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The use of existing environmental networks for the post-market monitoring of GM crop cultivation in the EU†

G. Smets,*[a] E. Alcalde,[bf] D. Andres,[cf] D. Carron,[f] P. Delzenne,[df] A. Heise,‡[fg] G. Legris,[fh] M. Martinez Parrilla,[cf] J. Verhaert,[df] C. Wandelt,[fg] M. Ilegems[ef] and P. Rüdelsheim[a]

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The European Union (EU) Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) into the environment requires that both Case-Specific Monitoring (CSM) and General Surveillance (GS) are considered as post-market implementing measures. Whereas CSM is directed to monitor potential adverse effects of GMOs or their use identified in the environmental risk assessment, GS aims to detect unintended adverse effects of GMOs or their use on human and animal health or the environment. Guidance documents on the monitoring of genetically modified (GM) plants from the Commission and EFSA clarify that, as appropriate, GS can make use of established routine surveillance practices. Networks involved in routine surveillance offer recognised expertise in a particular domain and are designed to collect information on important environmental aspects over a large geographical area. However, as the suitability of existing monitoring networks to provide relevant data for monitoring impacts of GMOs is not known, plant biotechnology companies developed an approach to describe the processes and criteria that will be used for selecting and evaluating existing monitoring systems. In this paper, the availability of existing monitoring networks for this purpose is evaluated. By cataloguing the existing environmental monitoring networks in the EU, it can be concluded that they can only be used, in the context of GMO cultivation monitoring, as secondary tools to collect baseline information.

Environmental impact

Existing environmental networks involved in routine surveillance offer recognised expertise in a particular domain and have the tools to capture information on important environmental aspects over a large geographical area. European Union Directive 2001/18/EC requires that General Surveillance, including existing environmental networks, is considered as post-market implementing measures of Genetically Modified (GM) crop cultivation. In this paper the availability of existing monitoring networks for this purpose is evaluated. By cataloguing the existing environmental monitoring networks in the EU, it can be concluded that they can only be used, in the context of GM crop cultivation monitoring, as secondary tools to collect baseline information.

Introduction

As part of the process for obtaining approval for the cultivation of a genetically modified (GM) crop in the EU, Directive 2001/18/EC[1] requires applicants to submit both a pre-market environmental risk assessment (ERA) and a post-market environmental monitoring (PMEM) plan. The PMEM plan is typically composed of case-specific monitoring (CSM) and general surveillance (GS). CSM is directed to monitor potential anticipated environmental effects caused by the cultivation of GM crops or by their use on human and animal health or the environment. It should only be developed when a potential risk or remaining uncertainties have been identified in the pre-market ERA. In contrast, GS is designed to address potential adverse effects, which were not anticipated in the pre-market ERA, *i.e.*, it is non-hypothesis driven. GS is a mandatory component of EU PMEM plans. Currently, the three cornerstones of GS activities performed by plant biotechnology companies for commercial products are (i) searching through peer-reviewed literature and assessing the impact on the safety of the specific GM crop, (ii) interrogating farmers about their observations in the field while cultivating the specific GM crop using questionnaires, and (iii) reporting on findings in the

[a]*Perseus BVBA, Belgium. E-mail: greet.smets@perseus.eu*
[b]*Syngenta, Spain*
[c]*Bayer CropScience, Belgium*
[d]*Monsanto Europe, Belgium*
[e]*DuPont Pioneer, Belgium*
[f]*EuropaBio, Belgium*
[g]*BASF Plant Science, Germany*
[h]*DOW AgroSciences, United Kingdom*

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‡ Current address: EuroChem Agro GmbH, Germany.

company-internal stewardship practices that ensure responsible global management of the specific GM crop.

GS for GM crop cultivation needs to consider potential environmental harm in relation to protection goals.[2] Protection goals reflect what society or stakeholders value.[3] Indications on what constitutes a protection goal can be found in the EU environment-related policies and legislation, such as the Habitats Directive 1992/43/EEC,[4] the Birds Directive 2009/147/EC[5] and the Water Directive 2000/60/EC.[6] In order to reveal a possible effect on a protection goal, quantifiable monitoring parameters are needed for the assessment (measureable endpoints) and interpretation of any differences found.[7] The values for those parameters will fluctuate with time and place, and the differences need to be put in the context of this natural variability.

Directive 2001/18/EC[1] introduced the possibility to make use of existing agricultural and environmental monitoring programmes as one of the components of GS. Council Decision 2002/811/EC[8] refers to monitoring of agricultural crops, plant protection, veterinary and medical products as well as ecological monitoring, environmental observation and nature conservation programmes. While these networks are referred to by different terms, the term 'existing environmental networks' (EENs) is used in this paper (in this context, 'existing' refers to already operating, independent of GS of GM crop cultivation).

Focussing on specific areas of the environment, EENs measure specific endpoints related to protection goals. Their approach is by definition independent of possible influencing factors. EENs therefore contribute to the broader environmental protection monitoring that Member States (MSs) have, or have to, put in place. Yet, there is no centralised register of these networks in the EU.

