baseline data assessing the status or variability of environmental parameters in question is considered crucial (see Chapter 3).

In Austria a large multi-year monitoring effort has been commissioned by the Austrian Competent Authority assessing the baseline variability of key parameters in Austrian agricultural environments (PASCHER et al. 2010).

Furthermore, it is currently unclear who will decide on further studies, how such studies should be designed and who will be responsible for their conduct. Information flow between the notifier and the CAs at an early stage will be necessary in order to decide on the need for further studies (EFSA 2006b). Furthermore it is clear that the monitoring reports need to contain proposals as to what should underlie further investigations based on the results and the interpretation of the data (ACRE 2004).

10.1 Definition of threshold values and adverse effects

At present no agreement exists concerning the definition of adverse effects or environmental damage, but this is regarded a prerequisite for decision making. BARTZ et al. (2009) suggest to define environmental damage as a significant adverse effect on a biotic or abiotic conservation resource (i.e. a biotic or abiotic natural resource that is protected by legislation) which decreases the value of the conservation resource itself, the conservation resource as an ecosystem component, or the sustainable use of the conservation resource. The application of this definition requires as a next step further normative determinations such as the choice of indicators or concrete threshold values to distinguish insignificant from significant effects (BARTZ et al. 2009).

11 PRESENT STATE OF MONITORING PLANS/MONITORING

11.1 Implemented monitoring plans for import and processing, food and feed uses

Generally finalised monitoring plans are not publicly available until the risk assessment of a specific GMO by EFSA is finished. They are annexed to the EFSA overall opinion, published in the EFSA Register of Questions (EFSA REGISTER 2009). Although the results of the monitoring carried out under part C have to be made publicly available (Directive 2001/18/EC, Article 20, 4.), currently no monitoring reports are released to the public. However, the European Commission, discussed publication of the reports on the internet.

Until spring 2009 monitoring plans according to Directive 2001/18/EC were only implemented for applications for placing on the market of genetically modified plants for food and feed uses, import and industrial processing. This comprises monitoring plans for several maize lines (NK603, MON863, 1507, MON810, 59122, NK603xMON863, NK603x1507, NK603xMON810), four oilseed rape lines (GT73, MS8, RF3, MS8xRF3) and the carnation “Moonlite”’. Monitoring reports for these applications are provided to the European Commission in a schedule according to the respective authorisations.
For applications which were initially authorized under Directive 90/220/EEC, like e.g. GM maize MON810, no comparable requirements for monitoring apply. For MON810 however monitoring is conducted at a voluntary basis or in response to requirements by Member States, e.g. Germany, adopted in the frame of national safeguard measures.

Since no adverse effects were identified in the ERA, the above mentioned monitoring plans do not contain any proposals for CSM. The mandatory plans for GS proposed by the notifiers vary only little. As key sources of information selected existing networks will be engaged in the surveillance program. However, these networks are not specified in detail in the monitoring plans. Further proposed sources are information gathered from media or the internet as well as submitted at telephone hotlines. For carnations also information from expert groups of botanists is requested as voluntary contributions. Details as to monitoring methods and parameters or as to where and when the monitoring is going to take place are generally not included in the monitoring plans.

Expectedly, the monitoring reports are not really enlightening concerning the details of observation. An estimation of the potential exposure of the GMOs to the environment is restricted to data on total grain imports into the EU by countries of destination. No indication is given on the volume or share of the respective GMP imported. Only for Florigene “Moonlight”, the number of flowers imported into Europe (Netherlands) are listed in detail, but no information on the re-export in other countries are given. For the establishment of an appropriate surveillance system as well as the interpretation of monitoring results, it is essential to have detailed information on actual volumes of GM grain imported and to know in which ports the shipments were unloaded and to where they were transferred.

The general surveillance is predominantly based on cooperation with three European Associations COCERAL, UNISTOCK and FEDIOL and is coordinated by EuropaBio. This implies that the European Associations inform and remind their member organisations and companies on an annual basis to monitor for potential unanticipated adverse effects and report back any findings. The Associations sent the collected information to EuropaBio (European Association for Bioindustry) in a format that reports on the outcome of the monitoring. In general it remains unclear which members or companies are involved in the monitoring and whether they are able to cover the scope of the monitoring (environment, human and animal health). No information is given on monitoring parameters, methods, frequencies and locations. According to the reports there have been no adverse health or environmental effects associated with the import or use of the GMPs so far, but no information is given on the data and statistical basis on which these statements and conclusions are drawn.

