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Concept for the Realisation of a GMO Monitoring in Germany*

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Keywords: Directive 2001/18/EC, genetically modified organisms (GMO), deliberate release, market release, monitoring, monitoring plan

**) Updated English version of "Konzept zur Umsetzung eines GVO-Monitoring in Deutschland",
Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 55, 2003*

Abstract

This paper presents a concept for the monitoring of genetically modified organisms (GMO) introduced into the market. The considerations are based on the regulations of the Directive 2001/18/EC. Monitoring is supposed to be an efficient tool in the risk management of GMO. To meet these demands suitable tasks have to be defined for notifiers, consent holders and public institutions, administration has to be efficient, and monitoring must be flexible to new situations. Partly, the paper explains the regulatory demands and background. Further, organisational structures are proposed stressing the role of already existing survey systems. To include such systems into GMO monitoring the exchange of information has to be optimised. Finally, general principles to design and install monitoring plans are introduced.

1. Introduction

The original date for Directive 2001/18/EC (referred to as 'the Directive' in the following) to be converted into German law was 17 October 2002. According to the precautionary principle the Directive demands that genetically modified organisms (GMO) placed on the market are monitored for possible harmful effects on the environment and on human health. It is expected that for a start mainly genetically modified higher plants (GMHP) will be placed on the market in the course of agricultural production, and so GMHP are in the focus of the discussions about monitoring aspects. Supplements to the Directive and explanations are given by guidance notes (referring to Annex II, Official Journal of the European Communities of 30 July 2002, L 200/pp 22; Annex VII, Official Journal of the European Communities of 18 October 2002, L 280/pp 27).

The Regulations of the European Parliament and of the Council regarding genetically modified food and feed have been published and will become effective within short for placing such products on the market. The modifications refer to the establishing of the European Food Safety Authority (EFSA) and the centralisation of the approval procedures it brings about. However, as to the aspects of the realisation of a GMO monitoring and risk assessment the relevant parts of the Directive are referred to¹. Besides, the national authorities will safeguard their influence on the regulations of the procedure of placing a GMO on the market².

The aim of a GMO monitoring is to identify direct, indirect, immediate, delayed, or unforeseeable harmful effects that GMO and their application might cause on the environment and on human health. The data obtained by such monitoring measures will, among others, be used to impose conditions, or to maintain, to renew, or to withdraw an approval for placing a GMO on the market. The notifier or the consent holder must submit an event-specific monitoring plan along with his application for approval of a GMO. Fulfilment of this monitoring plan serves to check the hypotheses of the environmental risk assessment (e.r.a.) required within the procedure, and to early identify adverse effects resulting from the GMO or its application which were not foreseen in the e.r.a. Additionally, the EU member states are free to initiate further monitoring measures which, however, are not described in detail by the Directive.

¹ Regulation (EC) No. 1829/2003: Art. 5 (5) and Art. 17 (5)

² Regulation (EC) No. 1829/2003: Art. 6 (3) b) and c), Art. 6 (4), Art. 10 (1), and Art. 18 (3) b) and c), Art 18. (4), Art. 22 (1), Art. 34 and in relation to Regulation (EC) No 178/2002 Art. 54.

A number of institutions all over Europe have striven for transferring the demands raised in the Directive into a practicable monitoring concept. In Germany, two major groups work on the realisation of such a concept who have submitted drafts and cornerstones. These are the “Workinggroup on monitoring environmental effects of genetically modified plants“, a group with members of institutions of the Government and of the *Länder* (B/LAG), headed by the Federal Environment Agency (UBA), and the „Working group on monitoring the cultivation of genetically modified plants in the agro-ecosystem“ (AGAM) headed by the Federal Biological Research Centre for Agriculture and Forestry (BBA) (B/LAG, 2003; WILHELM et al., 2002). Presentations of both working groups and their activities are available on the Internet (B/LAG: <http://www.umweltbundesamt.de/uba-info-daten/daten/bsg/bsg5.htm>; AGAM: <http://www.bba.de/> see: „Gentechnik“).

Meanwhile there were numerous suggestions as to which objectives should be investigated by which methods, and which institutions should probably become responsible (ZÜGHARDT, BRECKLING, 2002; EEP-MON, 2002; see <http://www.bba.de>). However, so far no criteria or strategies for a practicable GMO monitoring could be found that are accepted in Germany or throughout the EU. Therefore now as before this is still open to discussion and might be led by the “case by case” decisions on the first applications according to the novel laws. The concept we present here concentrates on the framework of a GMO monitoring which shall help to define monitoring parameters and tasks. Based on the contents of the Directive, and aiming at different levels of organisation, it creates the preconditions for ensuring that the data collected in a GMO monitoring give valuable information to assess potential adverse effects resulting from GMO. The concept is based on a common policy document of BBA and UBA from August 2002. Excerpts from the document were incorporated in this concept and printed in italics. This common document was also partly referred to in the concept of the B/LAG (B/LAG, 2003).

2. Basic facts for the development of a monitoring concept

2.1. Terms used in the Directive 2001/18/EG

Monitoring

The term *monitoring* is ambiguous in the English as well as the German version of the Directive, referring to the monitoring of the compliance with the regulations by the national authorities on the one hand, and to the practice and organisation of monitoring adverse effects

of GMO on the environment and on the human health on the other hand. If not stated otherwise, the latter definition is referred to in the text.

Environmental risk assessment (e.r.a.)

The environmental risk assessment investigates the impact of a GMO on the human health and the environment on a case by case basis. It classifies any scientifically potential risks by considering the potential consequences of the GMO release and the likelihood that these consequences will occur, from no or negligible risk to high risk. In the first case a monitoring may not be necessary.

Monitoring plan

The *monitoring plan* compiles GMO specific monitoring aspects and tasks for whose performance the notifier/consent holder is responsible. The tasks result from Annex VII of the Directive and comprise a case-specific monitoring as well as a general surveillance (see 2.2.2.).

Case-specific monitoring

On the basis of the e.r.a. performed within the authorisation procedure for GMO, concrete hypotheses regarding adverse effects of the placing on the market of GMO will be subject to scientific investigations (see 2.2.2.).

General surveillance

General surveillance serves to detect and identify adverse effects of GMO or resulting from their application, on the environment and human health, not foreseen in the e.r.a. General surveillance is set up independently from the specific aspects of the e.r.a. (see 2.2.2.).

Additional monitoring

This term refers to the option, elaborated in this concept, to perform federal GMO monitoring programmes which are mentioned but not specified in the Directive (Article 4(1) and (5)) and in the Annex VII guidelines (B.). Section 3.1 gives a detailed description of what might be aimed at. Additional monitoring is designed to record damages of a vague origin which cannot be assigned to single GMO effects right in advance, and to compare data of various potential causes and environmental changes.

Damage, adverse effects

The Directive does not provide a definition of ‚damage‘ (which is legally binding), so it must be derived from other legal rules or legal practice. However, this is not the main purpose of this concept. Whenever the term ‚damage‘ appears in the text it refers to damage as it is used in the Directive, or other valid legal standards (see 2.3.).

2.2. Directions of Directive 2001/18/EG and of the Annex VII guidelines

Detailed information on GMO monitoring, in so far as establishing and updating of a monitoring plan as well as of responsibilities is concerned, is given in the Directive (Articles 13, 16, 19, 20; Annex VII). It is the notifier/consent holder who is responsible for establishing, and fulfilling, a monitoring plan. However, neither the Directive nor the Annex VII guidelines exclude that supporting and, if required, extended (monitoring) measures are defined by the Member States (Directive 2001/18/EG, Article 4 (1), (5)³; Annex VII guidance notes: B, C.1.6.⁴). Thus the lack of experience in efficient GMO monitoring is taken into consideration in the Directive and in the guidance notes supplementing Annex VII in so far as the scope of legal action can on all levels be adapted to new findings and requirements.

The Directive and the guidance notes supplementing Annex VII set cornerstones for a GMO monitoring with regard to its organisation and contents. Monitoring results must be made available to the public in a suitable manner (Article 20 (4); Annex VII guidelines: C.3.2.).