Essentially, EENs operate in MSs either at the governmental or unaffiliated level, and monitor a range of natural resources and environmental characteristics like biodiversity, and water and air quality independent of the factors influencing them. Such EENs offer recognised expertise in a particular domain and have the tools to capture information on important environmental aspects on the regional, national or international scale.

EU MSs have certain responsibilities for broader environmental protection monitoring.[2] Plant biotechnology companies have certain monitoring obligations specifically imposed by the GMO legislation. The use of EENs intended for monitoring protection goals was suggested in Council Decision 2002/811/EC[8] as a tool to provide information for GS, in addition to other GS components, such as farmer questionnaires. EC[8] sets out guidance notes supplementing the PMEM indications in Annex VII to Directive 2001/18/EC.[1] The requirements for GS have been further elaborated in guidance documents, including those developed by the Panel on GMOs of the European Food Safety Authority (EFSA).[2,9–11]

Some EU MSs explored the possible uses of EENs from a GS and protection goal perspective. In Germany, Mönkemeyer *et al.*[12] critically reviewed some networks for their applicability in GS. In the Netherlands, an inventory of existing monitoring systems in agricultural areas was made for sugar beet, potato, maize and cereals.[13] In the UK, the capabilities and limitations of EENs and their statistical power to detect changes correlated with GM crop cultivation were evaluated.[14] In these publications, their authors identified technical concerns in terms of sensitivity, and the ability to identify changes and causality.

Also others pointed out that the availability of EENs which are suitable for the monitoring of commercially grown GM plants may be limited,[3,12,15–24] *e.g.* because they have been designed for other purposes.[18,25,26] Furthermore, quality differences, poor compatibility between data formats and the ownership of collected data were shown to hinder the integration of information.[2,12] Therefore, some authors have suggested that adaptations may be needed to harmonise and standardise the monitoring methodology from country to country to ensure comparability across the EU.[2,18,27] Schmidt *et al.*[28] did not recommend reconfiguring EENs for GM crop monitoring, but proposed to use EENs along with their reports "as they are", because they provide expert-based analysis, interpretation and assessment on the relevance of the parameter values. In addition, the limited value of additional monitoring efforts for the sake of GS should be weighed against the costs of gathering the information.[14]

In line with the monitoring recommendations made by the EFSA[2] and adding to the experience with previous PMEM efforts,[29–35] the plant biotechnology companies developed a process on how EENs can be selected for GS of GM crop cultivation, thereby achieving consistency in the characterisation of EENs, and the methodology followed in the assessment of data and surveillance reports. This harmonised process is justified because EENs focus on specific protection goals that are relevant to all GM traits developed by plant biotechnology companies. In addition to describing the harmonised process, this paper discusses how the results from EENs can be used for GS of GM crop cultivation.

Results

In contrast to other initiatives,[12–14,36] we developed an approach that applies a standardised set of criteria to assess the suitability of EENs for GS of GM crops. The process described in the methods section (see below) was used to identify and characterise EENs that can provide potentially useful information for GS of GM crop cultivation. Since the start of the project (2009), 205 EENs have been identified in EU Member State (MS) countries (Belgium, the Czech Republic, Germany, Spain, France, Hungary, the Netherlands, Poland, Portugal, Romania, Sweden, Slovakia, and UK) as well as EU-wide, and were selected on the basis of present or past deliberate release of GM crops into the environment for commercial (GM crop cultivation) and/or experimental (field trials) purposes (Table 1). The list of networks with the complete list of characteristics is available in ESI 1.†

Once identified, the first screening of EENs was performed in order to prioritise the appraisal efforts to those networks that are likely to be informative to GS (*e.g.* mentioning of a protection goal and/or influencing factors). Based on this screening,

Table 1 List of identified EENs

Belgium
Belgian Arachnology Association (Arabel)
Flemish nature conservation society (Natuurpunt)
Interuniversity Group on Applied Ecological Research (GIREA)
Research Institute for Nature and Forest
Soil Service of Belgium
Walloon nature conservation society (Natagora)

Belgium – not further characterised
Belgian Information Centre for Apiculture
Flemish Institute for Biotech (VIB)
Gembloux Agro-Bio Tech (Agricultural University)
University of Ghent; Terrestrial Ecology Unit (TEREC)

Czech Republic
Agency for Nature Conservation and Landscape Protection
Apiculture Institute
Central Institute for Supervising and Testing in Agriculture (UKZUZ)
Czech Hydrometeorological Institute
Czech Society for Ornithology (ČSO/BirdLife)
Min. of Agriculture: GMO location registers
Min. of Health: chief health officer and hygienic stations
National Institute of Public Health
Society for the Protection of butterflies (SOM)
State Phytosanitary Administration (SRS)

Germany
Consumer Protection and Food Safety (BVL): GMO register
German bee monitoring (DEBIMO)
German Butterfly Monitoring (TMD)
German Hunting Association (DJV)
German Ornithologists Society (DDA)
Information System for Integrated Plant Protection (ISIP)
Federal Environment Agency: core environmental indicators (KIS)
Society of the German Bee Research Institutes
Soil monitoring programs in different states