11.2 GM maize MON810

GM maize MON810 was the first GM-crop to be cultivated in the European Union. MON810 received permission for cultivation under the former Directive 90/220/EEC which does not contain any obligation to establish an environmental monitoring after placing on the market. However, since 2007 the consent holder of MON810 is conducting a monitoring on a voluntary basis. In April 2007 the consent holder submitted an application for renewal of notification for cultivation, import and use as food and feed in the EU. This application was positively evaluated by EFSA for decision making at an EU level.

Also in 2007 the consent holder was obliged by the German Federal Agency of Consumer Protection and Food safety (BVL) to establish a national environmental monitoring plan. The monitoring plan which was implemented in 2008 comprises two parts. Part 1 is identical with the plan provided by the consent holder with the application of renewal for MON810. Part 2 is about the analysis of monitoring data of specific existing surveillance programs in Germany. Both parts are publicly available (BVL 2008). Since the first part is identical with the application for renewal of MON810, it is the first time that a monitoring plan could be examined by the public during the approval process.

Part 2 of the monitoring plan is very brief and contains a declaration to evaluate the annual reports of selected networks in Germany, as far as they are publicly available. This concerns German monitoring programs of bees, birds, butterflies, game species and soil.

The report of this monitoring from March 2009 (**https://yieldgard.eu**) shows, that this approach is not feasible for several reasons. First, for some of these programs data are not publicly available; the consent holder thus has no access to them. Second, the questions behind the specific monitoring programs vary. Therefore the parameters monitored, the timeframe, frequency and scale of data collection, the analysis and reporting are hardly appropriate to identify potential adverse effects of MON810. Consequently, in March 2009 no monitoring data were available and no conclusions on environmental effects of MON810 in 2008 could be drawn in the report.

In general, a science based evaluation of the suitability of existing monitoring programs for GMP monitoring is still needed. According to EFSA (2006) "*Many of existing monitoring systems and networks collecting environmental data are unlikely to always provide data of relevance that may be used in monitoring of GM plants.*" If existing programs turn out to be not feasible, "*There may be a need for additional environmental surveys and to amend the monitoring objectives of existing monitoring systems.*"

It can be concluded from this first experience with monitoring of GM maize MON810 in Germany that for the use of existing programs aspects of organization should be clarified before authorisation is granted, e.g. agreements with relevant networks or programs, access to data, collection and analysis of data or the evaluation of results.

11.3 Amflora potato

Amflora potato (GM potato EH92-527-1) was authorised in March 2010 for cultivation in the EU for industrial processing according to Directive 2001/18/EC. The decision sets forth several conditions for use, e.g. requirements to prevent co-mingling and for monitoring.

Regarding conditions for use the consent holder is obliged to keep the GM potatoes physically separated from potatoes for food and feed uses during planting, cultivation, harvest, transport, storage and handling in the environment and to use them only for industrial starch processing at designated plants.

Regarding monitoring the decision requires that the proposed monitoring plan, including CSM and GS, as well as an Identity Preservation System are implemented, with modifications as outlined in Commission Decision 2010/135/EU.

The monitoring plan submitted by the consent holder consists of several elements:

- CSM directed to verification of ERA assumptions over a prolonged period. The CSM specifically assesses on the one hand the genetic stability of the inserted genes and the demonstration that no ORF4-related fusion proteins are expressed (from 80 pooled samples of seed potatoes) and that cultivated potatoes show the expected compositional changes (analysis conducted at 20 cultivation locations).
- GS to address general agronomical characteristics of the cultivated GM crop and of the use of the by-products in animal feed, as well as the following three parameters: 1) Susceptibility to diseases and pests, 2) management of volunteer potatoes by standard practices, 3) limitation of potatoes to the cultivated fields and no dissemination nor invasion of other habitats.
  Furthermore the GS consists of the usual elements of GS plans for EU notifications, like information providing and awareness raising measures, and collection of information on potential adverse effects from selected networks, literature or via communication with users or the public. However the scope of information sources is extended to surveillance networks for human and livestock health.

