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COLLABORATIVE PROJECT

Assessing and Monitoring the Impacts of Genetically modified plants on Agro-ecosystems

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D7.7 Report on the PMEM toolbox and recommendations to risk managers

Organisation names of lead contractors for this deliverable:

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CONTENT

1 INTRODUCTION

1.1 The AMIGA Project

Under the seventh framework programme “Food, Agriculture and Fisheries, Bio-technology” the project AMIGA (Assessing and Monitoring Impacts of Genetically Modified Plants on Agro-Ecosystems) has several major aims. First, it seeks to provide baseline data on biodiversity in agro-ecosystems in the EU and to translate regional protection goals into measurable assessment endpoints. Additionally, suitable bio-indicators for various European regions are to be defined and the knowledge on potential long-term environmental effects of genetically modified plants (GMPs) should be improved. Also post-market environmental monitoring, integrated pest management and economical aspects of GMPs are covered by AMIGA. Last but not least, the efficacy of the new EFSA guidance document for the Environmental Risk Assessment of GMPs (EFSA 2010) will be tested.

Work package 7 “Post-Market Environmental Monitoring” of the AMIGA project aims to design a comprehensive information system, methods and tools to help implementing a cost-effective Post-Marketing Environmental Monitoring (PMEM) in line with the updated EFSA guidance document (EFSA 2010). Specifically, the following objectives are formulated for work package 7:

- Assessing existing monitoring strategies in Europe and anticipation of expected impacts from experiences in GMO cultivating countries
- Adapting methods of monitoring and their validation on existing and AMIGA GM field releases
- Assessing the usefulness of exposure-hazard models for risk managers and setting up of efficient monitoring schemes
- Design of a prototype of a GIS-based monitoring information system
- Development of guidance for a renewed PMEM strategy in the context of the updated EFSA ERA guidance document
- Contribution to the overall AMIGA toolbox for a dynamic and integrated assessment of environmental and economic impacts of GM cultivation in Europe

Task 7.5. “*Design of a general framework and a toolbox for an integrated ERA/PMEM*” aims at providing practical recommendations for risk assessors and risk managers derived from the outcomes and experiences of all work package 7 task as well as of other relevant work packages of AMIGA. In particular recommendations should address the renewed PMEM strategy as outlined in the updated EFSA ERA Document and any other related EFSA PMEM initiatives. A focus will be on the integration and interoperability of AMIGA`s GIS based monitoring systems with existing monitoring networks.

2 METHODOLOGY

In this report the outcomes of the following AMIGA work packages were taken into consideration in order to generate recommendations for risk assessors and risk managers for post-market environmental monitoring:

- Work Package 2: Biogeographic regions and protection goals
- Work Package 3: Long-term effects
- Work Package 7: Post-market environmental monitoring

In addition, further documents published by EFSA and the European Commission were considered:

- EFSA ERA guidance document
- EFSA scientific opinion on existing monitoring networks
- EFSA guidance on post-market environmental monitoring
- EFSA opinion on yearly MON810 monitoring reports
- EC Working Group outcomes on post-market environmental monitoring

Where applicable, further reference was made to published reports on GMO monitoring from the scientific literature.

Based on the above-mentioned data sources in Chapter 3 an overview is given on the experiences with the implementation of post-market environmental monitoring in the EU. Secondly, shortcomings of the current approaches to PMEM are summarized and recommendations for improvements which have been claimed by different stakeholders reviewed.

Chapter 4 gives recommendations based on AMIGA results and outcomes of discussions for risk assessors and risk managers to be taken into consideration for future PMEM activities.

3 RESULTS

3.1 Experiences with the implementation of PMEM in the EU

3.1.1 Background

In the European Union applications for GMOs and food or feed products derived from GMOs must contain a monitoring plan which is part of the authorisation decision. According to Annex VII of Directive 2001/18/EC (EC 2001) applications for GMO cultivation must contain a post-market environmental monitoring plan (PMEM). Applications for GM food and feed need to include a post-market monitoring plan (PMM) additionally to the environmental monitoring plan (EC 2013). The PMM is requested in order to verify that the conditions of use are properly applied and to monitor the consumption of the product.

The PMEM comprises:

- A case-specific monitoring (CSM) to confirm any assumption about direct and indirect effects which have been identified in the environmental risk assessment and
- A general surveillance (GS) for the detection of possible unanticipated adverse effects.

The finalised monitoring plans for specific GMOs are annexed to the EFSA overall opinion for the respective GMO. (**http://www.efsa.europa.eu/en/publications/efsajournal**). Once an authorisation is given, the applicant must implement the monitoring plan and regularly report on it.

For GMOs with cultivation in their scope of application, the yearly monitoring reports are publicly available like the monitoring report of GM maize MON810 (Monsanto) and of the GM potato AMFLORA (BASF) for the years 2009 through 2014 (**http://ec.europa.eu/food/plant/gmo/reports_studies/index_en.htm**).