Denmark
Danish Forest and Nature Agency

Spain
Iberian Myrmecology Association
Min. of Agri. Food and Environment: GMO register
Min. of Agri. Food and Environment: maps on biodiversity
Min. of Agri. Food and Environment: Spain's Environmental Profile
National Information System on Drinking-water (SINAC)
Plant Protection Products Manufacturers Association (AEPLA)
Spanish Conservation Tillage Association
Spanish Food Safety Agency (AESAN)
Spanish Ornithological Society (SEO/BirdLife)
Spanish Plant Protection Experts and Magazines (PHYTOMA)
Spanish Society of Applied Entomology (SEEA)
Min. of Agriculture, Food and Environment: Veterinary Sanitary alerts network (RASVE)

Spain – not further characterised
Centre for Sociological Research (CIS)
Min. of Health, Social Services and Equality
Min. of Industry: Strategic Stockpile of Oil Products Corporation (CORES)
River Hydrographic Confederations (Institutions for water quality)
Spanish Feed Compounders Association (CESFAC)
Spanish Society of Allergology and Clinical Immunology (SEAIC)

Table 1 (*Contd.*)

European Union
BirdLife International, European division
Butterfly Conservation Europe
EC Rapid Alert System for Food and Feed (RASFF)
ENVironmental ASsessment of Soil for mOnitoring final report
ENVironmental ASsessment of Soil for mOnitoring inventory vol. IIa & IIb
EURING ringing scheme
European Conservation Agriculture Federation (ECAF)
European Crop Protection Association (ECPA)
European Red List
European Soil Bureau Network (ESBN)
European Soil Data Centre (ESDAC)
European Topic Centre on Water: Eionet Water
Prevention of COlony LOSSes network (COLOSS)
The European Birds Census Council (EBCC)

European Union – not further characterised
ECOlogical NETwork for the promotion of convergent conservation strategies in COastal HAbitatS of CommuniTy significance (ECONET-COAST)
Emerald network (EU + other countries) Bern Convention
European Phenology Network (EPN)
European Professional Beekeepers Association (EPBA)
Fish-based Assessment Method for the Ecological Status of European Rivers (FAME)
Green Cross International

France
EAUFRANCE, the water portal (semi-official network)
French Society of Odonatology (SFO)
Min. of Ecology, Sustainable Development and Energy: Observation and statistics service (formerly IFEN)
Min. of Food, Agri. and Forests: Regional services for plant protection
Min. of Food, Agri. and Forests: National strategy for biodiversity
National Water and Aquatic Environments (ONEMA)
Natural Science Museum: National inventory of the natural heritage
Natural Science Museum: Vigie-nature
Noah Conservation
Research Centre for Ringing Bird Populations (CRBPO)
Soil Research (GIS Sol)

France – not further characterised
Biodiversity Network for Bees
INRA: Environment and Agronomy dept.
INRA: Plant Health and Environment dept.
Min. of Ecology, Sustainable Development and Energy
Natural Reserves of France

Hungary
Environmental and Nature Conservation Inspection Service
Min. of Agri. and Rural Development: Rural Ag Master Network
Min. of Agriculture: Animal Health and Welfare Directorate
Min. of Agriculture: Office of Plant, Soil and Agri-environment
National Public Health Service

The Netherlands
Bryology and Lichenology Working Group (BLWG)
Dutch Butterfly Conservation Foundation
Dutch Mammal Society
Dutch Mycological Society (NMV)
Dutch Species Catalogue
Flora and Fauna Fieldwork Foundation (VOFF)
Foundation ANEMOON (Analysis, Education and Marine Ecology)
Foundation European Invertebrate Survey Netherlands (EIS)

Table 1 (*Contd.*)

Foundation FLORON (floristic research in the Netherlands)
Foundation TINEA (small butterflies)
National Museum of Natural History (Naturalis)
Netherlands Entomological Society (NEV)
Reptile, Amphibian & Fish Conservation Netherlands (RAVON)
RIKILT, Institute for Food Safety
SOVON Bird Research Netherlands
Wageningen UR: Applied Plant Research
Wageningen UR: Plant Research International, Bees

The Netherlands – not further characterised
Certification for sustainable products and services (Milieukeur)
Foundation Utrecht Landscape
University of Amsterdam: Dept. of Animal Ecology, Institute of Ecological Science, Faculty of Earth and Life Science

Poland
Institute of Nature Conservation (IOP)
Mazowiecki Agricultural Advisory Centre in Warsaw (MODR)
National Society for the Protection of Birds (OTOP)

Portugal
Portuguese Environmental Agency: GMO register
Iberian Myrmecology Association (AIM)
Min. of Agriculture, Sea, Environment and Spatial Planning: Office of Planning and Policies (GPP)
National Water Institute
Portuguese Agency for Food Quality (ASAE)
Portuguese Min. of Agriculture
Portuguese Society for the Study of Birds (SPEA)
Public Enterprise for the Development of Alqueva (EDIA)

Portugal – not further characterised
Biomedical Institute of Science
Gulbenkian Institute of Science
Instit. Dr Ricardo Jorge: research on Allergology and Immunology
Institute of Biology Research and Technology (IBET)
National Institute of Biological Resources
Nutrition and Food University (FCNAUP)
Portuguese Conservation Tillage Association
Portuguese Food Industry Confederation (FIPA)
Portuguese Min. of Environment
Portuguese Min. of Health
Veterinary Sanitary Entity