2.2.1. Directions for Organisational Matters

Authorities and Government

As far as monitoring is concerned, the authorities play a role, as defined by the Directive, for the approval procedure and for the observance of the compliance with the Directive and the conditions possibly attached to a consent. The national competent authority can take influence on the design and on the realisation of the monitoring plan by asking for additional information (Article 16) and by attaching conditions to their consent (Art. 19 (3) f; Art. 20

³ Directive 2001/18/EC, Article 4 - General obligations

1. Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with Part B or Part C, respectively. [...]

5. Member States shall ensure that the competent authority organises inspections and other control measures as appropriate, to ensure compliance with this Directive. [...]

⁴ Guidance notes supplementing Annex VII:

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

C. 1.6 Assigning responsibilities: [...] It should similarly be noted that it is not precluded that Member States carry out additional monitoring in the form of case-specific monitoring or general surveillance. The aim of such surveillance is to enable the risk manager to take appropriate measures without delay should any undesirable and unidentified effects arise in the framework of prior risk assessment. This should not, however, be considered a substitute for the monitoring plan, which remains under the responsibility of the notifier for implementation (although, with the consent of relevant parties, may form part of it). [...]

(3)) in co-ordination with the Commission (or with the Committee as per Article 30), if appropriate, the EFSA, and the competent authorities of the other Member States.

Under the German Constitutional Law (GG), and provided that the GG does not give scope for other definitions or exceptions, it is the authorities of the *Länder* that execute the Law. The Robert Koch Institute (RKI) is yet responsible for the execution of the Genetic Engineering Act, in accordance with the Federal Biological Research Centre for Agriculture and Forestry (BBA), the Federal Environmental Agency (UBA), and in specific cases the Federal Research Centre for Virus Diseases of Animals (BFAV). With the amendment of the Genetic Engineering Act converting the Directive into German law a re-organisation of the responsibilities is to be expected. The Federal Agency for Consumer Protection and Food Safety (BVL) will become the national competent authority, and the Federal Agency for Conservation (BfN) will replace the UBA. There may be further shifts in tasks and competences. The authorities of the *Länder* will supervise the compliance with the Genetic Engineering Act.

Notifiers and Third Parties

According to the Directive and guidance notes supplementing Annex VII it is the notifier/user who is responsible for the monitoring plan, its realisation, possible modifications, and report (Article 13, 16, 19, 20; Annex VII). The notifier is allowed to make sub-contracts with third parties (who may be public institutions), or to receive and use data supplied by third parties (Annex VII, C 3.2; guidance notes supplementing Annex VII C.1.3, C.1.6, C.1.7). It is the notifier/user to decide on contractual conditions with third parties.

Integration of existing and additional monitoring programmes

The Directive and guidance notes supplementing Annex VII inform the notifier/user of the choice of integrating own, or other, monitoring programmes that may be run by governmental institutions or agencies. No conditions have been specified for this. This means that, within the directions of national law, it must be worked out how to integrate these programmes into a monitoring, or into a monitoring plan, and how to regulate the responsibility for the correctness of the data obtained.

It is up to the Member States to arrange for additional monitoring tasks for public institutions as long as these are in conformity with the Directive and mean a completion but not a replacement of the notifier's tasks. The responsible institutions or the legislator have to decide whether, and to which extent, monitoring programmes have to be regarded as a public task or have to be executed by public institutions - a decision affording to weigh up public interest against the applicant's responsibilities.

2.2.2. Directions on how to proceed

Monitoring plan

Along with his notification the notifier submits a monitoring plan introducing the objectives of the monitoring and explaining the details of the process itself. The Guidance notes supplementing Annex VII of the Directive give attention to details of the monitoring plan. The monitoring plan is to take into account direct and immediate, as well as indirect and long-term effects of the GMO, and it is to comprise three formal sections (a survey on the formal elements is given in Table 1) about

- the monitoring strategy explaining the necessity of the aims and the process itself (guidance notes supplementing Annex VII: C.1.);
- the monitoring methodology describing the parameters and the practice of data collection (guidance notes supplementing Annex VII: C.2.);
- an analysis, reporting, and evaluation part describing the necessary evaluation steps, reports to the authorities, public presentation, and review of the monitoring plan (guidance notes supplementing Annex VII: C.3.).

Especially with regard to the objectives and parameters the ‚strategy‘ and the ‚methodology‘ parts are not clearly differentiated from each other (guidance notes supplementing Annex VII: C.1. and following; C.2.1.).

The monitoring plan specifies the tasks and the realisation of the ‚case-specific monitoring‘, of the ‚general surveillance‘, and of further monitoring strategies, if appropriate. Table 2 cites a list of criteria for the selection/compilation of objectives and parameters which was stated within the guidance notes supplementing Annex VII .

Case-specific monitoring

Based on the e.r.a. (the Directive, Annex II, guidance notes supplementing Annex II) concrete assumptions as to adverse effects resulting from placing a GMO on the market are, if appropriate, analysed or verified. A case-specific monitoring is to focus on major, scientifically justified potential risks (see Fig. 2), and to lead to a decision as to whether considerable adverse effects of a certain GMO will occur. It will be conducted for a sufficient time to make sure that not only direct and immediate effects but also delayed or indirect effects defined in the e.r.a. are considered.

General surveillance

The aim of general surveillance is to recognise and detect adverse effects which the GMO or its use may have on human health or on the environment and which the e.r.a. had not forecast. General surveillance is independent from the specific questions of the e.r.a., the questions to be answered arise under the process. As soon as environmental changes are

found differentiated analyses may become necessary (Annex VII, B. to the Directive). General surveillance will mainly be based on routine monitoring programmes and it shall be established for an extended period and in extended areas. *For this, appropriate parts from existing monitoring programmes may be used, or existing monitoring programmes may specifically be extended to meet the demands of a GMO monitoring* (see 2.2.1. for aspects of competence). The guidance notes supplementing Annex VII (B.) name the analysis of cumulative effects as a compulsory part of the monitoring plan⁵.

Objectives of the monitoring plan, parameters, realisation

The Directive does not contain generally binding objectives and parameters for a monitoring plan, and even Annex VII guidelines refer to this to a limited extent only (see Tables 2 and 3). Monitoring must be a case-by-case process (Annex VII C.1., the Directive; guidance notes supplementing Annex VII: C.2.1.). The mentioned cases give examples and should be discussed in the monitoring plan. Special attention is paid to a verification of the usefulness and necessity of the extent of the monitoring programme (guidance notes supplementing Annex VII, e.g., C.1.3.1.; C.2.2.).

Principally, the monitoring period and area must be in a reasonable relation to the objectives and parameters, which affords that exceptional regional environmental features must be considered. An analysis of cost efficiency is required. The monitoring process must be scientifically based and take into account the probability of an event to occur, and in case of need give a warning as early as possible.

The investigation of basic or comparative data for revealing effects of a GMO on the environment should be performed either before, or in parallel with its being placed on the market, by comparing data obtained in areas which are subject to, or free from GMO. The special emphasis put on the scientific aspects of the monitoring plan (Annex VII B. guidelines) represents a strict standard since in a scientific sense the choice of comparative data is not free.

2.3. Adverse effects, objectives of legal protection and objectives for a GMO monitoring

Monitoring serves to evaluate adverse effects on human health or the environment that may emerge from a GMO or its use. This requires a definition of 'adverse effects', which, however, the Directive does not provide in a satisfactory manner. Such a definition must be in compliance with EU laws and must not infringe principles of law and order. This means that

⁵ The Directive refers to this statement in consideration (20) and namely in Annex II.

an effect is not adverse merely because of the fact that it is found to be caused, directly or indirectly, by the application of a GMO, but because of the fact that approved, legally protected objects are violated.

The Directive refers to “the human health and the environment” as global objectives of legal protection (OLP). A damage in the field of plant protection can at least be characterised under civil law by an economic estimate of the production loss, whereas the ‘damage of biodiversity’, that is expressively stated in the Directive, is a juridical (or even scientific) problem. In its comments on the proposal for the directive on environmental liability (KOM(2002)17 final - 2002/0021(COD)), the Commission states the uncertainties in the term ‘environmental damage’, and in the quantification of adverse effects to the environment. Therefore, the Commission recommends to cling to existing protection standards as given by the community environmental laws⁶. The passing of the directive on environmental liability will offer a basis for an interpretation of the Directive⁷.

