Project Number 289706

COLLABORATIVE PROJECT

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

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D1.14 Report summarizing AMIGA outcomes with possible relevance for EFSA guidance documents

Organisation name of lead contractor for this deliverable: INRA, France

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Dissemination Level		
PU	Public	**X**
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

Testing the efficacy and feasibility of the Guidance on the environmental risk assessment of genetically modified plants (GD) (EFSA, 2010) to support the Environmental Risk Assessment (ERA) of genetically modified plants (GMPs) at the EU level was one of the major objectives of AMIGA. Most work packages refer to the EFSA ERA GD in terms of methodology and have assessed the relevance of the results obtained and their possible added value in confirming the efficacy and the practicability of the document. Where deemed useful, possible inputs for complementing the concepts as laid down in the GD are offered. The present report highlights those outcomes from AMIGA case studies that may be meaningful for the implementation of EFSA GD.

For each of the tools developed by AMIGA, this report indicates in a tabular format (i) the purpose of the tool, (ii) the level of development and testing of the tool, (iii) who could use it, (iv) at which step it could be used and (v) which expertise is needed to implement it. The table includes two parts:

- A. Tools that could be used in the current ERA framework for cultivation applications as laid down in the EU regulation;
- B. Tools that could be used in PMEM or in the broader context of risk management of GM crops.

In the table, reference is made to relevant deliverables of the project, where more details about each tool are available.

It is important to clarify that any further update of the existing Guidance on the environmental risk assessment of genetically modified plants is not in the remit of AMIGA. Therefore, this document offers suggestions that are the result of the research conducted within AMIGA in reference to each of the topics illustrated in the EFSA GD.

A. Tools available for possible use in ERA.

Tool	Brief description of purpose and added value	Level of maturity	Who could use it	At which point it could be used	What expertise/data would be needed
Decision matrix to select relevant receiving environments for ERA field studies (cfr. Deliverables 2.3 and 2.4)	- Transparent and consistent method for selection of field trial sites; - Ensure representativeness of selected sites	- Tested on two case studies. - Primarily applicable for faunistic NTO-field studies	- Applicants when deciding on location of sites for NTO studies; - Risk assessors/managers when considering outcomes of ERA	At planning stage of GM NTO field trials	- General agronomic and environmental knowledge; - Description of receiving environments across Europe; - Use of crop models
Protocols for statistical aspects of design in ERA field trials (cfr. Deliverables 9.2, 9.4)	Design of ERA field trial experiments, establish list of endpoints with associated pragmatic limits of concern, obtain prior information for power analysis	Ready-to-use	- Applicants; - Risk assessors in judging the suitability of experimental designs	- At planning stage of GM field trials; - During the evaluation of applications.	Statistical expertise, biological expertise to set pragmatic limits of concern/ effect sizes for power analysis
AMIGA Power Analysis software tool (cfr. Deliverable 9.3)	Design experiments with a good balance between replication and power, provide data templates and scripts for the statistical analysis	Ready-to-use, publicly available on the web	- Applicants; - Risk assessors in judging the quality of statistical analyses	- At planning stage of GM field trials - During the evaluation of applications.	Statistical expertise, information of targeted effect sizes and/or limits of concern
Mapping crop locations (IACS data and base maps or possibly LUCAS data): an adjunct	To define spatial location of crops as a guide to selecting receiving environments (enable estimation of where a GM	Methodology tested; needs to be further developed as a general tool.	- Applicants, in planning field sites; - Risk assessors in judging suitability of trial sites	From planning stage of GM field trials	Computational skills, spatial mapping: LUCAS data are readily available via the JRC