Romania
Academy for Agricultural and Forestry Sciences "Gheorghe-Ionescu Sisesti": Scientific Commission on Biotechnology
Institute for Beekeeping Research & Development (ICDA)
Min. of Agri. and Rural Development: GMO register (ISCOMG)
Min. of Environment and Forestry: Environment Dept.
Min. of Health: Public Health Institute
National Centre for Sustainable Development
National Environmental Protection Agency – Directorate for Nature Conservation, Biodiversity, Ground, Underground
National Sanitary Veterinary and Food Safety Authority (ANSVSA)
Natura 2000 NGO Coalition Romania
Research and Development Plant Protection Institute
Research Institute for Soil Science and Agrochemistry
Romanian Ornithological Society (SOR)

Romania – not further characterised
Association for Beekeepers in Romania
Min. of Agri. and Rural Dev.: Central Laboratory for Phyto-Sanitary Quarantine

Table 1 (*Contd.*)

Min. of Agri. and Rural Dev.: Institute of Food Bio-Resources
Min. of Agri. and Rural Dev.: National Inspection for Seed Quality
Min. of Agri. and Rural Dev.: Phyto-sanitary Directorate
Min. of Agri. and Rural Dev.: State Institute for Variety Testing and Registration
National Federation of Agricultural Producers of Romania
National Cinegetical Association
Romanian League of Agricultural Producer Associations
University of Agricultural Sciences and Veterinary Medicine of Banat Timisoara
University of Agricultural Sciences and Veterinary Medicine

Sweden
BioSoM – Biological Soil Mapping
Lund University: The Swedish Bird Survey
Swedish Environmental Protection Agency (EPA)
Swedish Ornithological Society (SOF)

Slovakia
Central Controlling and Testing Institute: Agriculture Department of Feeds and Animal Nutrition
Centre of Animal Research: Apiculture Institute
Lepidopteran Society of Slovakia
Min. of Agriculture: GMO location registers
Slovak Hydrometeorological Institute
Slovak Ornithology Society
State Nature Conservancy of Slovak Republic

Slovakia – not further characterised
Slovak Academy of Sciences

United Kingdom
British Crop Production Council (BCPC)
British Survey of Fertiliser Practice (DEFRA)
Butterfly Monitoring Scheme
British Trust for Ornithology (BTO)
Centre for Ecology and Hydrology (CEH)
Dept. for Environment, Food and Rural Affairs (DEFRA); farm practices survey
Dept. for Environment, Food and Rural Affairs (DEFRA); biodiversity indicators
Environment Agency
Joint Nature Conservation Committee (JNCC)
Linking Environment and Farming (LEAF): Farm Assurance Schemes
Meteorological Office
National Bee Unit (NBU)
National Biodiversity Network
National Soil Resources Institute (NSRI)
Natural England (formerly English Nature)
Pesticide Incidents Appraisal Panel (PIAP)
Defra Expert Committee on Pesticide Residues in Food (PRiF)
Red Tractor Farm Assurance Combinable Crops & Sugar Beet Scheme (formerly ACCS)
Royal Society for the Protection of Birds (RSPB)
SCIMAC guidelines
Scottish Executive Environment Directorate (SEED)
Scottish Natural Heritage (SNH)
The Food and Environment Research Agency (FERA): Pesticide Usage Survey
Water Service Companies, Drinking Water Inspectorate (DWI)
Wildlife Incident Investigation Scheme (WIIS)

United Kingdom – not further characterised
Chemicals Regulation Directorate (CRD)/Food Standards Agency (FSA): Pesticide Residue Surveillance

Table 1 (*Contd.*)

Consent holder, merchant trade, processors/end-users: commercial evaluation
Department for Environment, Food and Rural affairs (DEFRA)/Scottish Executive Environment and Rural Affairs Department (SEERAD) (NIAB/SAC): National List Trials
Employers, Medical practitioners, HSE *via* Reporting of Injuries, Diseases & Dangerous Incidents Regulations 1995
Environment Agency, Local Authority Environmental Health Departments: air quality
Farmers/Agronomists associations
GM-specific hotline, operated by consent-holder as per SCIMAC guidelines
Health and Safety Executive (HSE)/Chemicals Regulation Directorate (CRD): Pesticide Use/Health & Safety
Home Grown Cereals Authority (HGCA), Arable Research Centre (ARC), Morley, British Sugar, Maize Growers Association (MGA), British Society of Plant Breeders (BSPB)
National Institute for Agricultural Botany (NIAB): Variety Evaluation Trials
Scottish Agricultural Colleges (SAC)
Medical practitioners – collated by DoH & agencies *e.g.* PHLS, Public Health Observatories
Research Institutes, Technology Providers, Distributors: herbicide research
Scottish Executive Environment and Rural Affairs Department (SEERAD)

144 of the 205 EENs were retained for further analysis. EENs that were not retained were tagged as not further characterised (n.c.) in Table 1 of ESI 1† under the "type of organisation".