As the Directive does not give an exhaustive GMO-specific definition of ‘adverse effects’ or of objects to be protected, it exclusively refers to definitions from/by existing laws. This allows to consider accepted OLP for the GMO monitoring (as well as for the e.r.a.). Table 4 lists OLP and related, more detailed areas of concern (AoC) that are covered by the term “human health and the environment”.

The identification of OLP and AoC is of importance for the general surveillance to reach an operational state, that is without an e.r.a. and without distinct hypotheses on cause and effect. Nevertheless, objectives and parameters for the general surveillance can be considered by the relationship of the AoC and the specific GMO (case by case), i.e. GMO relevant parameters are identified that represent the state within an AoC. E.g., the abundance of plant diseases may be evaluated in correlation to the cultivation of GMP.

All OLP and AoC may also be influenced by factors other than GMO, bringing about the problem of differentiating between effects resulting from GMO, or non-GMO. Therefore, other existing monitoring programmes should be linked with GMO-oriented investigations, or they may be extended in order to differentiate effects.

⁶ COM(2002) 17 final - 2002/0021(COD) - Proposal for a directive of the European Parliament and the Council on environmental liability with regard to the prevention and remedying of environmental damage: „[...] 6.2 [...] Environmental damage should be defined whenever possible by reference to the relevant provisions of Community environmental law – the Habitats and Water Framework Directives – so that common criteria could be used and uniform application could be promoted. Account should nevertheless be taken of specific situations where the aforementioned Directives allow for certain derogations to the level of protection afforded to the environment. Biodiversity should also be defined by reference to areas of protection or conservation that have been designated in pursuance of national or sub-national legislation on nature conservation. Environmental damage should also cover those situations where serious potential or actual harm to human health exists when this serious harm results from land contamination.“ (See also Art. 2 1.(2),(5),(18); Art. 2 2.)

⁷ Related Directives are 92/43/EC (Habitats), 79/409/EEC (Birds), 2000/60/EC (Water Framework).

2.4. The GMO-Monitoring within the regulatory framework

A GMO monitoring shall be a basis which on the one hand allows to maintain an approval of placing GMO, or GMO-containing products on the market (the Directive, Articles 13, 17), while on the other hand justifying precautionary or protective measures taken against damage (the Directive, Annex VII, C.6.). This includes the analysis of critical e.r.a. results, the identification of unforeseen effects (the Directive, Annex VII A), and the information of the public (the Directive, Article 20(4)). So, GMO monitoring represents a tool of official risk management.

The monitoring of GMO is based on the step-by-step procedure of developing a GMO and introducing it in the market. Its main function is to record GMO effects on space and time scales beyond those of laboratory and field trials (aspects of approval according to Part B of the Directive). Indirect, long-term, and combined mechanisms are typical of such effects. The step-by-step approach of approving GMO and products containing GMO in the EU requires that appropriate safety evaluations are made at each stage of development and approval, and that GMO imported from non-EU countries underwent a corresponding safety evaluation. According to the Directive the monitoring of GMO after their introduction into the market is not a detailed scientific programme for a safety evaluation of GMO but deals with aims/questions linked with potential specific risks of their market introduction (guidance notes supplementing Annex VII: Introduction, C.1.3).

2.5. Co-ordination and harmonisation within the EU

The Directive regulates that a GMO is approved for being placed on all EU markets. A co-ordination between the competent authorities of the Member States, the EFSA - if appropriate - and the Commission is necessary in the course of the release procedure, in order to maintain the approval, as well as in case of conditions demanded by the authorities. This refers especially to communication about the GMO monitoring and means that an EU-wide co-ordination and harmonised procedures should be aimed for, whereas, however, standardisations will be rather restricted for the following reasons:

- There are regional fluctuations as to the possible risks associated with an introduction into the market (e.g., area of spread, limited areas for cultivation of GMHP);
- The approval procedure (including the e.r.a.) must be designed for the individual case (specific characteristics of the transgene, kind of market introduction).

An EU-wide harmonisation should include a unique evaluation scheme (as to procedure, criteria) and an optimisation of communication (see 3.4.).

3. GMO-Monitoring - Organisational design

3.1. Responsibilities in a comprehensive GMO monitoring

In general, GMO must not be regarded as the only potential adverse factors with regard to the OLP. The higher the level of integration (e.g., ranging from the individual to the population, and above), the more difficult to differentiate between, and identify the potential influence of the GMO and the part played by other potential causing agents. Starting from an analysis of causal risks it is possible to include potential channels of damage, once identified, in a monitoring plan (case-specific monitoring). Unexpected adverse events have to be identified first, and then their causative agent. An unpublished position paper on the monitoring of GMP written by UBA and BBA suggests OLP and AoC to circumscribe legally relevant areas that may be affected by GMO releases. However, since several factors other than GMO (see Table 5) may bring about short- or long-term, small- or large-scale changes, the detection of causal relations should be the first step of monitoring. This means that the question of responsibilities cannot be settled right from the start. This is especially true for large scales of time and space. It must be defined here which of the tasks should be carried out within the general surveillance (i.e., within the monitoring plan and under the responsibility of the notifier/consent holder, even if orders were placed with third parties or federal institutions), and which of them should be put under federal responsibility as an additional monitoring. For a clear structure of legal distribution of tasks and responsibilities the terms ‚case-specific monitoring‘ and ‚general surveillance‘ should be separated from ‚additional monitoring‘⁸. Some central questions will allow to make a differentiation between monitoring aspects. On the whole, the aim of such a differentiation would be to assign those monitoring questions to the general surveillance which are in an immediate, or mediate, relation with the GMO, and to have unclear situations checked under federal responsibility in order to guarantee for an extensive risk management and not to ignore other influences. The following central questions can be integrated into a “decision tree” (Fig. 1):

- Is there a hypothesis of cause and effect?

⁸ **Directive 2001/18/EC: Considerations (44):** Member States should be able, in accordance with the Treaty, to take further measures for monitoring and inspection, for example by official services, of the GMOs as or in products placed on the market. – See also footnotes 2 and 3.

- Can clear situations with dominating GMO effects be derived?
- Who can supply data on the GMO monitoring?
- Who can supply comparative data relevant for other potential factors?
- Who is able for a competent evaluation of these data?
- How to regulate accessibility of these data?

The notifier (user) will consider the following tasks in his monitoring plan, and it is he who is responsible for the monitoring plan to be designed accordingly and duly executed:

1. An analysis of questions which, on the basis of the e.r.a., include a cause and effect hypothesis for the GMO (case-specific monitoring);
and, in the sense of a general surveillance,
2. An investigation of open questions,
 - 2.1) if it can be focussed on a GMO effect by specific methods (usually small-scale investigations),
 - 2.2) for which an easy access to the GMO related data is given,
3. Collection of data relevant to the GMO that are required for a comparison of data regarding potential causes.

This means the Member States are responsible for necessary additional investigations beyond the monitoring plan, concerning those (open) questions where no exclusive relation with the GMO can be drawn in advance (e.g., large-scale dynamics of pests, or plant sociological tests in cases where the symbiosis is subject to the GMO and to several additional factors. The notifier delivers comparable data for the GMO required within the case-specific monitoring or general surveillance). In addition to this, federal institutions can be active within the monitoring plan in the frame of a contract with the notifier.

3.2. Networks and coordination in a GMO monitoring regime

In view of the complex subject of monitoring, an efficient coordination and splitting of tasks by the notifier/consent holder, authorities (on a federal as well as on the level of the individual *Länder*), public institutions and contractors is required to make the monitoring an effective tool in risk management. The organisational directions of the Directive were already described in Chapter 2.2.1. These rules and further operational considerations led to a list of tasks for various, e.g, German institutions within a monitoring regime (Tab. 6).

As mentioned earlier, it is monitoring of large-scale environmental effects that necessitates a common approach to identify causes and initiate efficient measures. The authorities involved in the evaluation of the monitoring plans and their results should be offered the possibility of

recalling data from public programmes and of initiating investigations. Coordinating structures for the GMO monitoring regime are required in order to include the various aspects of the GMO problem (see Fig. 1) and a network involving the active players. This is far beyond the mere administration of gathered data.