help to support decisions on locating field trials (cfr. Deliverable 3.6)	crop could be grown)				web site; IACS data would need to be obtained country by country
Protocols for sampling soil-surface based arthropod assemblages (cfr. Deliverable 5.2)	- To establish baseline conditions; - To assess impact of GM plant on soil-living NTOs ;	Ready-to-use	Applicants when collating data in their field trial sites	In NTO field experiments	Entomological parataxonomic expertise, with occasional specialist input
Protocols for sampling plant-based arthropod assemblages (cfr. Deliverable 5.2)	- To establish baseline conditions ; - To assess impact of GM plant on plant dwelling NTOs;	Ready-to-use	Applicants when collating data in their field trial sites	In NTO field experiments	Entomological parataxonomic expertise, with occasional specialist input
Protocol for measuring natural enemy activity as an ecosystem service (cfr. Deliverable 5.2)	- To establish baseline conditions, - To monitor impact of GM plant on an ecosystem service	Methodology tested on dummy caterpillars, aphid mummies, egg predation; needs to be further developed as a general tool	Applicants when collating data in their field trial sites	In NTO field experiments	Parataxonomic expertise, familiarity with the cropping system
Characterization of soil microbial diversity, including	Methods which allow to quantitative and qualitatively describe the	Ready-to-use	Applicants to be used as a baseline for comparison	NTO field experiments	Expertise in molecular methods including PCR and

rhizospheres (D4.1 and 4.2)	structural and functional diversity of soil microbes		when evaluating potential harm for soil microbes		novel DNA-sequencing technologies as well as in bioinformatics
Protocol for measuring pollination as an ecosystem service (cfr. Deliverable 6.2)	To establish baseline conditions, to monitor impact of GM plant on an ecosystem service	Ready-to-use	Applicants when collating data in their field trial sites	In NTO field experiments	Parataxonomic expertise, familiarity with the cropping system
Protocol for sampling pollinators (cfr. Deliverables 6.2, 6.3)	To estimate pollinator activities and possible exposure to GM crops	Ready-to-use	Applicants when collating data in their field trial sites	In NTO field experiments	Parataxonomic expertise
Protocol for statistical analysis of data from NTO field trials (cfr. Deliverables 9.2, 9.4)	- Analyse data using appropriate methods; - Present results in graphical format; - Integrate across endpoints, sites and years	Ready-to-use	- Applicants ; - Risk assessors in judging application	During assembly of data to support an application, then during the evaluation of the application	Statistical expertise
Protocol for testing potential effects of GM crop residues on focal earthworm species (cfr. Deliverable 4.6)	Laboratory ERA test system on life-history traits of earthworms in NTO studies	Ready-to-use	Applicants when collating data for dossiers	In NTO laboratory experiments	Basic expertise in culturing earthworms
Protocol for testing potential effects of GM crop on bees (cfr. Deliverable 6.1)	Improved laboratory ERA test system on life-history traits	Ready-to-use	Applicants when collating data for dossiers	In NTO laboratory experiments	Bee rearing systems

Spatially-explicit model prototypes (cfr. Deliverables 7.3, 7.4)	- To model scenarios of GM crop adoption in different contexts (e.g. impact of HT on weed life cycle and plant biodiversity); - To develop a more quantitative ERA	Approach tested on HT and Bt maize crops; potential to develop as a general tool for other GM crops and cropping systems at large	Multiple potential uses by applicants, risk assessors and risk managers to understand the context in which the GM crops would be deployed	Large scale impacts on NTOs and impacts of changes in management practices	Computational skills, spatial mapping, understanding of ecological processes
Process based model of crop production and associated biogeochemical processes (cfr. deliverable 3.6)	- To extend indicators and metrics available from plot-based field trials; - To assess impact in receiving environments	Prototype tested on blight tolerant potato	Risk assessors and risk managers to understand the context in which the GM crops would be deployed	Throughout the ERA of the cultivation application	Knowledge of modelling procedures; high level IT skills
The AMIGA database as a prototype of a possible European information system (cfr. Deliverable 3.1)	- Reference to previous GM field trials; - Repository of data and tools; - Support methods for defining receiving environments	A prototype has been developed with a representative sample of datasets; querying is possible ; the database needs to be further populated	Applicants and EFSA	Throughout the ERA of the cultivation application	Moderate IT skills for querying, downloading; specialist skills for each protocol, crop type, statistical procedure