Commission Decision 2010/135/EU will result in relevant modification of the monitoring plan as proposed by the notifier in 2004, including the following elements:

- The monitoring should be implemented for the whole time-period of consent validity, i.e. 10 years, with annual reports to be submitted to the European Commission and the competent authorities of Member States.
- The consent holder shall ensure that data concerning the area cultivated to GM potato EH92-527-1 and the quantity of the harvested material are reported.
- The scope of monitoring needs to be extended to all farmers cultivating GM potato EH92-527-1 with the use of farmer questionnaires for information gathering.
- The consent holder has to demonstrate that the specified monitoring networks indeed gather relevant information and agree to make this information available to the consent holders and authorities.
- The consent holder shall carry out field studies to monitor potential adverse effects of cultivation of GM potato EH92-527-1 on model potato-feeding organisms representing key ecological functions of the agricultural environments.
- Furthermore the monitoring plan as proposed by the applicant in 2004 shall be revised according to the above mentioned conditions.

However it still needs to be seen whether the revised monitoring may sufficiently address the issues outlined in the decision, e.g. the monitoring of potential effects on potato-feeding organismsin all areas of cultivation of GM potato EH92-527-1.

Criticism regarding the monitoring plan was raised by several EU Member States, including Austria and Germany. They concluded that significant improvements have to be introduced to the monitoring plan to meet the general requirements of Annex VII of Directive 2001/18/EC and the obligations according to COM decision 2010/135/EU. Improvements were requested with regard to general shortcomings (lacking adequate detail and not addressing all potential exposure routes), with regard to CSM (regarding monitoring horizontal gene transfer and potential indirect effects of the identified compositional changes), and with regard to GS taking into account the recent experiences with monitoring for cultivation of GM maize MON810 (see chapter 11.2) and the recommendations of the Working Group on Monitoring of the European Commission and Member States (EU-MWG 2008b).

11.4 Pending applications for cultivation

There are still two pending applications for cultivation under Directive 2001/18/EC: 1507 maize and Bt11 maize. The assessment process for these events is already completed. Even though many Member States stressed that beside aspects of the risk assessment the monitoring plans are not in line with Directive 2001/18/EC, EFSA did not object to the monitoring plans provided by the notifiers.

Under Regulation (EC) No 1829/2003 many new applications for cultivation, import, industrial processing, food and feed uses as well as applications for renewal are in the pipeline. This concerns mainly maize and cotton events, but also potatoes, oilseed rape, sugar beet, soybean, rice and flowers (carnation). Many of them have stacked genes produced by conventional cross breeding of GM plants with different traits.

The proposed monitoring plans for cultivation are very similar. Specific risk management measures are only proposed for GMPs with insect tolerance traits. Some notifiers classify the proposed insect resistant management (IRM) plan as a risk management strategy (e.g. GM maize Bt11, 1507, 1507xNK603, 59122) while others consider it as a method under case specific monitoring (e.g. GM maize MON810, MON810xNK603).

With respect to general surveillance several tools for data collection are mentioned by the notifiers. The central component of general surveillance in most cases is a survey by farmer questionnaires (for details see Chapter 5). Further information will be gained via technical literature, websites, official registers, government publications, media, the Internet or by record keeping via the company network or a toll-free telephone hotline. A second key component of general surveillance is the use of information collected by existing networks. Usually, these networks are not specified in the notifications, not to mention details on selected networks in individual countries.

In these monitoring plans generally no information is given on monitoring objectives, parameters, methods or frequencies. The baseline proposed for the analysis of general surveillance data is mostly limited to historical knowledge and experience of the users of the GMP. Furthermore details as to where and when the monitoring is going to take place are generally not included in the monitoring plans. In some cases the notifier stated that the intensity of the general surveillance is unlikely to be the same in each of the different EU countries and that the activities will be mainly focused on areas where the GMO will be grown.

It applies to all monitoring plans proposed by notifiers, that they are very cursorily and imprecise. Detailed information on monitoring objectives, the monitoring design, analysis of data or on monitoring areas are not included, also selected networks engaged in the surveillance are not specified. Furthermore the scope and content of current monitoring plans do not fulfill key requirements stated by Directive 2001/18/EC and Council Decision 2001/811/EC. They are thus in need of fundamental improvement.