On the organisational level, the coordination of the GMO monitoring should be linked with the approval/renewal procedure itself as the competent authority must have an influence on the basis upon which they may decide. Scientific and administrative expertise by the competent authority is a must to fulfil the tasks of evaluating the monitoring plans and their results, setting up appropriate conditions for further releases and initiating adequate measures, as well as giving advice to the notifier. The German Genetic Engineering Act in force fulfils the demand for expertise, providing a competent authority (= RKI, prospectively BVL) and commenting authorities (= BBA, UBA, BFAV, prospectively RKI, BBA, BFAV, Federal Institute for Risk Assessment, i.e. BfR, and BfN). When converting the Directive into national law such a structure of organisation should be maintained. Mainly three scientific areas are involved in a GMO monitoring performed in accordance with the Directive: consumers' health protection (RKI, prospectively BVL), nature and environment protection (UBA, prospectively BfN) and agriculture (BBA), and these areas should be safeguarded by the corresponding federal authorities who should be considered for the coordinating tasks of the GMO monitoring. Besides, a GMO monitoring data base should be established (see 3.3.).

3.2.1 Modular coordination

On the national level the GMO monitoring should be coordinated by the competent authority and by the expert authorities (in Germany: federal authorities of the ministries involved). The coordination comprises the relevant main foci (modules) of

- agriculture – with the effects of GMO on the agro-ecosystem, the interpretation of data on the agro-ecosystem, and the evaluation of measures taken with regard to agricultural practice;
- environment – dealing with the effects of GMO on the protection of environment and nature, the interpretation of data on aspects of the protection of environment and nature, and the evaluation of measures taken for the protection of environment and nature;
- health – dealing with the effects of GMO on human health, especially the safety of food and feed, the interpretation of data, and the evaluation of measures taken for a precautionary health care.

Health aspects are already covered by various regulative areas and institutions. It remains to be clarified in how far the demands of a GMO monitoring are met.

The modular coordination should deal with

- recommendations for the collection, evaluation, and assessment of data;
- the initiation of federal investigations or research work;
- the evaluation and assessment of the investigations of general surveillance and additional monitoring;
- the coordination of immediate measures;
- the feedback of management measures;
- recommendations on approval/maintenance;
- public relations on monitoring.

For immediate communication and flexible actions all players involved in the monitoring regime should be integrated in the coordination process. This may be realised via a coordination within one of the modules under the leadership of the relevant expert authority (e.g., in case of the ‚agriculture‘ module, this might be the „Working group on monitoring the cultivation of genetically modified plants in the agro-ecosystem“ headed by the BBA). This necessitates that the legal involvement of the state authorities and of other federal institutions, as well as of the notifiers and others is clarified.

3.2.2 Networks of the ‚Agriculture‘ module

The agriculture module offers direct links between placing on the market, monitoring, and risk management (e.g., notifiers and breeders are immediately involved in the process of placing on the market and monitoring, and, if required, give recommendations on the cultivation practice). A detailed list of (potential) ‚players‘ in Germany is given in Table 7. The coordinators (e.g., the BBA) should include the administrative tasks in a close feedback and extend communication (e.g., take up observations made by the plant health services and make them available to all notifiers, authorities, etc., for coordination).

Agricultural production is linked to all OLP and AoC listed in Table 4. However, the competence of the ‚players‘ is focused on the agro-ecosystem and agriculture. So, the agriculture module should concentrate on aspects of

- sustainable agriculture
- soil function
- plant health
- agro-ecology.

The issue of coordination should not only be monitoring, but also measures of the cultivation management, since there is a feedback of GMO effects, monitoring, and measures. Some ‚players‘ are working out, or are even using nation-wide information systems that might be involved in a monitoring concept. For example, in Germany, the ‚Information System Integrated Plant Production‘ (ISIP) which is being established, and which among others is funded by Chambers of Agriculture and supported by the Plant Health Services in some of the *Länder*, offers access to a nation-wide data base on plant pests. Such data might be used for the general surveillance or for an additional monitoring depending on the problem at stake. Linking such systems with a GMO monitoring should be supported and coordinated.

3.2.3 Networks of the ‚Environmental Conservation‘ module

In Germany, the working group on ‚Monitoring environmental effects of genetically modified plants‘ headed by UBA discusses possible ‚players‘, programmes, and tasks with a view to the monitoring of GMO in the field of conservation and the protection of environment. Main foci of the coordination in this field might be

- ecological relationships (integrity of ecosystems, habitats)
- biodiversity.

These should be linked to aspects of soil function and sustainable agriculture, as far as they are of general importance beyond the agro-ecosystem. Important ‚players‘ in the ‚Environmental Conservation‘ module are all those involved in the environmental surveys , e.g., of the German Government and the *Länder* (see Table 8).

In addition, institutions of the *Länder* as well as UBA and BfN keep data (collections) which are relevant to environment and nature. The conclusion of a research project carried out for UBA was that existing environmental surveys are covering GMO monitoring to a certain extent (ZÜGHARDT, BRECKLING, 2003).

As in case of the agriculture module, the competent authority, expert and monitoring authorities, as well as notifiers and breeders would have to be integrated in the network.

3.2.4 Coordination of the „Consumers‘ Health Protection“ module

So far, organisational aspects of consumers‘ health protection were hardly discussed in context with GMO monitoring. A GMO-related typical aim of protection in this area is human health in dependence of product quality (ingredients), especially with regard to allergy risks. For a long-term and medium-term future, antibiotic resistance (markers) is expected to play a decreasing role for the introduction of GMO into the market.

Along with notifiers and breeders, the central ‚players‘ will be those institutions in charge of the official food and feed control. The tasks of the Government and of the *Länder* are laid down in the Food and Other Commodities Act (LMBG). The food control authorities of the *Länder* monitor that the rules are followed⁹.

These legal directions for food do already integrate organised monitoring programmes, documented methods^{10,11} as well as a binding exchange of information and documentation which, however, largely target (bio)chemical parameters, like plant protection agents, heavy metal, toxins, etc.; this is also true for the monitoring of food¹² which is explicitly mentioned in the LMBG.

The monitoring of food is performed as an independent legal task within the official food control regime; this means that the official food control authorities of the *Länder* are obliged to monitor foodstuffs by taking, and analysing, samples in addition to their routine investigations. The data obtained are passed on to the BVL where they are registered and evaluated, and the results are published¹³.

The LMBG would principally offer a legal basis for integrating aspects of the GMO monitoring into the food control after a corresponding agreement between the Government (Federal Ministry for Health and Social Affairs, i.e. BMGS, BMVEL) and the *Bundesrat* (House of the *Länder*). The directions given in the Regulation (EC) 1830/2003 (on traceability of GMO) might be included as well.

It seems unnecessary to include detailed health aspects as separate investigations into the monitoring plan or into a comprehensive GMO monitoring. Above all, one should aim for a promotion of the communication in the fields of food control, health, and introduction of GMO into the market, which would help to identify risk potentials, e.g., within an additional monitoring.

The institutions that should additionally be integrated into the network of food and feed control still have to be selected.

3.3. A Monitoring data base and data administration

The GMO monitoring will raise comprehensive, and partly complex data of three quality categories:

⁹ LMBG, Section 7, Monitoring

¹⁰ LMBG § 35

¹¹ Regulation (EC) No. 1829/2003: Art. 32, Annex – The Community Reference Laboratory

¹² LMBG § 46 d

¹³ Schriftenreihe „Lebensmittelmonitoring“ (Proceedings on Food Monitoring), published by BVL. Accessible to EC or WTO committees.

- *global data*, whose rational interpretation is only possible in context with the whole range of monitoring programmes (e.g., in the frame of the additional monitoring) and whose evaluation should preferably be made by the authorities and federal institutions;
- *results* according to a notifier's monitoring plan, for evaluation/assessment by the authorities;
- *additional information* which is necessary for the evaluation of data and which, if necessary, must be passed on.