For each of the retained EENs a detailed information record was established covering organisation (entry number; official name of the network; other names; type of organisation; coordinates; website; funding; conflict of interest; part of other network(s); grouping of other network(s)), monitoring subject (description; protection goal(s) and/or influencing factor(s); duplication of farmer questionnaire), specificity (geography; parameters; crop; trait/treatment; GMO), methodology (observations; frequency; future; quality of performers; quality of data; analysis; quality of analysis), reporting (language; availability; frequency; historical reference) and comment(s) (parameters are described in detail in ESI 1†). Covered protection goals include biodiversity (general; amphibians; birds; insects; butterflies; other invertebrates; mammals; plants; fungi; reptiles; fish), sustainable agriculture, soil function, water quality, animal health, human health and plant health. Captured influencing factors include agronomic practice, environmental conditions, GMO cultivation and plant protection as the most relevant factors.[36] Table 2 shows the distribution of the retained EENs over the different protection goals and influencing factors (*i.e.*, factors that could have an effect on the measured endpoints, hence, can influence variability), and countries after the first screening.

Overall, the retained EENs were divided into four types of networks.

- Governmental networks: official EU-wide or MS networks focussing on particular policy areas. Reports are usually publicly available, but they may not be published on a frequent basis (ESI 1†). Although these networks are officially endorsed, they lack information on methodology in many cases. The most common protection goals covered by the 72 governmental networks characterised here are water quality ($n = 17$), biodiversity: general ($n = 15$) and sustainable agriculture ($n = 14$).

- Academic networks: networks that focus on performing scientific research (*e.g.* national academy of science). These networks are typically managed by and composed of scientists. Reporting by the network itself is usually minimal. Publications typically cover a specific research subject or project rather than routine monitoring. The most common protection goals covered by the 15 academic networks characterised here are soil function ($n = 6$), sustainable agriculture ($n = 7$) and biodiversity: general ($n = 5$).

- Nature conservation networks: organisations involved in education on the promotion and observation of nature. These networks typically have a strong conservation orientation and therefore combine reporting on the status of natural components with recommendations on how to protect them. Data can include large volumes of observations made by volunteers from the general public, and which are entered in distribution databases. These data might be difficult to interpret in the frame of GS. In addition, some have official publications, most of which can only be accessed when being a member or paying a subscription fee. The most common protection goals covered by the 45 nature conservation networks characterised here are biodiversity: birds ($n = 17$), biodiversity: butterflies ($n = 10$) and biodiversity: general ($n = 8$). Only biodiversity protection goals are covered by these networks. None of the nature conservation networks surveyed collected data on 'agronomical practices', 'Plant protection' or 'GMO cultivation' influencing factors.

- Professional networks: they provide a forum for special interest groups addressing issues of trade (*e.g.* bee keepers, farmers, crop protection producers). The people involved include scientists and trade professionals. The main interest is recommendations on how to improve the activity and address negative influences (*e.g.* diseases). Usually, these networks have few routine publications, but they may offer targeted recommendations and observations on the status of their activities. The most common protection goals covered by the 13 professional networks characterised here are sustainable agriculture ($n = 4$) and biodiversity: bees ($n = 4$).

The number of EENs identified per country differed considerably. In the group of EENs dealing with biodiversity, the EENs on birds and insects, predominantly butterflies, were best represented. Such networks work and cooperate under the umbrella organisations BirdLife Europe and Butterfly Conservation Europe, respectively. These European-wide networks support and harmonise their monitoring programmes, their data collection methods and statistical processing. They often do not organise monitoring activities themselves, but rely on contributions from affiliated organisations in countries. Most protection goals are covered at the EU level except for a few specific biodiversity aspects (Table 2). At a country level, interest for the various protection goals varies (Table 2). Protection goals such as 'bird biodiversity' or 'sustainable agriculture' are well

Table 2 EEN distribution over protection goals, influencing factors and countries (note: one network can cover several protection goals and/or influencing factors and may therefore be counted more than once)

		EU	BE	CZ	DE	DK	ES	FR	HU	NL	PL	PT	RO	SE	SK	UK	Total
Protection goals	Biodiversity: general	1	2	1	—	1	2	3	1	5	1	—	2	1	—	7	27
	Biodiversity: birds	3	2	1	2	—	1	2	—	1	1	1	1	2	2	2	21
	Biodiversity: insects	1	2	1	2	—	2	2	—	3	—	1	1	—	2	1	18
	Biodiversity: butterflies	1	2	1	1	—	—	2	—	2	—	—	—	—	1	1	11
	Biodiversity: other invertebrates	—	2	—	—	—	—	1	—	2	—	—	—	—	—	—	5
	Biodiversity: mammals	—	2	—	1	—	—	1	—	1	—	—	—	1	1	—	7
	Biodiversity: plants	—	2	—	—	—	—	1	—	2	—	—	—	—	—	—	5
	Biodiversity: fungi	—	2	—	—	—	—	—	—	2	—	—	—	—	—	—	4
	Biodiversity: reptiles	—	2	—	—	—	—	—	—	1	—	—	—	—	—	—	3
	Biodiversity: amphibians	—	2	—	—	—	—	—	—	1	—	—	—	—	—	—	3
	Biodiversity: fish	—	—	—	—	—	—	1	—	1	—	—	—	—	—	—	2
	Sustainable agriculture	3	1	—	1	—	2	2	2	2	1	1	3	1	1	4	24
	Soil function	5	2	1	1	—	2	2	1	—	—	1	2	1	—	2	20
	Water quality	1	1	1	—	—	2	3	1	—	—	2	1	—	1	4	17
	Animal health	2	—	2	—	—	2	1	1	1	—	1	2	—	1	1	14
	Human health	2	—	2	—	—	1	—	1	1	—	1	1	—	—	2	11
	Plant health	1	—	2	—	—	2	2	—	—	—	—	1	1	1	—	10
Influencing factors	Agronomic practice	2	—	2	2	—	3	3	2	1	1	2	5	—	1	7	31
	Environmental conditions	4	1	2	1	1	1	4	1	—	—	2	3	—	1	5	26
	GMO cultivation	—	—	1	1	—	1	1	—	—	—	1	2	—	1	2	10
	Plant protection	—	—	—	1	—	2	—	1	—	—	—	2	1	—	2	9
	Total	26	25	17	13	2	23	31	11	26	4	13	26	8	13	40	