Detailed information on all aspects of the monitoring plan provided with the application is a precondition for the evaluation of the plan within the approval process. Therefore, they have to be as precise as possible. To adjourn any specification of the plans to after the first year of placing on the market (EFSA 2006a) is insufficient and is not in line with Directive 2001/18/EC and Council Decision 2002/811/EC.

12 CONCLUSIONS

The current discussion at the national as well as EU-level shows that GMO monitoring is a crucial requirement in GMO regulation and does deserve the necessary attention. Our analysis of the experience with implementation of GMO monitoring however indicates that a lot of issues have to be addressed in more detail to meet the needs of applicants, regulators and the general public. An illustration of the different steps of the regulatory process and their interconnections is provided in Annex 1 to give an overview on the complex interplay of the different elements that need to be considered with regard to GMO monitoring. The illustration also highlights areas, which in our view should be improved as indicated below.

The current discussion on the development of the ERA for GMOs will be of considerable importance for further developments concerning GMO monitoring. We highlighted the relevance of the design and interpretation of the ERA for GMO monitoring, specifically for CSM. We recommend an approach to implement more CSM measures than done presently to better address data gaps and uncertainties. This approach should provide suitable information to evaluate and to confirm the conclusions from ERA. This discussion needs to follow up the results of a Working Group on Monitoring convened by the European Commission and is specifically important with regard to the substantial number of notifications of GM crops for cultivation which are presently pending.

Likewise the interplay between CSM and GS need to be discussed further to establish adequate monitoring designs. The GS plans proposed by the applicants need to consider characteristics of the respective GMOs and take into account all exposure pathways as well as the protection goals relevant to the exposed environments. It is only against this background an appropriate selection of monitoring parameters can be achieved.

Furthermore the tools for observation of the identified parameters need to be developed further. The focus should be shifted to the scientific approaches for CSM as well as GS, their improvement and their implementation. This needs to be done to better complement information gathered from farmers by means of questionnaires, taking into account the limitations of these surveys. Another important aspect is the use of data from existing monitoring schemes and networks, like the networks of users and handlers of GMOs coordinated by EuropaBio, as well as observation programs collecting data on parameters which are relevant for GMO monitoring. Based on current experience we suggest that the present approaches are scrutinised, with regard to specification of details in monitoring plans, with regard to establishing working terms with involved networks and with regard to ensuring that conclusive data are established by the involved networks. Monitoring of exposure is another issue that is relevant in our opinion and should deserve more attention.

Another important topic in our view is the harmonisation of methods for monitoring. The development of national standards in Germany as an input for EU-wide harmonization as presented in Chapter 9 of this paper is an example of how to proceed. Additionally some urgent efforts are necessary with regard to integration of data from different Member States and different monitoring schemes to ensure that integration and consistent analysis of data from different sources is possible and will result in conclusive results.

Finally, the interpretation of the monitoring results and the decision on further risk assessment studies need to be discussed. Specifically it needs to be clarified which environmental changes should be further investigated, how follow up-studies should be designed and who shall be responsible for implementing these further studies.