EFSA regularly publishes scientific opinions on the annual PMEM reports, e.g. on the PMEM report of maize MON810 (EFSA 2014a and 2015a).

3.1.2 Monitoring plan of maize MON810 and results of monitoring reports

Currently, the renewal procedure of the authorization of maize MON810 seeds for cultivation as well as food and feed uses is still ongoing (**http://ec.europa.eu/food/dyna/gm_register/index_en.cfm**). Until a final decision has been reached, the authorisation from 1998 remains valid which does not contain an obligatory monitoring of maize MON810. However, the applicant proposed to monitor insect resistance of target pests and implemented a general surveillance scheme on a voluntary basis. Maize MON810 expresses the Cry1Ab toxin in order to confer resistance to certain lepidopteran target pests.

In the Scientific Opinion for the renewal of the authorisation of maize MON810 (EFSA 2009), the EFSA GMO Panel concluded that the monitoring plan should comprise the monitoring of resistance evolution of target pest populations (in the context of both CSM and GS). No case-specific monitoring of other European lepidopteran species than the target pests (i.e. non-target species) of maize MON810 was recommended by the EFSA GMO Panel (EFSA 2009) although management measures were recommended for certain areas of high abundance. In later opinions the EFSA GMO Panel concluded that risk mitigation measures may be needed under specific conditions in order to reduce the exposure of extremely sensitive non-target Lepidoptera to *Bt* maize pollen (EFSA 2012d, EFSA 2012e).

The methodology proposed by the applicant for general surveillance consists of four elements:

- farmer questionnaires to assess unusual observations where maize MON810 is cultivated

- use of information from existing observation networks
- company stewardship programs
- screening of other information sources (scientific publications, reports etc.)

This proposal for a voluntary GS was acknowledged by the GMO Panel but more detailed information on the collection of information was requested from the applicant (EFSA 2009).

From the monitoring reports submitted from 2009 to 2013 by the consent holder to the European Commission and evaluated by the EFSA GMO Panel, no adverse effects on the environment, human and animal health due to maize MON810 cultivation during the observed growing season were identified. In addition, the data submitted did not indicate a significant and consistent decrease in susceptibility of the target pest field populations to Cry1Ab protein in Spain over these growing seasons (see EFSA 2011a, 2012c, 2013b, 2014a, 2015a, 2015b).

3.1.3 Monitoring plan of the GM potato EH92-527-1 and results of monitoring reports

In 2010 GM potato EH92-527-1 (Amflora) with enhanced content of the amylopectin component of starch was authorised for cultivation and industrial processing (Commission Decision 2010/135/EU). The Decision requires the implementation of a monitoring plan as well as of an Identity Preservation System. The Monitoring Plan submitted by the consent holder contained the following aspects:

- Case-specific monitoring in order to address the genetic stability of the inserted genes as well as the expected compositional changes.
- General Surveillance addressing the susceptibility to diseases and pests, management of volunteer potatoes and the limitation of potatoes to the cultivated fields in addition to information collection and communication measures with selected networks, the scientific literature and the public.

Commission Decision 2010/135/EU extended the submitted monitoring plan and introduced several further requirements, such as the extension of farmer questionnaires to all farmers cultivating the GM potato and additional field studies to monitor the potential adverse effects on potato-feeding organisms.

From the monitoring reports submitted by the consent holder in 2010, 2011 and 2012 the EFSA GMO panel concluded (EFSA 2012a, 2012b, 2013a) that

- the four case-specific studies do not provide scientific evidence that would invalidate the previous safety evaluations of potato EH92-527-1
- the results of the General Surveillance do not indicate any adverse environmental impacts associated with the cultivation of potato EH92-527-1

However, in its first Scientific Opinion on potato EH92-527-1 the EFSA GMO Panel noted a number of shortcomings in the methodology for the CSM studies as well as for GS and gave specific recommendations for improvement of the strategy, methodology and reporting for GS of potato EH92-527-1 (EFSA 2012a, 2012b). As cultivation of GM potato EH92-527-1 was limited and then discontinued in the European Union in 2012, limited data and information were provided by the consent holder. The EFSA GMO panel could therefore not conclude on the absence of enhanced fitness of the GM potato.

3.1.4 The use of existing monitoring networks

Existing networks for GMO cultivation purposes

The European legal provisions as well as current EFSA guidance documents recommend using existing monitoring schemes and networks for the monitoring of potential adverse effects when GMOs are placed on the market (EC 2002, EFSA 2011a, and EFSA 2011b).