covered in most of the investigated MSs. On the other hand, 'fish biodiversity' or 'plant health' appears to have lower coverage by all network types (Table 2 and ESI 1 Table 1†).

In most countries, monitoring 'human health', 'water quality' and 'sustainable agriculture' is performed by governmental organisations, such as health, environment and/or agriculture Ministries. Although every EU MS watches over 'human health', data may not be publicly available and therefore are not represented in Table 1 of ESI 1.† For 'animal health', 'soil function' and 'plant health' often government as well as research institutes are involved.

Methods of data collection are rarely provided in the publicly available information. If mentioned, they are usually described as instructions to those who perform the survey. Also data analysis is often rudimentarily explained. Few sources explained statistics, yet only references to statistical methods were provided. Results were often presented as a summary in a graph or table. For none of the 144 characterised networks, raw data were publicly available. Some EENs provided more detailed information for their registered members. Occasionally, data were available upon request and after consideration by the data owners. Access to raw data was not requested in this study.

In general, EENs focussed on trends over long periods. Assessments over 10, 20, sometimes 30 years have been reported and can therefore provide valuable insights into population dynamics and the performance of species. Meteorological services, rapid alert systems and EENs surveying plant pests or water quality for example almost all report their findings immediately. Scientific institutions publish their findings in scientific journals, instead of reports made available to all from their websites. Reports or updates are usually produced yearly, but occasionally with a considerable time lag (*e.g.* 2012 results may only become available during 2013 or later). Out of 59 EENs regularly issuing annual reports, 9 provided them the same year as the observations were made; 30 the year after; and 20 after 2 or more years. Also the regularity of reporting was not consistent.

For this study four influencing factors were retained, as they may contribute to a change observed in one of the protection goal-related endpoints considered relevant for GS of GM crop cultivation: 'Agronomic practices', 'Plant protection', 'GMO cultivation' and 'Other environmental conditions'. These influencing factors, which might provide information in the case of a causality–effect relationship investigation, were not collected for all EENs. EENs focusing on biodiversity components were only seldom collecting information on influencing factors at the same time.

The available EEN reports considered different factors that influence the fluctuations in biodiversity including:

- Loss and fragmentation of habitats.
- Degradation of habitat quality.
- Changes in land and crop management (intensification/extensification; changes in the area of arable land, changes in crops, plant protection applications, soil treatments, deforestation/afforestation, and degradation of land quality).
- Changes in climatic conditions (temperature, rainfall).
- Naturally occurring diseases.
- Other human activities (*e.g.* hunting).

Some reports clearly illustrate the effect of nature conservation measures and modifications of agricultural regimes (*e.g.* the evolution from intensification, to set-aside rules and agricultural policies). There are however nearly no indications on

how causality is established, linking the observed effect with the influencing factor. Finally, GM crop cultivation was not cited as a potential influencing factor causing a change in a protection goal endpoint by any of the 144 EENs.

Discussion

While recognising the monitoring expertise of EENs, not all of their activities are relevant for GS of GM crop cultivation. Therefore, the development of harmonised criteria for the systematic identification, specification and analysis of existing surveillance networks across the EU is considered important by EU GMO regulators.[2] In contrast to other initiatives,[12–14,37] the plant biotechnology companies developed a systematic and scientifically robust approach.

Using the methodology developed here, EENs have been identified and characterised. An initial examination of relevance and availability of information from the EENs was performed in line with the EFSA recommendations.[2] On this basis, the number of retained EENs was reduced by 30%. The use of pre-defined criteria as well as a verification step by a local contact person from a EuropaBio member to check our characterisation were introduced to reduce the risk for bias in this step. For all the retained EENs, additional information on methods of data collection, analysis, and reporting as available was systematically collected from the public domain (*e.g.* websites, publications, communications).