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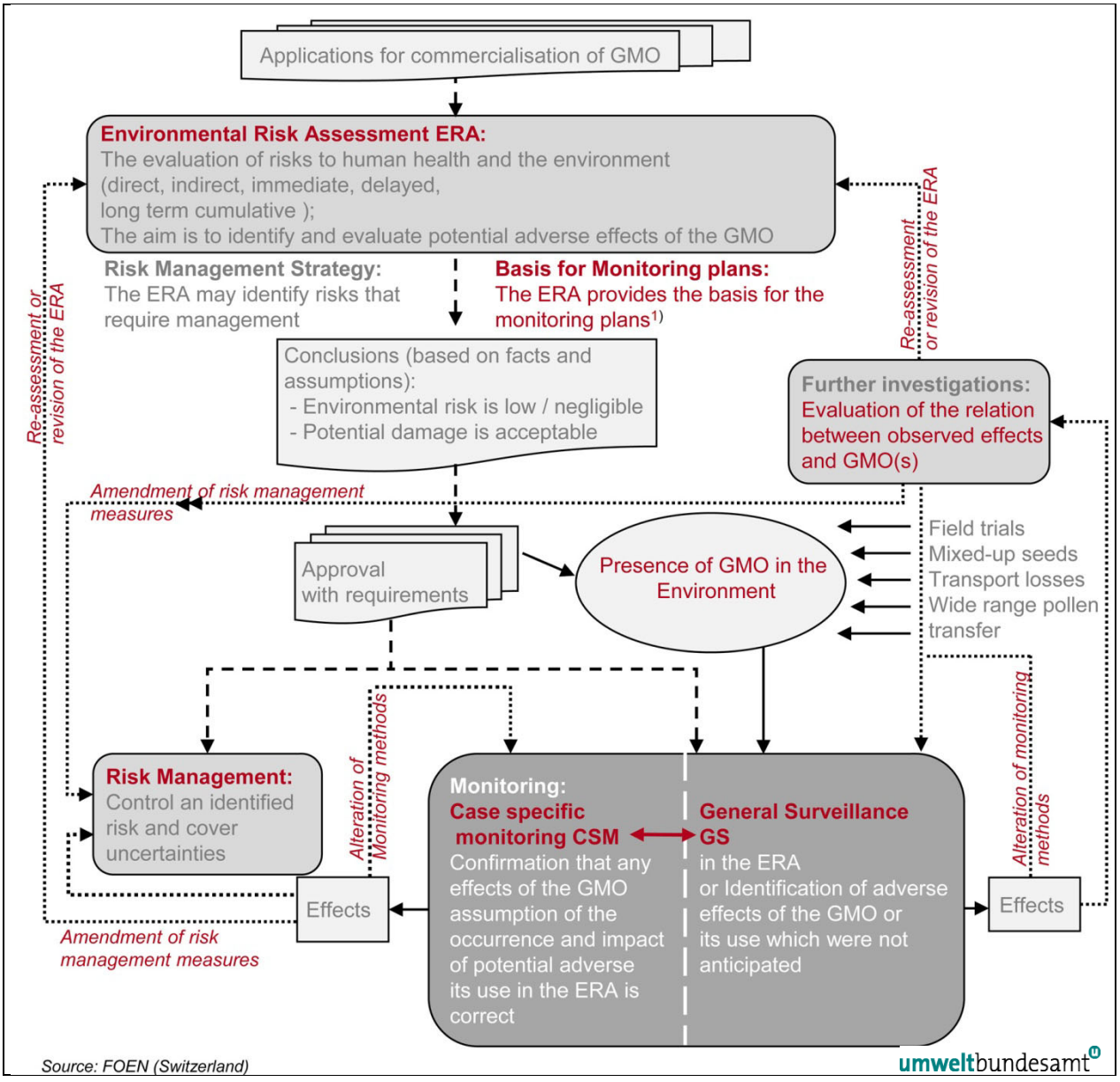
ANNEX 1: GMO MONITORING AND THE INTERCONNECTION WITH OTHER ELEMENTS OF THE REGULATORY PROCESS

The following illustration summarises the connections of environmental risk assessment, risk management and GMO monitoring based on the legal requirements of Dir 2001/18/EC; Decision 2002/811/EC; as well as Swiss RO (SR 814.911).

Elements which deserve further discussion and improvement according to our analysis are highlighted in red (dark) colour.



1) *to be developed on a case by case basis taking into account the ERA, the modified characteristics, the intended use of the GMO and the receiving environment.*

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The mandatory monitoring of environmental effects is an important element of the regulatory frameworks for genetically modified organisms (GMOs) in the European Union and Switzerland.
However the implementation of GMO monitoring at the national and EU-level, specifically for the cultivation of GM plants, proved to be a challenging issue and is subject to ongoing discussions.
To provide substantial input the National Environment Agencies in Austria and Switzerland and the Federal Agency for Nature Conservation in Germany jointly outline necessary elements and requirements for an appropriate GMO monitoring in this policy paper.
The recommendations are based upon the expertise of the three Agencies as competent authorities or advisory bodies with regard to GMO monitoring and interrelated issues of environmental protection and nature conservation.

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