In 2007, the German Federal Agency of consumer Protection and Food Safety (BVL) required the consent holder of maize MON810 to establish an environmental monitoring plan. Farmer questionnaires were the central element of the national monitoring plan for maize MON810 in Germany, but the use of monitoring data of specific existing surveillance programs in Germany was also incorporated into the monitoring plan (Monsanto 2009). The monitoring report provided by the consent holder in 2009 included evaluation of available information from suitable existing networks such as game species, birds, butterflies, soils and bees as well as data from influencing factors such as biodiversity indicators in agriculture and plant protection services and the register for GM crop cultivation in Germany (Monsanto 2009). However, the operators of the nationwide butterfly monitoring in Germany criticized that they were not integrated into the analyses and dissociated themselves from the results presented in the monitoring report. In addition, they stated that the current sampling methodology for butterflies does not allow any scientific conclusions for potential effects of maize MON810 (**https://idw-online.de/de/news308665**). In April 2009 the cultivation of GM maize MON810 in Germany was prohibited by a national ban and therefore the national monitoring plan was not continued (**http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en.htm**).

Generally, monitoring reports of maize MON810 intended for cultivation do not contain any specific reference to the use of existing monitoring schemes and programmes in the European Union when monitoring for adverse effects on human health or the environment (with exception of one year in Germany, see above). In its latest scientific opinion on the monitoring report of maize MON810 the EFSAGMO Panel points out that no information collected from existing monitoring networks in the EU was provided for the monitoring report of maize MON810 (EFSA 2015b).

The consent holder of GM potato EH92-527-1 did not provide details on existing environmental networks which are active in biodiversity surveys (EFSA 2012). However, the EFSA GMO Panel considered that due to the small-scale release of potato EH92-527-1 environmental networks "*would have been unlikely to detect changes in environmental impacts due to the cultivation of potato EH92-527-1 in 2010*" (EFSA 2012) but recommended the identification of relevant environmental networks when cultivation of potato EH92-527-1 in the EU will increase.

The necessity and practicability to use such existing networks in particular for general surveillance has been addressed in detail by EFSA (2014b). Although a range of existing networks have been identified that are potentially suitable for GS, several limitations regarding limited data accessibility, reporting formats and data connectivity with GMO registers as well as lacking sufficient statistical power to detect effects (EFSA 2014b).

Existing networks for GM food and feed use, import and processing

In contrast to GMOs placed on the market for cultivation purposes, monitoring plans for GMOs intended for food and feed use, import and processing involve existing monitoring and surveillance programmes and networks for GS on a regularly basis. In general, European Trade organisations like COCERAL (importers and traders), UNISTOCK (storekeepers for agricultural commodities) and FEDIOL as representative for Oil and Protein Meal industry (processors) are involved in monitoring. The applicants of GM crops usually indicate that these associations

- will be involved in GS by observing and reporting any unanticipated adverse effects of the respective GMO,
- will be informed about the authorisation and characteristics of the GMO and the conditions of use,
- will be contacted annually to reminding them to report on any unanticipated adverse effects,

and that the selected European trade associations themselves

- will inform and remind their member organisations to monitor for unanticipated adverse effects,
- will report to the authorisation holder annually or if any adverse effects are reported to them.

3.2 Shortcomings of currently implemented GMO monitoring systems and recommendations for improvements

3.2.1 Currently implemented monitoring plans

For the two GMOs that are placed on the market (maize MON810) or had been placed on the market but are no longer authorized (GM potato) in the EU for cultivation purposes the EFSA GMO Panel emphasized the following shortcomings:

- Lack of identification of hotspot areas with high GM adoption rates and/or target pest populations for CSM (maize MON810)
- Statistical issues (flaws in the sampling and monitoring methodology, no indication of the detection level, use of differentiated effect sizes etc.
- Monitoring sampling size too small and/or lack of prospective power analysis to determine the necessary number of monitoring sites(see GM potato
- Lack of a relevant comparator (GM potato, GM maize)
- Lack of identification of existing monitoring networks collecting information on biodiversity (GM potato)
- Flaws in the interviews with farmers (questions asked, standardisation, validity checks, statistics etc.)
- Lack of consideration of regionally important pest species in GS
- Lack of identification of relevant existing monitoring networks to be used for GS (GM potato) and lack of cooperation with existing monitoring networks regarding the collection of relevant data and information (maize MON810)
- Lack of indication of criteria to select relevant publications from the published literature and of discussion of results thereof in the context of the ERA of the GMO in question

The following general recommendations were made by EFSA in its Scientific Opinions on the monitoring reports of maize MON810:

- adoption of management measures especially in areas of abundance of non-target Lepidoptera populations in order to mitigate the possible exposure of these species to maize MON810 pollen
- follow up of research results on possible adverse effects of maize MON 810 on rove beetles (Coleoptera: Staphylinidae)

The following specific recommendations for CSM of MON810 were made by EFSA:

- recommendations specific to the implementation of non-*Bt* refugia
- to identify “hotspot-areas” with respect to target pest generations and *Bt* maize adoption
- to strengthen farmer education
- to concentrate sampling of target pests in “hotspot-areas” and to include surviving target pests within *Bt* maize fields in order to increase the likelihood of detection of resistance
- to consider other, regionally important pests (other than ECB and MCB) in the monitoring plan
- the revision of the monitoring protocol in “hotspot-areas”, i.e. areas with high MON810 maize adoption rates (increased sampling or F2 screening)

