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National coordination of GMO monitoring – a concept for Germany

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Abstract: The concept of monitoring according to the Directive 2001/18/EC has two focuses: (1) to confirm possible adverse effects of the genetically modified plants (GMP), identified in the formal risk assessment procedure (Case Specific Monitoring), and (2) to identify the occurrence of adverse unforeseen effects of the GMP or its use which were not foreseen in the environmental risk assessment (General Surveillance). In addition, Member States should be able to take further measures for monitoring and inspection of the GMP as or in products placed on the market (2001/18/EC, item 44) for example by official services. As national competent authority, the *Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* (BVL) serves as national Reporting and Coordination Office. This Office will provide the platform for information exchange between applicants and other involved authorities regarding monitoring plans and reports according to Annex VII of Directive 2001/18/EC. Advice to applicants will be given in the selection of appropriate existing monitoring systems, in developing systems which may provide useful data in Germany and in selecting existing surveillance systems. BVL will establish technical discussions with different applicants and third parties in order to stimulate and coordinate data collection and analysis from different monitoring programmes. Specific emphasis will be given to coordination and active involvement of the *Federal Bundesländer* since general environmental monitoring falls under their legal responsibility. The BVL will actively support the development of mechanisms for reporting and collating monitoring data both at Member State and EU level. This will facilitate scientific analysis of these data, provide scientific conclusions and enable informed decisions on the future cultivation of GM crops as well as future improvement for risk assessments.

Zusammenfassung: Die Umweltbeobachtung von gentechnisch veränderten Pflanzen (GVP) nach Richtlinie 2001/18/EG umfasst zwei unterschiedliche Ansätze, (1) zu bestätigen, dass eine Annahme und die Wirkung einer etwaigen schädlichen Auswirkung eines GVO oder dessen Verwendung in der Umweltverträglichkeitsprüfung (UVP) zutrifft (fallspezifische Beobachtung) und (2) das Auftreten schädlicher Auswirkungen des GVO auf die menschliche Gesundheit und die Umwelt zu ermitteln, die in der UVP nicht vorhergesehen wurden (allgemeine Beobachtung). Weiterhin besteht die Möglichkeit, weitere Maßnahmen, die der Beobachtung von GVP dienen, beispielsweise durch amtliche Stellen durchführen zu lassen. Als zuständige Bundesoberbehörde dient das Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) als die nationale Koordinierungsstelle. Die Koordinierungsstelle bietet eine Plattform zum Informationsaustausch zwischen Antragstellern und beteiligten Behörden hinsichtlich Beobachtungsplänen und Berichten von GVP nach Annex VII RL 2001/18/EG. In diesem Zusammenhang soll den Antragstellern Hilfestellung gegeben werden, damit geeignete Daten aus existierenden Umweltbeobachtungsprogrammen für die Allgemeine Beobachtung von GVP identifiziert werden können. Das BVL wird hierzu Fachgespräche mit allen Beteiligten führen, um eine Einbeziehung existierender Beobachtungssysteme anzuregen und die notwendigen Aktivitäten zu koordinieren. Insbesondere die Bundesländer sollen in die Fachgespräche einbezogen werden, da viele Beobachtungsprogramme in ihrer Verantwortung liegen. Weiterhin wird das BVL aktiv die Entwicklung von Strukturen zur Sammlung und Auswertung von Beobachtungsberichten und Beobachtungsnetzwerken unterstützen. Die Analyse und Bewertung der Beobachtungsergebnisse soll Entscheidungen über den Anbau zukünftiger GVPs oder die Bewertung innerhalb der Umweltverträglichkeitsprüfung erleichtern.

1. Introduction

Post Market Environmental Monitoring (PMEM) of genetically modified (GM) plants is a mandatory requirement for applicants. The concept of monitoring according to the Directive 2001/18/EC has two focuses: (1) the possible effects of the GMP,

identified in the formal risk assessment procedure (Case Specific Monitoring, CSM), and (2) to identify the occurrence of adverse effects of the GMP or its use which were not foreseen in the environmental risk assessment (General Surveillance). The directive foresees the possibility that applicants could additionally include data of routine surveillance networks such as monitoring of plant protection, plant health, agricultural practices, seed approval, biodiversity monitoring programmes (e. g. birds, butterflies) or the FFH monitoring (EC, 2002). However, existing monitoring systems and networks collecting environmental data are unlikely to always provide data of relevance in the present way of performance. Thus there might be the need to adapt appropriate networks for GMO monitoring (Bartsch et al., 2006; EFSA, 2006). As applicants should specify their monitoring plans with details on monitoring strategy, methodology, analysis, and reporting according to the EFSA guidance on PMEM (EFSA, 2006), this document aims at guiding risk managers and applicants in Germany for a common selection process of monitoring plan specification.