Furthermore, a public register of the location of GMO releases¹⁴ must be established.

The approval and control authorities shall use the data collected during monitoring, and all relevant reports, for risk management and for their future decisions. Reports shall be available to the public in an appropriate manner, they shall be communicated EC-wide and on an international level, and they shall be compared with other information available. Thereby tasks arise to manage the access to information, and to evaluate this information in terms of decision making. The comprehensive data collections and the organisation of information exchange make a data base for the GMO monitoring a must, guaranteeing a reliable accessibility of information. Suitable interfaces for handling input and output of qualitatively heterogeneous sources of data have to be defined to provide different recipients.

The requirements made on a national data base comprise the technical and organisational realisation of

- collecting and recording data,
- making (processed) information available to notifiers and authorities,
- making (processed) information available to the public,
- data processing for evaluation and assessment of information relevant for monitoring,
- exchange of data.

The volume of the data base necessitates its technical and editorial administration, that the data are reviewed and up-dated, and that the communication among the institutions and the public using the data base is organised. The maintenance of the data base should be integrated into the modular coordination (3.2.). The coordination should be within the competent authority who following its function is mainly dependent on the accessibility of data. The data base should comprise

¹⁴ Directive 22001/18/EC Art. 31 (3) b

- the public register,
- the archives of the monitoring results and reports,
- an evaluation and statistics module,
- a library of decisions, assessments and recommendations,
- a library of monitoring-relevant information from third parties/
from the Member States and EC authorities.

The data base should offer input and output intersections with notifiers, authorities, EU contract countries, and international data bases, and, for output only, with the public. In order to guarantee the evaluation, especially, of global aspects of the general surveillance and of the additional monitoring the inputs should be linked with an evaluation module/interface so that the correlation of detailed results can be processed statistically.

For the health, environment and agriculture modules the relevant assessment rationales and questions should be defined in order to make the evaluation technically feasible. It has to be considered in which way an evaluation can be realised either within the data base system or by an interface to other systems of data processing. The increasing amount of data requires to realise a plausibility and consistency check. An algorithm would be helpful which, however, affords that data received can be codified and adapted to an evaluation format, and that a test reflects actual knowledge (which means that possibly obsolete data have to be re-evaluated). It has to be defined which details have to be included in the evaluation to harmonise with the requirements.

The coordinating authorities should be allowed to initiate further data requests on the basis of the information and experience gathered. The basis may be, e.g., a geographic assignment of observations in relation to the public register (e.g., in combination with geographic information systems). To give an example, central and global questions in the agricultural module would be the correlation of the cultivation (as per register) of individual GMO and groups of GMO with the occurrence/spread of plant diseases. The comparative data, partially processed, may be obtained from the Plant Health Services.

4. Operational design of the GMO monitoring

4.1. The monitoring of GMO in context with the “step-by-step approach”

The GMO monitoring is not meant to be a broad research programme on environmental effects of GMO but to provide reliable data for the risk assessment and risk management after a GMO's introduction into the market.

The guidance notes supplementing Annex VII suggest to design the monitoring on the basis of the step-by-step approach/introduction of GMO (laboratory – field test – market introduction) and of safety research¹⁵.

GMO monitoring is not a repeated processing of biosafety objectives but is to fill the specific gap within the data that is linked with the market introduction, i.e., the time and area of spread. The concept of the GMO monitoring and of the monitoring plan (objectives, parameters and methodology) is also based on subjects already dealt with in the e.r.a. and in earlier investigations and approval procedures and whose applicability must be checked. A foresighted planning of an approval for the market introduction of a GMO can render basic data for the e.r.a. and for the monitoring plan, e.g., during field releases (assessments on the variability of characteristics, a selection of non-target species, procedures to assess effects on non-target organisms, etc.). A detailed and focussed planning is supported by the clear identification of OLP and AoC subjected to relevant GMO impacts (see Table 4).

4.2. Identification and categorising of objectives for a GMO monitoring

The AoC described in Table 4 give a general orientation on safety and monitoring relevant objectives according to German or European law. The objectives will be identified by a comparison of AoC and the traits of the GMO as well as of the specific conditions of the introduction into the market. It should follow case by case evaluation and is based on the e.r.a.¹⁶. The impact of the GMO in relation to an AoC is decisive for the objectives to be included in the monitoring plan, and the intensity with which a parameter/variable will be monitored. In general, the monitoring should focus on what will be helpful in assessing the risks possibly linked with the GMO, in order to avoid waste of valuable resources by the collection of low-value information¹⁷. In addition, data of uncertain information contents provide an inadequate basis for (legally justified) actions.

For example, in our opinion a general analysis of the GMO / transgene exposition is largely unnecessary within a monitoring. General regional and time effects from GMO can sufficiently be evaluated on the basis of the public register. Since no *a priori* comment on the kind and the likelihood of an unexpected adverse effect can be made, it is principally necessary to investigate whether an observed effect can be dependent directly from, or

¹⁵ Guidance notes supplementing Annex VII; C 1.3. Approach

¹⁶ Directive 2001/18/EC Annex VII C.1.

¹⁷ Guidance notes supplementing Annex VII; B: [...] cost effectiveness of case specific monitoring and general surveillance should be taken into account.

correlate with the release of the GMO. In a well-targeted and hypothesis-based approach a concrete proof of a GMO effect must then be furnished.

Objects for a case-specific monitoring shall result from the hypotheses and conclusions of the e.r.a.¹⁸. Therefore, they are based on the cause-and-effect hypotheses regarding the traits of the GMO and the identified risks that must not be ignored but which would not exclude an introduction into the market (Fig. 2). Risks that should not be ignored but are considered to be acceptable, and corresponding parameter values that should not exceed certain thresholds, can be linked with

- a considerable intensity of damage but expected to be acceptable and controllable
- a considerable likelihood of occurrence but expected to be acceptable and controllable
- an unclear chain of events which, however, not make expect unacceptable or negligible damage or likelihood (it should be considered whether the situation can be clarified before the introduction into the market, or whether it can be taken into account within the general surveillance).

The objectives of the general surveillance, or moreover of an additional monitoring, are to be focussed on unforeseeable events. To state the relevance the primary question is: Are there potentially negative events to be expected with regard to OLP and AoC (see Table 4). In deviation from the case-specific monitoring it has to be checked whether an event indicating a potential damage can be linked, or correlates with the introduction of one (or several) GMO. In many cases the AoC are objects of other investigation programmes (see Table 4) that trace questions as to which changes occur, and whether causes can be narrowed. The general surveillance and the additional monitoring should complete the ‚open‘ (AoC-related) questions by GMO-specific information and evaluations, in order to integrate relevant and problem-specific know-how and experiences into the GMO monitoring regime. This is the only way to differentiate between GMO effects and other causes if the previous information was insufficient. An important operational element of the general surveillance is the exchange of information (data) between various institutions and the notifier/consent holder (see 3.2.). Nevertheless, the question has to be considered whether other surveillance programmes are able or can be modified to provide additional GMO-related data within an AoC at all. Such a consideration would start with the characteristics of the GMO and the conditions of the introduction into the market.

The monitoring plan should explain (compare Fig. 1)

¹⁸ Directive 2001/18/EG; Annex VII: A., C.3.1 and Guidance note B.

- the questions that can be investigated GMO-specifically, and in a plausible manner,
- how plausible information can be obtained via other surveillance programmes,
- how information from other data collections can be integrated into a GMO-related assessment.

The simplest case might be to establish a complete monitoring of a specific GMO on the basis of other surveillance programmes (public and/or private). Then the monitoring plan would formulate the questions, describe the retrieval of data from the institutions, and give instructions for the assessment of the data obtained.

The additional monitoring can be supported by the public register which would allow to determine correlations between a GMO's introduction into the market and large-scale (environmental) changes. Especially for other monitoring purposes the public register would offer the chance to obtain basic data for comparison with the occurrence of GMO. However, legal arrangements regarding access to detailed data are still to be made.