The following specific recommendations for GS of MON810 were made by EFSA:

- recommendations for the sampling scheme for farmer questionnaires including the setting up of national cultivation registers to improve the sampling frame of the farmers survey
- identification of a comparator including the relevant management practices
- standardisation of interviews (by independent parties) and control and auditing procedures
- use of additional questions to better characterise the cultivation area and the receiving environment
- inclusion of additional indicators and parameters (e.g. regionally important lepidopteran pests other than ECB and MCB, occurrence of damaged maize MON 810 plants)
- recommendations for statistical procedures including the provision of raw data

The recommendations for improvements of the monitoring of potato EH92-527-1 addressed by the EFSA GMO panel included the following aspects:

For the CSM studies

- improvements with respect to the methodology (use of appropriate comparators, improved sampling method and prolonged monitoring duration) in the potato-feeding organisms study
- setting of a clear hypothesis when monitoring GM potato volunteers and improvement in methodology including a detailed description of crop management practices and weather conditions
- provision of raw data and quality control documents

For GS (farmer questionnaires)

- standardisation of interviews
- statistical improvements of evaluation of results of farmer interviews
- clear identification of selected comparators
- increase of number of locations surveyed
- inclusion of changes of input volumes (pesticides, fertilizer)
- inclusion of the assessment of potato-feeding organisms and pest management practices in the farmer questionnaires
- development of a questionnaire for the use of by-products of potato EH92-527-1
- explanation of criteria used for the literature review and discussion of results

In addition to EFSA`s critical comments on the implemented monitoring by consent holders of GMOs also EU Member States expressed their concerns on the monitoring systems as applied by consent holders of maize MON810 and potato EH92-527-1.

In particular, the reliance on farmer questionnaires as the main monitoring methodology was criticized by certain EU Member States (e.g. AT, HU, DE). Farmer questionnaires as proposed and implemented by the consent holders as the only methodology for General Surveillance is not considered to be sufficient to identify adverse effects on the environment, human and animal health and needs to be complemented by other methods, as recognized by EFSA (EFSA 2011a) The use of independent scientific assessment strategies in order to detect unexpected environmental effects is considered to be necessary instead. In addition several methodological shortcomings were addressed when farmer questionnaires are used. Validation of the data gathered was considered necessary and the need to complement interview data with scientific data generated by experts using appropriate scientific methods expressed. In this context the usefulness of existing environmental monitoring networks was emphasized. It was also criticised that such networks have so far not been successfully integrated in GMO monitoring. Member States required that a comprehensive system for the involvement of environmental monitoring networks should be elaborated to adequately address the specific needs of GMO monitoring.

In a joint policy paper on GMO monitoring by the Environment Agencies of Austria, Switzerland and Germany (Umweltbundesamt 2011) several aspects necessary for the improvement of the GMO monitoring were summarized:

- The strengthening of case-specific monitoring measures to better address data gaps and uncertainties as well as to confirm conclusions made in the ERA
- The consideration of specific GMO characteristics and relevant protection goals of the respective GMO in the context of GS
- Appropriate tools and surveillance systems need to be optimized or developed for the study of impacts on exposed organisms and environments that cannot be surveyed adequately by existing observation programs. Harmonisation of monitoring methods at EU level, integration of data from different monitoring schemes and consistent an analysis of data from different sources
- Further guidance on the interpretation of monitoring results and decision criteria for further (follow-up) risk assessment studies in case environmental changes have been detected.
- Monitoring of exposure of the environment to GMOs, parts of GMOs and transgene products and environmental exposure routes by GS

3.2.2 Existing monitoring networks

As outlined above, existing networks such as Trade organizations are currently involved by applicants for the monitoring of GMOs for food and feed uses, import and processing. In their comments on the monitoring reports of authorized GMOs EU Member States generally address the limitations of the involvement of trade associations for the monitoring of adverse effects on human and animal health. Several shortcomings were pointed out in this context such as the absence of specified monitoring procedures, objectives, methods, locations and frequencies (see also Züghart 2010). In addition, no information on national responsibilities of involved associations is provided and detailed monitoring results are generally lacking from monitoring reports thereby impeding the verification by Competent Authorities of the individual EU Member States (Umweltbundesamt 2011). Therefore it has been claimed that all members and companies of European Associations involved in monitoring GMOs for food and feed use should be listed and their ability to cover the scope of GS be demonstrated in the monitoring plan (Umweltbundesamt 2011).

With regard to the cultivation of GMOs in the EU the experience up to date has shown that the use of existing monitoring networks was not successful. This was either due to a lack of effort by the consent holder to identify, contact and involve relevant existing networks (as in the case of GM potato) or because no agreements were established regarding the access to data with relevant institutions (as in the case of maize MON810).