2. EU wide adoption of monitoring plans

Monitoring plans are evaluated intensively by the European Food Safety Authority EFSA. National competent authorities have partial influence during the EU commitology procedure on the design of monitoring plans. This applies mainly at the EU wide consultation and decision making of the risk management process. One instrument to gain influence is delaying the approval process by objection during voting in the Regulatory Committee or the Council of Ministers in case of disagreement with the monitoring plans. However, single Member States could be overruled in case of qualified majorities or opposite EU Commission decision in case of neither qualified majority decision. In any case Member States can make use of monitoring measures outside the responsibility of applicants and set up additional GMO monitoring in line with item 44 of Dir. 2001/18/EC, e. g. if Member States feel uncomfortable with the extent of the applicant's monitoring requirements.

3. Use of existing monitoring networks

The *Federal Bundesländer* are involved in national aspects of general environmental monitoring and monitoring of GMO. Considering the use of existing networks, monitoring should be cost effective and proportionate to the extent of market introduction. For example Marquart and Durka (2005) listed estimates for monitoring measures that could potentially be used in General Surveillance. Measures includes mapping of landscape structure, biotopes and outcrossing partners of oil seed rape as well as monitoring of pollen dispersal and non-target organisms such as birds, butterflies, carabid beetles and herbivores. The five-year costs for such a programme in Germany based on the ecological area survey would easily be about 17 Mio € consisting of with 9 different parameters in relation to herbicide tolerant and insect resistant plants. This sum contrasts the maximum turnover of e. g. all maize breeders for selling Bt-maize, which is estimated to be 25 Mio € in 5 years. This calculation is based on 40,000 ha European corn borer infestation area that exceeds the economic threshold in Germany.

4. The Federal coordination task of monitoring

Since 2004, the BVL is the competent federal authority responsible for regulating the field of genetic engineering in Germany. The BVL fulfils the mandate as national competent authority according to the German Genetic Engineering Act and Directives or Regulations of the European Union. The BVL thus assesses notifications for the experimental use of genetically modified organisms (GMO) and is involved in the approval of GMOs in connection with food and feed. It is also responsible authority for the evaluation of monitoring plans and thus for the coordination of GMO monitoring.

Risk managers in Member States (MS) should guide applicants in the selection of appropriate existing monitoring systems and in developing systems which may provide useful data in their country/region and in selecting existing surveillance systems. A mechanism should be established for considering the interactions of several different GM plants subject to different applications. EFSA proposed that national Competent Authorities should establish liaison with different applicants in order to coordinate data collection and analysis from different monitoring programmes. Mechanisms should be developed by risk managers for reporting and collating monitoring data both at MS and EU level.

This will facilitate scientific analysis of these data, provide scientific conclusions and enable informed decisions on the future cultivation of GM crops as well as future improvement for risk assessments. There should be a close interplay between applicants, risk assessors and risk managers in order to acquire the best possible experience and effectiveness for PMEM (EFSA, 2006).

General surveillance for adverse impacts of GMPs at complex regional and/or national levels may be beyond the applicant's direct capability. Increasing complexity and interaction of GMP use with other land management systems should be studied in other ways. Utilising existing surveillance systems established by land-use and environmental organisations is a potential approach to increase the scope of the general surveillance. This approach would have the advantage of collecting information which is related to the combined effects of GMP in a region. Utilising other environmental monitoring programmes will allow higher ecological integration of data and use of their established base lines and trends.

In this respect, BVL can serve as national Reporting and Coordination Office. The office will provide the platform for information exchange between applicants and other national authorities involved regarding the use of existing networks suitable for monitoring plans and reports including the establishment of additional GMO monitoring in line with item 44 of Dir. 2001/18. It also serves as information exchange with the European Commission or other Member States. Furthermore, the public will be informed about the monitoring activ-

ities in Germany via the web pages of the BVL (Fig. 1). Further tasks are the monitoring plan assessment, the evaluation of monitoring reports, collation, distribution, evaluation of the monitoring data. As these tasks could not be put into practice by the BVL alone, it needs to be completed by the professional competence of other national authorities. This should be realized by the sub-coordination of the Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA) in the scope of agriculture, by the Bundesamt für Naturschutz (BfN) in the scope of broader environmental issues including nature conservation, and by the Robert Koch-Institut (RKI) in the scope of human health.

Monitoring plans of applicants could consist of different tools such as stewardship programmes, questionnaires for farmers and processors, respectively, or own surveillance programmes. The plans could also include useful data from existing environmental monitoring programmes. These monitoring plans must be assessed whether they are designed in accordance with the council decision 2002/811/EC supplementing Annex VII. However the applicant needs guidance in selection of appropriate existing monitoring programmes. Specific emphasis must be given to coordination and active involvement of the Federal Bundesländer since general environmental monitoring falls mostly under their legal responsibility (Middelhof et al., 2006).