B. Tools available for use in PMEM and in defining the broader context of GM introduction

Name	Brief description of purpose	Level of maturity	Who could use it	At which point could it be used	What expertise would be needed
The AMIGA database as a prototype of a possible European information system on relevant datasets for supporting PMEM (cfr. Deliverable 3.1)	Reference to previous GM trials or monitoring studies, repository of data, tools; methods for defining receiving environments and hotspot situations	A prototype has been developed with a representative sample of possible datasets and documents; querying is possible; the database needs to be further populated	Open access for all involved in PMEM	When planning case specific monitoring, to help identify hotspot zones.	Moderate IT skills for querying, downloading; specialist skills for each protocol, crop type, statistical procedure
Protocols for sampling soil-surface based arthropod assemblages (cfr. Deliverable 5.2)	To monitor in commercial fields	Ready-to-use	Environmental monitoring network for GS and applicant for CSM	In monitoring programs whenever needed	Entomological parataxonomic expertise, with occasional specialist input
Protocols for sampling plant-based arthropod assemblages (cfr. Deliverables 5.2)	To monitor in commercial fields	Ready-to-use	Applicants for CSM	In monitoring programs if required	Entomological parataxonomic expertise, with occasional specialist input
Protocol for measuring natural enemy activity as an	To monitor in commercial fields	Methodology tested; needs to be further	Applicants for CSM	In monitoring programs if required	Parataxonomic expertise, familiarity with the cropping

ecosystem service (cfr. Deliverable 5.2)		developed as a general tool			system
Protocol for measuring pollination as an ecosystem service (cfr. Deliverable 6.2)	To monitor in commercial fields	Ready-to-use	Applicants for CSM	In monitoring programs if required	Parataxonomic expertise, familiarity with the cropping system
Protocol for monitoring pollinators (cfr. Deliverables 6.2, 6.3)	To monitor in commercial fields	Ready-to-use	Environmental monitoring network for GS and applicant for CSM	In monitoring programs if required	Parataxonomic expertise
Cost-effective monitoring protocol for farmland butterflies (cfr. Deliverable 7.2)	Dynamics of butterfly monitoring data across countries, sites and years; guidance to estimate required sample size and involved costs	- The protocol has been tested in three regions (Catalonia – Spain, Scania – Sweden, Romania) - Ready-to-use	Multiple use by applicants and risk managers to plan and assess necessary number of sites to be monitored, and to estimate costs.	- Risk managers: when monitoring impact of agricultural practices at large, including e.g. use of existing monitoring systems - Applicants: whenever required, based on the outcomes of the ERA and in preparation of their PMEM schemes	- Knowledge of butterflies species - Statistical expertise
Spatially-explicit model prototypes (cfr. Deliverables 7.3, 7.4, 7.5)	To test different management scenarios and identify risk mitigation measures,	Prototypes have been developed	Multiple potential uses by applicants, risk assessors and risk managers to understand the	When assessing the impacts of changes in agricultural practices at landscape level (*ex-ante, ex-post*)	Computational skills, spatial mapping, understanding of ecological processes

	e.g. for potential impact of HT crops on weed life cycle and related biodiversity		context in which the GM crops would be deployed		
Spatial analysis of the impact (e.g. on yield, pesticide load) of introducing a GM crop into a receiving environment (cfr Deliverable 3.6)	Use of IACS data to identify actual crop sequences and crop systems to help upscale monitoring data and enable estimation of effects on metrics such as national pesticide usage	Prototype tested on GMHT oilseed rape and blight-tolerant potato	Risk managers, national agencies, EC-wide assessment of impact	Potential use to select target areas and metrics for PMEM	High level IT skills, geospatial mapping and analysis, agricultural systems knowledge
Multi-criteria decision making tool to assess impacts of GM crops on ecosystem services (DEXiES) (cfr. Deliverable 3.6)	- Comprehensive analysis of ecosystem structure; - Comparative assessment of receiving environments, crops and systems	Prototype tested on GMHT crops, blight tolerant potato and high- and low-input cropping systems	Risk managers, national agencies, EC-wide interests	Potential use for ex-ante assessment of upscaling effects, in PMEM and in ecosystem planning and design: valuable for distinguishing what is and what is not affected by the GM crop	DEXi software is relatively easy to use; specific versions of DEXiES need to be constructed and populated by biologists/ecologists with knowledge of agro-ecological systems and risk assessment
Bio-economic models (cfr. Deliverable 10.3)	To assess the cost-benefit of GM crops under various scenarios	Ready to use	Primarily for policy-makers when assessing benefits/risks of GM crops.	Potential for use in planning introductions and ex-post evaluation of GM cultivation	Access to relevant existing economic data regionally

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