A collection of five existing European agro-environmental monitoring programs and four European data infrastructure schemes were scrutinized for their suitability for GS of GMOs by a EU Member State Working Group on PMEM (EU-MWG 2008). In this analysis several limitations for the use of the existing networks were identified, such as the partial overlap of the agro-environmental monitoring programmes with areas cultivated with GMOs. However, the usefulness of certain agro-environmental monitoring programmes and infrastructure schemes and their applicability for GMO monitoring was emphasized (EU-MWG 2008). Also efforts undertaken at EU level to harmonise and coordinate monitoring data could serve as a guideline on how to harmonise GMO monitoring data for GS (Bruetschy & André 2007). Integration of GMO monitoring systems (both nationally and EU-wide) into existing EU-wide agro-environmental monitoring networks was considered to be feasible although further scientific and administrative consultation was considered necessary (EU-MWG 2008).

A follow up of the Monitoring Working Group was formed in 2011 (European Commission Expert Group on PMEM) and operational until 2013, represented by experts of EU Member States. The objective was to reflect on the feasibility and harmonisation of PMEM activities of EU Member States taking into consideration the discussions of Member States cultivating GM maize MON810 and taking into account the results delivered by the monitoring working group set up under Directive 2001/18/EC from 2004 to 2008 (EU-MWG). The outcome of these activities was not officially published and the original plan to draft a Commission recommendation on PMEM resulting from these activities was not taken further by the European Commission (EC 2014).

In between, a Scientific Opinion was adopted by the EFSA GMO Panel regarding the usefulness of existing environmental networks for GMO monitoring (EFSA 2011b). In this scientific opinion the potential for the use of existing environmental surveillance networks for PMEM was considered and a set of criteria that can be used to identify relevant existing networks developed (see also Figure 1)

Several existing environmental networks potentially suitable for GS were identified by the EFSA GMO Panel. However, also limitations were addressed such as data accessibility, data reporting format, connectivity with GMO registers and sensitivity of statistical analyses. In particular the latter aspect deserves further attention and could be improved by increasing sample sizes or by combining data from different networks (EFSA 2011b).

Due to the heterogeneity of existing environmental monitoring programs and networks several major prerequisites for the involvement of such existing programs and networks include (Umweltbundesamt 2011):

- The programs and networks involved need to provide robust data using the relevant indicators, parameters and methods but also are flexible enough for necessary adaptations of parameters, intervals and sites relevant for GS.
- The spatial range of the programs and networks need to be in line with the cultivation area of the respective GMO.
- The institutions of the programs and networks need to agree to collect and provide data for GS purposes.
- Data access of programs and networks involved as well as long-term funding for gathering relevant data must be guaranteed.