4.3. Selection of suitable monitoring parameters

Principally, the reliability of the possible monitoring parameters regarding the OLP/AoC and for an assessment of potential risks posed by the GMO has to be evaluated. The interdependencies of OLP/AoC, GMO effect, and parameters should be outlined in a clear manner to emphasise the meaningfulness of the parameters. The suitability of the parameters selected for the GMO monitoring should be evaluated. The monitoring should allow clear statements about GMO effects on OLP/AoC by a limited number of parameters that can be recorded at low expenditure.

Usually, monitoring parameters will indicate tendencies. In addition, individual events may be important indicators for GMO impacts, necessitating a special analysis of causes.

The monitoring plan and the questions/parameters selected therein should be comprehensible and revisable. Therefore, the criteria given in Table 9 should be broken down into parameters and be used in a uniform manner (compare the instructions of the Annex VII guidelines in Table 2). The general aim should be to link the data collection with options for decision making. Questions and parameters in the monitoring plan which cannot be linked with options for the risk management are of no use. They may be analysed in the course of an additional monitoring for other reasons.

4.4. How to perform a monitoring

4.4.1. Detection methods

Apart from statistical evaluation and support of the measuring results the guidance notes supplementing Annex VII provide for the application of standardised measuring methods¹⁹ which would promote the comparability of results (on a European level). However, one cannot expect that an optimised standard method is available for each question *ad hoc*, especially with regard to long-term monitoring and reliability. This means that for the time being one will, as far as possible, rely on the experience made with other surveillance programmes, and a *preliminary* evaluation of methods. Existing surveillance programmes and ecological investigations do already use methods of problem-oriented observation which were gradually developed and revised in the past and take into account the problem of weighing limited resources and reliability. Depending on the objective it has to be considered to which extent these methods can be applied for, or adapted to a GMO monitoring.

4.4.2. Time period and area for a GMO monitoring

The outline and conditions²⁰ of an introduction into the market, objectives of the monitoring, the variability of the parameter values as well as the reliability of the results, are the determinants for the choice of areas, time period, frequency and density of sampling or observation. They depend on the methodological requirements and on the relevant agricultural practice. *If sufficient experience and data are available they may be modified accordingly and be adapted to the actual requirements of the monitoring. In order to have reliable data available soon it is recommended to start with a high frequency of inquiries which should allow for a statistical support. Possibly a sufficient reliability of the results is only achievable in combination with additional parameters.* The general conditions of the introduction to the market must also be considered with regard to the achievable confidence intervals for the results.

Observation areas show typical requisites that are relevant to AoC and parameters (e.g., presence of crossing partners, pests). They may be categorised by

¹⁹ **Guidance notes – C.2.4. Sampling and analysis:** [...] Standard methodology, as provided for by the likes of European CEN Standards and OECD-methods for monitoring organisms in the environment, should be followed where appropriate [...]

²⁰ **Guidance notes - C1.5. Time-period:** Monitoring should be carried out over a time period of sufficient length to detect not only immediate potential effects, where appropriate, but also delayed effects which have been identified in the environmental risk assessment. [...] It should also be considered whether it is necessary to extend the monitoring plan beyond the period of the consent. This may be the case, for example, where the persistence of GMOs in the environment has the potential to be significant. [...]

- *characteristic / dominant and special use,*
- *cultivation of GMP / exposed region / comparative site / special sites (e.g., nature reserves),*
- *existence of special biota (e.g., spread of certain species) and*
- *existence of special abiota (soil, air, climate).*

Exemplary sampling sites or observational networks are to be chosen within these observation areas depending on the regional and temporal distribution as well as on the variability of the parameter values. The BMBF research cluster „Development of methods for the cultivation related monitoring of genetically modified plants“ analyses the optimisation of observation networks for the monitoring of GMO, taking into account prioritised objectives and parameters. This will allow to design monitoring plans for the general surveillance and the additional monitoring in a cost saving but efficient manner.

In any case, the time period for the monitoring must be „appropriate“ in a scientific sense and take into account the probability of an event to occur²¹. For the case-specific monitoring a period appropriate to achieve results should be defined²¹. The period of the consent for the introduction of a GMO into the market is not binding for the minimum or maximum time frame of a monitoring.

4.4.3. „Baselines“ – Comparative and control data²²

The comparative system to the GMO-influenced system ideally differs only by the GMO-specific elements (see also 4.4.2: Selection of monitoring areas). In the field of agriculture, this would presently be a comparison between conventional, GMP-free cultivation and the GMP cultivation regime. Moreover, sites of cultivation regimes complying with special standards - e.g., sites of organic farming - can be included to answer special questions.

There are two ways to compare data with the controls, which possibly may or must be combined:

- *Comparison of the actual state with the state after the GMO introduction (subsequent comparison),*
- *Comparison of areas exposed to GMO with areas not exposed (time parallel comparison).*

²¹ **Guidance notes supplementing Annex VII – C.1.3.1. Case-specific monitoring:** The approach should; [...] define a specified time period in which to obtain results.

²² **Guidance notes supplementing Annex VII; B., C.1.4., C.3.1.**

The approach of subsequent comparison will be sufficient only if the variables show low variation coefficients. There possibly is a data base by other monitoring programmes documenting long-term fluctuations/periodicities. However, it is agriculture, independently from GMP cultivation, that is especially subjected to long-term changes which are predictable to a limited extent only. With regard to the interpretation of long-term changes an analysis based on an approach of subsequent comparison will be of minor importance, and it is to be linked with additional information about the „natural“ variability and the dynamics of the analysed variables.

Whenever control data from other monitoring regimes are included in a GMO monitoring it must be guaranteed that comparable methods have been used.

4.5. Standardisation of monitoring plans and methods

Presently a (crop-specific) standardisation of GMO monitoring plans and methods is under discussion and methods. However, the precondition for this is that the quality of monitoring plans and methods can sufficiently be assessed. Since especially in the field of the general surveillance only limited (international) experience is available, any feasibility study is presently not possible. Therefore, an evaluation should refer to the experience made, and to the consideration of plausibility. A systematic and consecutive documentation of the experiences gained from the GMO monitoring should be striven for in order to establish revisable methodological handbooks.

The (early) finalisation of monitoring plans and methods prior to the release of the GMO counteracts the quick adaptation to new insights²³, and also the case-by-case approach. Moreover, according to Article 20 of the Directive the Competent Authorities may initiate a modification of a consent after an EU-wide agreement²⁴.

Acknowledgement

The authors are grateful to the German Federal Ministry for Consumer Protection, Food and Agriculture for funding the work of Dr. R. Wilhelm, and to the German Federal Ministry for Education and Research, for supporting the work of Dr. L. Beißner, within the cluster project „Methodenentwicklung für ein anbaubegleitendes Monitoring von GVP im Agrarökosystem“.

²³ **Guidance notes supplementing Annex VII, C.3.3.:** Monitoring plans should not be viewed as static. It is fundamental that the monitoring plan and associated methodology is reviewed at appropriate intervals and updated or adapted as necessary.

²⁴ In addition: **Guidance notes supplementing Annex VII, C.3.3.**

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Table 1. Structure of a monitoring plan and its intended use according to the guidance notes supplementing Annex VII

I Structure of a monitoring plan
1. Monitoring strategy
1.1. Concept
• Consideration of e.r.a.
• Considering background information
1.1.1. Case-specific monitoring
• Consideration of relevant objectives (according to the results of the e.r.a.)
1.1.2. General surveillance
• [Consideration of relevant OLP and AoC]*
1.2. Baseline and controls
1.3. Time scale of monitoring
1.4. Responsibilities
2. Monitoring methods
2.1. Identification of parameters and methods that are valid and fit-for-purpose
2.2. Methods for sampling and analysis
• Use of standardised methods - if applicable
• Adaptation to “state of the art”
2.3. Sampling sites and networks
2.4. Frequencies
2.5. Collection and collation of (single) results/recorded data
• Responsibilities
• Frequencies and deadlines
• Formats
3. Intended analysis and reporting
3.1. Frequency of the review and discussion of an overall analysis
3.2. Intended analysis of the data
• Consideration of extraordinary conditions
• Statistics
3.3. Intended modalities of reporting and publication
• Communication between notifier, authorities and third parties
• Publication of the results
II Evaluation and report
1. Evaluation of the monitoring results
2. Evaluation of the efficiency of the monitoring plan and its elements, if necessary modification
3. In case: consideration of further measures
4. Presentation of the results for the renewal of the consent
5. Publication of the monitoring report