The detailed survey revealed that EENs can be divided into four types each reflecting specific characteristics in terms of structure, funding, approach, methodology, analysis, reporting and continuity (*e.g.* fixed-term projects). These four types of EENs have a different focus and therefore differ in their usefulness for GS of GM crop cultivation. Nature conservation networks may focus on biodiversity without data collection on agricultural influencing factors. Scientific projects may provide relevant information for a protection goal in a well-documented scientific way, but may not guarantee continuity beyond the project lifetime. Such time-limited projects provide information that may fit better in the literature search component of GS. Government supported observations (*e.g.* of water quality) provide officially endorsed references, but may not provide much insight into the monitoring practice or analysis. Professional networks advise on best practices and provide statistics on *e.g.* pesticide use.

Taken together, the retained EENs cover all protection goals and influencing factors as described in the EFSA guidance.[2] However, EENs were not identified for all subjects in all selected MSs. As a bias may have been introduced by the visibility of EENs (for instance by the availability of a website, language barriers and the different degree of development of EENs across the EU countries), the actual coverage might be more comprehensive than described here. The landscape of EENs presented here therefore also represents the ease of access to monitoring data on a EU-wide perspective. On the other hand, some protection goals receive more attention (*e.g.* biodiversity: birds) than others (*e.g.* biodiversity: fish).

Diverse contributions of EENs to GS have been suggested. EENs have been proposed to be used to describe the state of the environment (baseline approach) and determine natural variation.[19,23–25,28,37–42] They may indicate whether an effect is unusual and potentially adverse (early warning system).[8] Council Decision 2002/811/EC[8] states that 'the approach [of a monitoring strategy] should provide the means to detect potential adverse effects at an early stage of manifestation'. Some EENs documented in this study, in particular those that monitor the development of trends over time, may be of interest. Examples include the Pan-European Common Bird Monitoring Scheme (PECBMS) as they describe population trends in bird species over time. However, using EEN data as an early warning system may have technical constraints: *e.g.* delayed publishing of data, trends that are only visible in the long-term due to natural fluctuation in populations.[3] Short-term effects are detected by other PMEM activities focussing directly on the GM crop cultivation such as the farmer questionnaire or company stewardship activities.

The monitored indicator, its natural variation and other factors such as the number and location of sampling points, influence the ability to detect changes. Glandorf[37] observed that the Dutch Ecological Monitoring network would be able to detect on average 5% shifts in population levels in a given year, but the Biological Indicator System of Soil Quality network would only reveal 20% changes on average due to the less intense monitoring frequency. Aviron *et al.*[38] questioned whether GS of GM crops will enable the detection of unusual variation from the overall environmental variation in biodiversity since, in their case study with butterflies in Switzerland, only 1.4% of the variability could be explained by agricultural management practices (of which GM crops are only a fraction). Further, only drastic changes may be visible due to the high variability of the species. These changes are influenced by a myriad of confounding factors. Therefore, if during commercial planting of the GM crop an adverse effect to a certain protection goal would be observed which can be demonstrated to be caused by GM crop cultivation, this effect should be of such a magnitude that it almost certainly would have been detected in the pre-market risk assessment.

Spatial distribution of information and trend analysis must be taken into account. Networks that are focused on environmental protection goals are more – although not solely – focussed on unmanaged or semi-managed landscape components. Therefore, the question can be raised if these observations are relevant for PMEM as the potential effect of a GM crop can be expected in the agro-ecosystem and habitats immediately adjacent to fields with GM crops. This is in line with Mönkemeyer *et al.*[12] concluding that although data are generally of good quality, the sampling frequency and distribution might not overlap with GM crop cultivation, amongst other limitations. Therefore, in the case of the observation of an effect in a field with GM cultivation (*e.g. via* the use of the farmer questionnaire), the data generated by these EENs could be used to provide background information at the landscape level.

Based on the data generated by EENs, the cause of an environmental change typically cannot be determined.[14,38,40,41]

Owing to many influencing factors, it will not be possible for an EEN as such to establish a relationship between cause and effect. While some EEN reports indicated plausible causes for the observed changes, it was usually not clear how causality was established. GM crop cultivation was not cited as a potential influencing factor for a given environmental change by any of the retained EENs. While this can be expected due to the still limited introduction of GM crops in the EU, it would in most cases also not be possible for the EEN to make such correlations given the methodologies that they use. Even for GS of GM crop cultivation with all its tools (farmer questionnaire, literature searches, stewardship and EENs), it still needs an expert interpretation and further study, to determine the cause of an identified change.[14] Once an effect is identified, further interdisciplinary studies – beyond the scope of any EEN – will be needed to determine the cause.[2] In this respect, EENs may be useful to provide contextual background information at the landscape level for an observed effect.