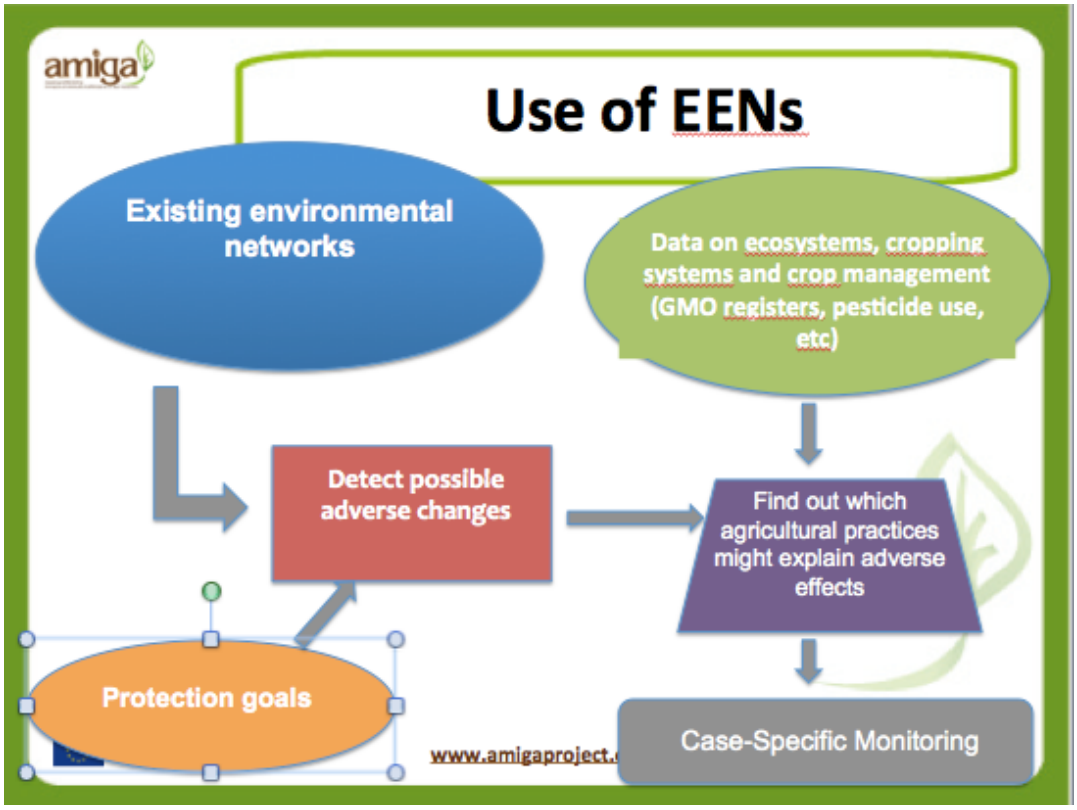

Figure 1. Integration of existing environmental networks into PMEM

Several individual EU Member States evaluated independently their national monitoring und surveillance Programs for the usefulness and applicability for PMEM of GMOs. An evaluation of the usefulness and applicability of an existing soil monitoring network in Germany showed that the existing network can serve as a suitable basic grid for GMO monitoring but requires certain adaptations e.g. regarding data on certain organism groups and the development of a site-specific reference system (Römbke et al. 2014). Mönkemeyer et al. (2006) examined several national agricultural networks in Germany and concluded that all of them may be relevant for GMO monitoring but also addressed some shortcomings e.g. regarding lack of specific data or harmonisation. In the Netherlands the monitoring and recording of certain agricultural parameters was considered useful for GS purposes for a range of crops (Van den Brink et al. 2012). In the UK the use of the existing networks such as the water quality monitoring or the breeding bird survey was recommended although specific data analysis and supplementary monitoring would be required (ACRE 2013). One conclusion of the ACRE-commissioned assessments was that the existing networks could be used to detect unanticipated effects due to the cultivation of GMOs only if GM adoption rates were high and local effects significant before larger-scale effects are detectable (see ACRE 2013, Annex 10).

A recent inventory of Environmental Surveillance Networks in Europe, both at EU-level and nationally, concluded that existing monitoring networks are of potential use for PMEM if they fulfil certain important criteria (Henrys et al. 2014). The authors examined the statistical power of existing networks and recommended, among other, combining and pooling of data across geographic regions in order to increase power and detect ecosystem changes (Henrys et al. 2014). A recent analysis and overview of existing environmental networks in several EU Member States emphasized the diversity of existing networks and protection goals covered by these (Smets et al. 2014).

4 RECOMMENDATIONS

The aim of post-market environmental monitoring (PMEM) of GMOs is to identify any direct or indirect, immediate and/or delayed adverse effects of GMOs, their products and their management to human health or the environment after the GMO has been placed on the market (Annex VII of Directive 2001/18/EC).

The task of AMIGA with respect to PMEM of GMOs was to provide a framework for a revised PMEM strategy in the context of the revised and updated ERA guidance document by EFSA (EFSA 2010) and to provide science-based and cost-effective tools and methodologies for an efficient PMEM.

A review on existing PMEM schemes worldwide in the context of the AMIGA project showed that practical experience with GMO monitoring is very limited. This is due to either lacking regulatory requirements for a compulsory PMEM of GMOs (e.g. USA, Argentina) or a lack of implementation of PMEM despite respective regulatory requirements (e.g. South Africa, see SANBI 2010). In addition, difficulties in the coordination between GMO monitoring and existing monitoring systems hamper the practical implementation of GMO monitoring.

Therefore, major challenges for implementing a science-based and effective monitoring of potential adverse effects of GMOs are still prevailing. Due to the above mentioned shortcomings there is an urgent need to improve GMO monitoring systems in order to ensure a sound and scientifically based monitoring of potential adverse effects of GMOs for human health and the environment.

In order to achieve a significant improvement of GMO monitoring as currently implemented by the relevant stakeholders, the following recommendations should be followed:

4.1 Recommendation 1: Better integrate ERA and PMEM

The aim of case-specific monitoring is to confirm assumptions on adverse effects made during the ERA (Directive 2001/18/EC, EFSA 2010a). Consequently, a sound and science-based ERA is crucial to the formulation of risk hypotheses to be assessed by case-specific monitoring after the GMP is placed on the market. Limitations of the ERA regarding the validity of its results for large-scale commercial cultivation of GMOs have to be recognized. Limitations refer of the scale of the ERA (e.g. contained systems or field release versus large-scale release in different receiving environments), limitations with respect to the species selected for testing purposes (e.g. a few focal species), limitations regarding modelling of exposure (e.g. extrapolations of exposure time and scale) and limitations regarding experimental methods (e.g. lack of testing of toxin interactions).