Additional monitoring of third parties needs also coordination for any identification of appropriate networks and parameter collection. A precondition is the ability of the institutions to participate in such monitoring activities. Data from the different resources should be collected, harmonised and evaluated. A suggestion for the evaluation procedure of monitoring reports is presented in Fig. 2. These reports are delivered to the BVL by the applicant and forwarded to other national authorities. After evaluation BVL could demand, if appropriate, that (i) monitoring plans should be improved and (ii) appropriate measures are taken if unanticipated adverse effects are detected.

A further challenge is to set up measures to collect, collate, analyse, evaluate, archive, and manage monitoring data. Therefore a database is needed which meets the national demands but also provides the opportunity to exchange data with the EC or other Member States. For this purpose standardisation and harmonisation for the data exchange is required.

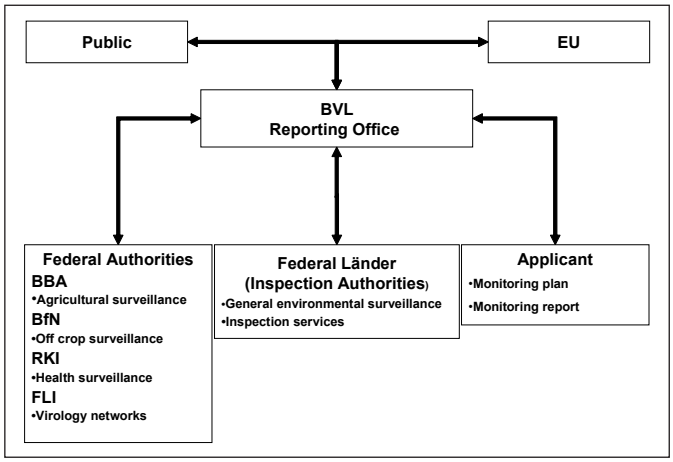

Fig. 1 The potential coordinative role of BVL Reporting Office for monitoring in Germany. (BBA = Federal Biological Research Centre for Agriculture and Forestry; BfN = Federal Agency for Nature Conservation; RKI = Robert Koch Institute; FLI = Friedrich Löffler Institute)

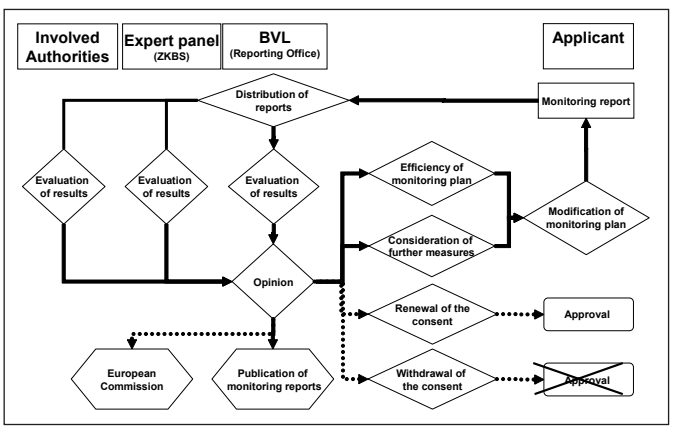

Fig. 2 Evaluation of monitoring reports (Flow-chart): These reports are delivered by every applicant to the reporting office and then are forwarded to other national authorities. In addition the reports are assessed by the German Commission of Biological Safety (ZKBS) and by the BVL itself. After evaluation BVL could demand if appropriate that (i) monitoring plans should be improved and (ii) appropriate measures are taken if unanticipated adverse effects are detected.

5. Conclusions

The environmental monitoring of GMO needs infrastructure and concepts for General Surveillance on national levels in the EU. An appropriate integration of suitable monitoring networks into General Surveillance supports a meaningful and cost-effective monitoring. Guidance to applicants should be given by risk managers for the selection of appropriate existing monitoring systems and in developing systems which may provide useful data, in our case for Germany. The access and handling of a large number of environmental network data is a challenge for the applicant alone, in particular considering the interactions of several different GMP subject to different applications. The BVL office will be the platform for regular technical discussions with different applicants and third parties in order to stimulate national monitoring programmes. Specific emphasis will be given to coordination and active involvement of the Federal Bundesländer since general environmental monitoring falls also under their legal responsibility. The BVL will actively support the development of mechanisms for reporting and collating monitoring data both at MS and EU level. This will facilitate scientific analysis of these data and provide scientific conclusions for informing decisions on the future cultivation of GM crops as well as future risk assessments.

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