Regarding data compatibility and harmonisation between networks, the documentation process was based on publicly available data. In most cases, these are presented only as data summaries, averaged over a large area. Raw data or even data subsets of smaller regions are not available. This was also recognised by Schmidt *et al.*[28] who stressed the advantages of collecting reports from EENs rather than raw data. The EEN reports use the full functionality and data management structure of the EENs and rely maximally on their expert opinion. In few cases, efforts are made to harmonise data collection and processing over different countries, such as the European Bird Census Council and the Butterfly Conservation Europe. Yet, quality differences, poor compatibility between data formats and ownership of collected data have been pointed out as factors hindering integration of information.[2,12] Therefore, some authors have suggested that adaptations may be needed to harmonise and standardise the methodology from country to country to ensure comparability across the EU.[2,18,27] Taking the successful European-wide examples as a model, this calls for a specific umbrella initiative that surpasses the area of GS for GMOs. EFSA guidance[2] advises plant biotechnology companies to make in collaboration with MSs appropriate agreements with the EENs to adapt the monitoring effort to the needs of GS. This will largely depend on the willingness of the EENs to cooperate (*e.g.* provide access to raw data) and the intrinsic flexibility of their potential for extensions/adaptations (*e.g.* indicator or parameter sets, intervals and sites of data collection). The plant biotechnology companies have no authority and more importantly no interest to modify the EEN's methodology, since this would hinder the independence of the network. Adaptations of EENs can be part of an integrative effort supported at the EU level, but clearly transcends the capacity of the plant biotechnology companies. Similarly, the value of analysis by the EEN can be fully captured on the basis of publicly available information.

Many factors active in agricultural environments impact upon productivity, biodiversity and ecosystem functioning. Urging MSs to enable their EENs to detect changes in assessment endpoints with special attention for the cultivation of GM plants introduces a bias. Adapting the scope or methodology of EENs to improve GM crop cultivation monitoring would not prove beneficial. Directed to a broad range of protection goals, society may benefit more from further improving the way EENs operate (*e.g. via* statistical support), instead of singling out GM crops as the main stressor being subject to GS. The cultivation of GM crops is one out of a multitude of practices available to agriculture, and agriculture is only one of the myriads of influencing factors impacting protection goals. It therefore seems appropriate for plant biotechnology companies commercialising GM crops to use the information from EENs only as confirmatory data or to provide background information at a landscape level. This action would only be triggered if effects are detected by the other GS tools. Farmer questionnaires, literature search and company stewardship activities would therefore be the primary tools of GS.

Conclusions

After defining a harmonised identification and characterisation methodology, EENs relevant for GS of GM crop cultivation were identified in all investigated EU member states ($n = 13$). Although these EENs cover a broad range of protection goals, their coverage across the EU is far from uniform and complete. Even if geographical overlap would exist between certain EENs or if similar protection goals would be monitored, their difference in the data collection methodology or data analysis makes it difficult to compare conclusions. Notwithstanding that the EENs retained in this study were functional and seemed to fulfil their original objectives, the systematic analysis of characteristics revealed that none met all requirements outlined in this paper. In conclusion, none of the EENs provided all information that would make it suitable as a primary tool for GS in GM crop monitoring. They, however, could be valuable to provide background information or confirmatory data to help validate findings from another GS tool.

Methods

EENs were identified in the first place through EuropaBio members and their representatives in EU MSs, as they were best placed to list EENs active in their country that would cover one or more protection goals and/or influencing factors. Secondly, these lists were complemented by public domain searches conducted by Perseus BVBA (*e.g.* targeted search for environmental agencies, like EPA Sweden). Thirdly, suggestions from third parties (*e.g.* other networks, authorities and other stakeholders) were further added to the list (*e.g.* European-wide EENs were identified from national EENs). In the absence of a formal definition of what can be considered a "network", the scope was interpreted broadly, ranging from formalised organisations with a specific legal structure to informal collaborations or project teams. The information was compiled for EU countries with potential to cultivate GM crops (present or past deliberate release of GM crops into the environment for commercial (GM crop cultivation) and/or experimental (field trials) purposes). This enquiry provided an initial, broad list of EENs potentially

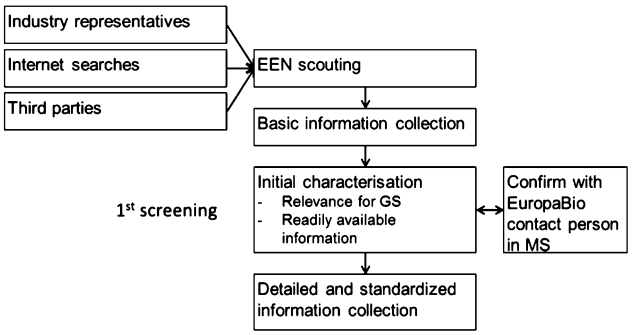

Fig. 1 EEN systematic documentation process.

relevant for GS. Each EEN was further specified in the documentation procedure (Fig. 1).

A basic record was established for each reported EEN including the network name(s), country(ies) where the EEN is active, protection goals studied, website, general description and information on accessibility. The information collected in the basic record was used to conduct the first screening, which took into account the following two aspects as suggested by EFSA:[2]

- the relevance for GS: EENs not providing information on protection goals and/or influencing factors were deemed not relevant for GS;

- the availability of information: for some EENs it was not possible to access information on the network and their observations.

A record of each of the EENs not expected to contribute readily to GS (no relevant protection goal or influencing factor indicated or no information readily available) was kept in the database. This first evaluation was verified by a EuropaBio contact person in the MS(s) where the specific EEN was active.

For EENs that passed the first screening, detailed information was collected in a standardised format. Monitoring subjects were specified in terms of protection goals (aspects of the environment that need to be protected from harm according to environmental protection goals set out by the EU legislation)[11] and influencing factors (factors that may cause an effect on a protection goal).

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