Strengthening the ERA, e.g. by using efficient ERA approaches will increase precision of and confidence in the results of the ERA and reduce the uncertainty on conclusions about potential risks for the environment. The results thereof would then translate into an improved PMEM strategy This would also mean to consider certain decision criteria in the ERA which indicate the requirement of PMEM implementation (see Umweltbundesamt 2011):

- Indirect effects that may have been identified in the ERA but could not be assessed in the ERA (e.g. indirect effects, food chain effects, such as effects on weed communities)
- Effects that have been tested in the ERA but the results have a certain level of uncertainty (e.g. sensitivity of lepidopteran species to Cry toxins)
- Effects that may be different under large scale release of the GMP or in different receiving environments not considered during the ERA and that would change the outcome of the initial ERA;
- Adverse effects that are irreversible (e.g. the occurrence of herbicide-resistant weed species)

Consequently, an improved PMEM would benefit ERAs of subsequent GM crops applications with the same or similar GM traits as it broadens the knowledge and closes data gaps on effects of the respective GM crop on the environment (Umweltbundesamt 2011).

4.2 Recommendation 2: Consider exposure to GMOs and GM products in PMEM

GMOs and GM products are able to reproduce, spread and persist in the environment (Heissenberger et al. 2003, Heissenberger et al. 2004, and Pascher et al. 2010a) which may entail unforeseeable adverse environmental effects. The level of environmental exposure influences the extent of PMEM, CSM and GS, which should take spread, establishment and persistence of the GM plant into consideration (EFSA 2010). Knowing where GMPs and GM products are located in the environment is therefore a good starting point for PMEM.

In the context of AMIGA two spatially explicit exposure-hazard models were developed; one for *Bt* maize and selected non-target Lepidoptera, the second for herbicide-tolerant maize and weeds.

In the first case the model included several components which influence the impact of *Bt* maize on non-target Lepidoptera, such as the structure of the landscape (e.g. proportion and aggregation of GM fields, host plants in field margins), spatio-temporal dynamics of the non-target lepidopteran species, *Bt* maize pollen dispersal and mortality due to *Bt* pollen exposure and consequences for the exposed organisms.

For the second case study the FLORSYS model (Colbach et al. 2014) was used and extended to include the maize-based cropping systems and the specific weed flora related to it. The model includes climate, location details such as soil texture and latitude, the initial weed seed bank and the cropping system for a simulated period (i.e. crop sequence and operations). Impacts considered are effects on farmland biodiversity (e.g. life-cycle parameters of weeds) as well as resistance development of weeds.

The two developed models allow assessing impacts of *Bt* maize cultivation on lepidopteran larvae at a regional scale and enable the *ex-ante* assessment of effects of cropping systems and of herbicide management regimes on weed abundance and diversity as well as resistance development. Both exposure-hazard models intend to (i) better frame the outcomes of the ERA (by specifying the domain of validity of conclusions and/or identifying uncertainties), (ii) help risk managers to undertake mitigation measures and (ii) set up efficient and optimal monitoring schemes for *Bt* maize and herbicide-tolerant maize. Their principles can be extended to other crop/trait situations.

4.3 Recommendation 3: Establish a general risk hypothesis for general surveillance (GS)

Experience with GMO cultivation from overseas (and partly in Europe) is useful for the identification and anticipation of risks to the environment when large-scale cultivation is considered. Although general surveillance intends to identify the occurrence of unanticipated adverse effects of GMPs on the environment that were not anticipated in the ERA, EFSA clearly recognizes the difficulty to design monitoring, and specifically GS, for unanticipated adverse effects (EFSA 2010). Also, due to the uncertainty related to the outcomes of the ERA and/or the context-dependence of some effects, it is not always easy to draw a strict line between what should be addressed through CSM with a clear hypothesis and experimental protocols and GS where no assumption or driver can be identified. Although general surveillance should not be hypothesis-driven *per se*, general surveillance might be driven by considerations such as the actual exposure or the characteristics of the receiving environ-

ments rather than considering every possible aspect. In this context the use of modelling, as developed by AMIGA (e.g. exposure models), is considered helpful for the identification of possible hotspot areas of risk to be monitored by GS. However, it should be stressed that GS cannot be driven by a specific stressor only (one GM event or even GM crops only) but should be put in the broader context of monitoring impacts of agricultural practices.

4.4 Recommendation 4: Establish baselines for different receiving environments

Baseline environmental data, i.e. data on the environmental status before introduction of GMOs into the environment, is particularly helpful in order to identify effects occurring when GMOs are commercially cultivated and to put them into context (EFSA 2010). However, standardised baseline data on biodiversity in agrarian landscapes in Europe is rare, except for a few examples (see e.g. Pascher et al. 2010b, 2011).

Results from the AMIGA project provide data on arthropod fauna in maize and potato fields complementing existing arthropod databases for GMO-relevant crops (see e.g. Meissle et al. 2012). Baseline ecological information for receiving environments into which GM maize and GM potato may be released were evaluated (e.g. van Capelle et al., 2016) as reference points against which any potential adverse effects observed by PMEM can be compared. The existing database contains data from 31 countries in which 15 different methods for collecting arthropod species were used. The number of available reports is very variable among countries. AMIGA has also produced the first available record referring to potato cultivation in Bulgaria. Differences in the species abundance of non-target arthropod taxa in different regions have to be accounted for, nevertheless harmonization of sampling methods for specific taxa across regions and the development of general monitoring guidelines when assessing non-target arthropod fauna is recommended. Methods proposed by AMIGA have been validated in field conditions for the two crops, which were the subject of the project.