*) „[...]“ it is not mentioned in the guidance notes, but recommended according to this proposed concept

Table 2. Criteria named within the guidance notes supplementing Annex VII to consider objectives and parameters of the monitoring plan (CSM = case-specific monitoring; GS = general surveillance)

Criteria	Category of monitoring	Citation in the guidance notes suppl. Annex VII
In addition, monitoring of <i>potential adverse cumulative long-term effects</i> should be considered as a compulsory part of the monitoring plan.	CSM GS	B. para. 5
Case-specific monitoring should, when included in the monitoring plan, focus on potential effects arising from the placing on the market of a GMO that have been highlighted as a result of the conclusions and assumptions of the environmental risk assessment	CSM	B. para. 6
... <i>cost-effectiveness</i> of case-specific monitoring and general surveillance should be taken into account.	CSM GS	B. para. 7
... accordance with the latest scientific insights and practices ...		
... appropriate approach ...		
... appropriate time scale ...;		
... time period of sufficient length ...	CSM GS	C.1.; C.1.5.
... <u>likelihood</u> of potential direct, indirect, immediate or delayed adverse effects ...		
... the establishment of a cyclic monitoring process in order to be able to <i>continuously improve the quality</i> of the programme.	CSM GS	C.1.3.
... The design of monitoring plans for GMO should be built using a <i>step-by-step</i> approach ...		
... detect potential adverse effects at an early stage ...		
Confirm ... scientifically sound assumptions, in the environmental risk assessment ...		
Where the conclusions of the risk assessment identifies an absence of risk or negligible risk, however, then case-specific monitoring may not be required.	CSM	C.1.3.1.
Potential adverse effects that are identified in the environmental risk assessment should only be included in the monitoring plan on the basis that monitoring could contribute to the <i>confirmation or rejection of the assumptions</i> associated with these effects.		
... largely based on routine observations ...		
... longer time period ...	GS	C.1.3.2.
... wider area ...		

Table 3. Objectives for consideration in a monitoring plan explicitly named in the guidance notes supplementing Annex VII

Monitoring-objectives	Citation in the guidance notes supplementing Annex VII
<p>Changes in the population of target insects as a result of the toxin produced by the GMO</p> <p>Changes in the population of non-target insects as a result of the toxin produced by the GMO -effects on organisms that normally feed on these insects.</p>	<p>C.1. (general example)</p>
<p>pollen transfer</p> <p>persistence</p> <p>dissemination</p> <p>insect resistance</p> <p>transfer of antibiotic resistance genes</p>	<p>C.1.3.1. (case specific monitoring)</p>
<p>changes in bio-diversity, cumulative environmental effects</p>	<p>C1.3.2. (general surveillance)</p>

Table 4. Assignment of goods/values to be protected and fields of action for a GMO-/GMP-risk analysis and for performance of the GMP monitoring to

- aspects of the e.r.a. according to Annex II of Directive 2001/18/EG (+ = explicitly mentioned in the Directive; (+) = derived),
- other legal regulations or technical recommendations (QM = Quality management, GAP = „good agricultural practice“, CBD = Convention on Biological Diversity),
- protagonists and programmes in the field of the goods/values to be protected and fields of action (BDF = Soil areas under permanent observation; VDLUFA = Association of German Agricultural Control and Research Institutions).

Objectives of legal protection (OLP)	Areas of Concern (AoC)	Mentioned in Directive 2001/18/EC Annex II	Other laws and regulations relevant in Germany	Protagonists
1 Ecological systems and biodiversity	Invasiveness / spreading	+	e.g., BNatSchG; Dir 92/43/EEC; CBD	Environment observation, programmes for species and nature protection ; farmers
	Functional symbioses	(+)		
	Diversity	+		
2 Soil function	Soil fertility	(+)	e.g., BBodSchG; GAP	BDF; agricultural advisors, farmers
	Soil biology	(+)		
	Mineralisation	+		
	Loss of soil (erosion, compression)	(+)		
3 Sustainable agriculture	Balance of fertilisers	(+)	e.g., BNatSchG, BBodSchG; GFP; (SEK(2001)517) . SaatVerkG; QM, GAP; 2001/0173 (COD)	Agricultural advisors, evaluation of seeds; farmers
	Balance of pesticides	(+)		
	GMO persistence	+		
	Cultivation methods	(+)		
	GMO traits	(+)		
4 Plant health	Plant diseases	+	e.g., PflSchG; QM;	Plant Health Services of the <i>Länder</i> , observation programmes of breeders/producers, evaluation of seeds; farmers
	Animal pests	+		
	Weeds / weediness	+		
5 Human health	Ingredients / toxicity	+	e.g., LMBG; VO(EG)178/2002, KOM/2001/0425	Institutions for food control and quality management: e.g., VDLUFA, private laboratories
	Pathogenicity	+		
	Allergenic potential	+		
	Medical therapy and prevention	+		
	Nutrition quality	(+)		
6 Animal health	Ingredients / toxicity	+	e.g., KOM/2001/0425	Institutions for feed control and quality management: e.g., VDLUFA, private laboratories; farmers
	Pathogenicity	+		
	Allergenic potential	+		
	Veterinary therapy and prevention	+		
	Nutrition quality	(+)		

Table 5: Global factors influencing environment and health (without GMO)

Factors
Chemical pollution
Traffic and transportation
Urban sprawl
Climate impact
Agricultural practice (cultivation methods)
Agricultural use (crops)
Landscaping and restructuring (mining, cultivation measures, landscape design)

Table 6. Organisation of GMO monitoring in Germany, protagonists and tasks

Protagonists / Institutions	Tasks
<i>Notifiers</i>	<ul style="list-style-type: none"> • Establishment of a monitoring plan • Responsible performance of the case-specific monitoring • Responsible for partial aspects of the general surveillance • Organisational realisation of the monitoring plan • Evaluation of results • Obligation to pass on information
<i>Sub-Contractors of the Notifiers</i>	<ul style="list-style-type: none"> • Involved in partial aspects of the monitoring plan
<i>Public institutions (Government and Länder)</i>	<ul style="list-style-type: none"> • Responsible for partial aspects of the monitoring plan • Responsible for partial aspects of additional monitoring • Delivery of data for the GMO monitoring and/or for the assessment of the monitoring results
<i>Competent authority</i>	<ul style="list-style-type: none"> • Evaluation of the monitoring plans • Final evaluation of the monitoring results (monitoring plan, additional monitoring) • EU-wide coordination • Imposition of conditions if required • Central coordination and data administration • Identification of research demand • Identification of additional monitoring tasks • Obligation to pass on information
<i>Expert authorities involved</i>	<ul style="list-style-type: none"> • Technical evaluation of the monitoring plans • Evaluation of technical global questions regarding additional GMO monitoring • Technical evaluation of the monitoring results • Technical advice / coordination • Technical maintenance of the data base • Obligation to pass on information • Identification of additional monitoring tasks
<i>Control authorities (of the Länder)</i>	<ul style="list-style-type: none"> • Control of / advice on the realisation of the monitoring • Involved in partial aspects of the monitoring plan if required • Involved in partial aspects of the additional monitoring if required • Delivery of data for the GMO monitoring and/or the evaluation of the monitoring results • Obligation to pass on information