Baseline diversity for soil microorganisms associated to maize and potato was determined from different geographical areas in Europa in AMIGA work package 4. This constitutes the largest available data set of molecular sequences to be used as background against which stresses on the system can be compared.

However, baseline data also refers to the background agro-ecological conditions into which a GMO may be introduced. These conditions also exert a strong influence on potential adverse impacts a novel cropping system may have. Results of work package 3 indicate that background agricultural, economic and environmental factors may be different in different regions but may also have some common features (e.g. general trends in yield, fertiliser input etc.). Current and historical changes of these background factors complicate assessments of environmental impacts of novel crop technologies. Nevertheless, knowledge of these important factors in agricultural production systems is essential in order to put impacts of GMOs, in particular with reference to long-term effects, into context.

Nevertheless harmonization of sampling methods for specific taxa across regions and the development of general monitoring guidelines when assessing non-target arthropod fauna is recommended.

4.5 Recommendation 5: Integrate selected indicators in existing monitoring networks

The use of indicators is a key aspect in PMEM that needs careful consideration with regard to the results of the ERA and the risk hypotheses in question. In addition, general indicators reflecting the baseline situation including historical changes in the agro-ecosystems are of high value for interpre-

tation of PMEM results. Once relevant indicators have been selected decisions on where, how and by whom these indicators should be monitored, have to be made. Evaluations of existing monitoring networks have shown that a range of networks may be useful for GMO monitoring if necessary adaptations are made.

Results from AMIGA`s Work Package 3 provide examples of indicators for key components of agro-ecosystems which are easy to monitor and represent the status and changes of agricultural systems. Such indicators refer to different spatial and temporal scales and have been proposed from patch scale through field and farm scale up to regional and national scales.

As an example of a risk hypothesis-driven indicator non-target Lepidoptera have been selected in Work Package 7. Recommendations include monitoring methodology for lepidopteran species for use in PMEM that has been validated on AMIGA field sites. Baselines of lepidopteran species and their abundances to be expected in monitoring studies have been established as well variances of species richness and day-active Lepidoptera in arable land have been identified.

In addition, an evaluation of existing volunteer butterfly monitoring schemes in Europe for their suitability for GMO monitoring purposes was made. A range of butterfly monitoring networks in 16 EU countries was identified although only a few were considered to fulfil basic requirements to be used for GMO monitoring.

The results of AMIGA therefore provide background information of relevant indicators in different biogeographic regions of Europe and give examples on how selection of necessary key monitoring indicators for PMEM could be done.

4.6 Recommendation 6: Consider regional agro-environmental specificities

Generally, PMEM refers to the geographic scale of Europe, if authorisation is given for cultivation of a GM crop. Results of AMIGA`s work package 2 has shown that environmental specificities, in particular protection goals, vary considerably across Europe. Also receiving environments and management systems are highly diverse across Europe and the actual impacts of GM cultivation may vary considerably. The consideration of protection goals is a specific requirement for the ERA of GMOs, also in the context of the definition of so called “Limits of Concern”, i.e. thresholds for the acceptability of environmental effects caused by GMOs. In addition, not only protected natural resource or resource services are of relevance for PMEM but also different baselines with respect to economic, agronomic or environmental factors. Results of work package 2 and work package 7 showed that baseline data on non-target arthropods in European agro-ecosystems revealed striking differences with respect to species occurrence, abundance as well as protection status between different agro-ecological regions.

As a consequence such regional differences must be accounted for by PMEM e.g. by adapting monitoring priorities and methodologies in order to be able to assess potential adverse effects and interpret results of monitoring in different biogeographical regions.

4.7 Recommendation 7: Harmonise monitoring methodology

The use of common methodology for PMEM across EU Member States where GMOs are intended for cultivation is an important prerequisite in order to assess and compare results of PMEM. AMIGA has contributed to the harmonization of monitoring methods, e.g. by the development, testing and validation of standardised monitoring approaches for GMO monitoring of lepidopteran species. The methodology for monitoring of non-target Lepidoptera was validated on AMIGA field sites in several countries. A common methodology and protocols for monitoring were developed and used at all

sites. This included beside sites and duration the number of transect counts, the lengths of transects, the number of counts per season, and the recorded species. In addition, other aspects such as the time of the year and the time of the day for the visits as well as the walking speed were defined. Additional necessary recordings were also determined. In addition to Lepidoptera, standardised sampling methods and durations for non-target arthropod fauna (e.g. pitfall traps for predators in maize and potato, pan-trap for insect pollinators) were suggested.

The development of general monitoring guidelines for arthropod monitoring in specific crops and regions will facilitate harmonized PMEM in different Member States for the crops in question.

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