Table 7. Protagonists and their specific activities in the ‚agriculture‘ module

Protagonists	Activities a.o.
Notifiers / consent holders	<ul style="list-style-type: none"> • Responsible performance of the monitoring • Fulfilment of conditions • Recommendations for cultivation and management
Breeders	<ul style="list-style-type: none"> • Seeds development • Seeds management • Recommendations for cultivation and management
Competent authority	<ul style="list-style-type: none"> • Evaluation of the monitoring plan • Evaluation of the monitoring results • (International) Exchange of information • Imposition of conditions • Evaluation of monitoring data • Initiation of research
Expert authorities involved	<ul style="list-style-type: none"> • Evaluation of the monitoring plan • Evaluation of the monitoring results • Collection and supply of information • Evaluation of monitoring data • Accompanying research
Control authorities of the <i>Länder</i> as per Genetic Engineering Act	<ul style="list-style-type: none"> • Control of the realisation of the monitoring plan and the conditions • Execution of partial aspects of the monitoring plan
Federal Office of Plant Varieties	<ul style="list-style-type: none"> • Seeds approval tests
Official institutions for seed control	<ul style="list-style-type: none"> • Seeds trade control • Seeds certification
Plant Health Services of the <i>Länder</i>	<ul style="list-style-type: none"> • Control of the presence of pests • Observation of the occurrence of damages • Testing of plant pesticides and their efficiency • Observation of the impact of climatic conditions
Official institutions involved in the programme for soil areas under permanent observation	<ul style="list-style-type: none"> • Execution of permanent observation of soils
VDLUFA	<ul style="list-style-type: none"> • Service in the field of quality protection of agricultural production means and products
Chambers of agriculture	<ul style="list-style-type: none"> • Advisors and information networks on agricultural problems in production and management
Private control institutes (e.g., Institute for Sugar Beet Research)	<ul style="list-style-type: none"> • Execution of controls/analyses for the private industries • Order-based research within monitoring
Scientific institutions	<ul style="list-style-type: none"> • Scientific investigations on biosafety and monitoring • Order-based research within monitoring

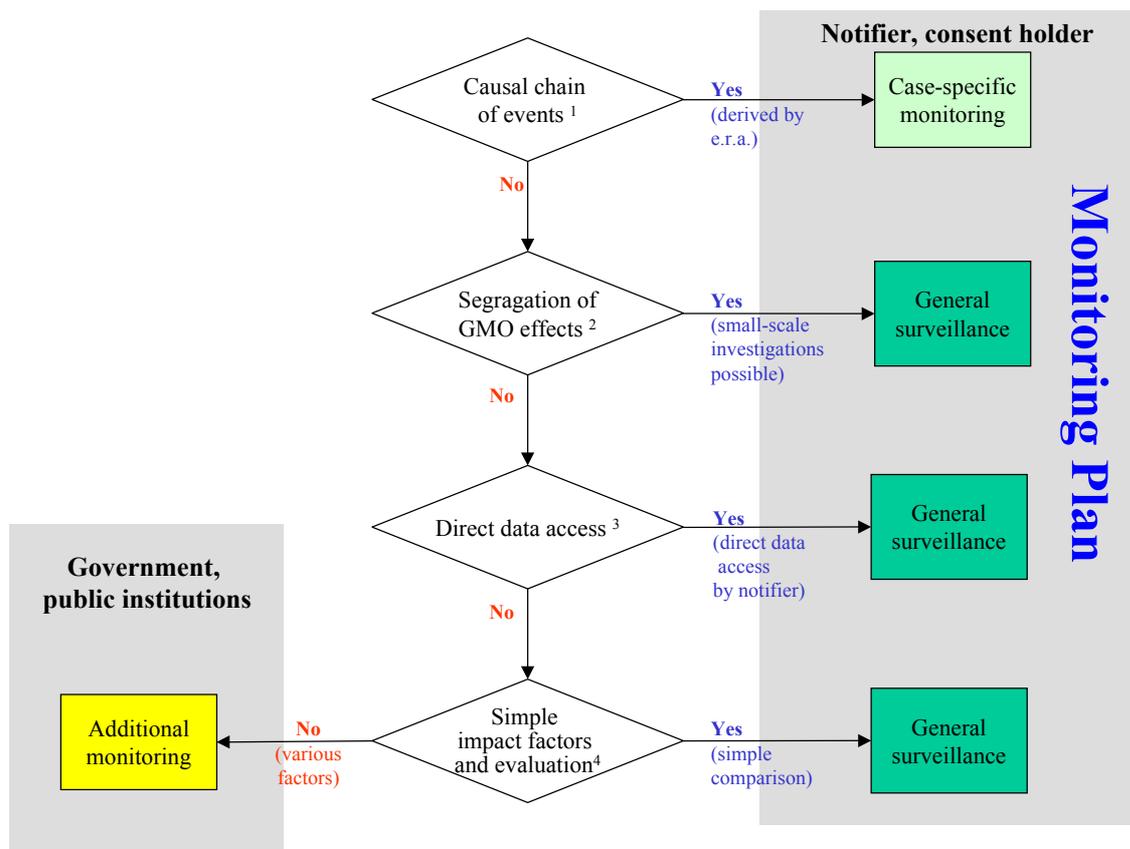
Table 8. Programmes for environmental observation (Government and *Länder*) in the 'environment' module according to the working group on 'Monitoring environmental effects of genetically modified plants' (B/LAG, 2002)

Programme for soil areas under permanent observation (BDF)
Assessment of the health condition of German forests
Assessment of forest damage
Assessment of the condition of soils
Immission and deposition networks
Monitoring of surface waters
Air pollution control
Bank of environmental samples
Survey of the environment
Monitoring programmes for the protection of species and nature

Table 9. Key issues for categorising and selection of objectives and parameters for GMO monitoring

Criteria for tests and comparisons	Objectives and remarks
1. <i>Relevance</i>	<i>Objective: Question and parameter should be relevant and plausible for assessment of a GMO risk</i>
<ul style="list-style-type: none"> • Relation of the parameter to the goods / values to be protected / field of action / question • Relation of the parameter to GMO traits • Relation of the parameter to potential series of effects 	<p>Assignment of a question and parameter to certain goods or values to be protected, or to a field of action</p> <p>Limitation of the relation to the GMO, approach for data interpretation; case-specific monitoring.</p> <p>Limitation of the relation to the GMO, approach for data interpretation; general surveillance</p>
2. <i>Frame conditions</i>	<i>Objective: General conditions must be clearly circumscribed and plausible</i>
<ul style="list-style-type: none"> • Preconditions required • Background information required • Comparative data required 	<p>Limitation of the necessary data inquiries</p> <p>Dependency on the data collected</p> <p>Dependency on the data collected</p>
3. <i>Measuring method</i>	<i>Objective: A simple and safe (standardised) methodology</i>
<ul style="list-style-type: none"> • Methods • Reliability • Time and area of recording • Period and space of execution • Responsibility for the data inquiries • Evaluation 	<p>Options; criteria for the reliability of 5.</p> <p>Selection of observation areas / time frame in context with reliability.</p> <p>Possibly organisation of data transfer among various institutions.</p> <p>Preconditions for linking with 2 and 5.</p>
4. <i>Assessment of expenditure (costs)</i>	<i>Objective: Limitation of expenditure to the necessary extent of inquiries</i>
<ul style="list-style-type: none"> • Methods • Reliability • Period and area of execution • Responsibility for data inquiries • Assessment 	<p>Comparison of costs and benefit of the options listed in 3.</p>
5. <i>Risk assessment and management</i>	<i>Objective: Plausible linking of data inquiry and risk management</i>
<ul style="list-style-type: none"> • Thresholds • Options for further measures 	<p>Linking of parameter values and options of action</p>
Significance and information gain of the parameter / of the question	Total evaluation (1-5)

Fig. 1. Segregation of different tasks within a GMO monitoring regime



Explanations

- (1) The analysis of a defined chain of cause and effects – as a typical feature of the e.r.a. and consequently of the case specific monitoring – is to be attributed to the monitoring plan and an obligation to the notifier or consent holder. Undefined objectives – as it is to detect unforeseen effects of GMO – are broken down further on.
- (2) Some potential effects of GMO may be relevant in a large-scale context but can be surveyed in focus on small-scale plots if the GMO effects dominate on a small scale according to an appropriate setting (e.g., effects on soil fauna).
- (3) The notifier or consent holder may have an immediate or easy access to single large-scale data on GMO e.g., by contracting with third parties. In contrast, data will be distributed between different institutions and resources in case of complex large-scale interdependencies.
- (4) The notifier / consent holder will not gain complete data access to differentiate between multiple impact factors. But the notifier / consent holder may provide GMO-linked control data for a thorough analysis of potential effects.

Fig. 2. Evaluation of “risk” and the need for a case-specific monitoring according to Annex II and Annex VII of the Directive.

