Monitoring Working Group Report

on the

Applicability of existing EU monitoring programmes and data infrastructure schemes for GMO monitoring and options for implementing data coordination and harmonisation

Contents

1 Introduction

1.1 Legal framework relating to GMO monitoring data coordination and harmonisation

Directive 2001/18/EC hereafter referred to as 'the Directive', on the deliberate release of genetically modified organisms (GMOs) requires the implementation of a monitoring plan of GMOs in order to trace and identify any direct or indirect, immediate, delayed or unforeseen adverse effects on human health or the environment after they have been placed on the market.

Neither the Directive nor any other legal framework foresees a specific coordination and harmonisation of GMO monitoring data between European Member States (MS). Article 31 of the Directive merely regulates the creation of national registers for GMO cultivation, which may be used for monitoring.

On 3 October 2002, the Council of the European Union (EU) adopted a Decision[1] establishing guidance notes supplementing Annex VII to the Directive. The guidance notes recommend using existing monitoring systems such as food surveys, nature conservation, long-term ecological monitoring systems, environment observation programmes and veterinary surveys. Furthermore, the guidance notes recommend using standardised monitoring methodologies, standardised mechanisms for data collection and collation, and statistical analyses.

1.2 Purpose of data coordination and harmonisation

The purpose of coordination and harmonisation of EU-wide GMO monitoring data is to:

a) provide a basis for the establishment of an EU-wide GMO monitoring information system for analysing monitoring reports and supplementary raw data;
b) provide a strong and reliable basis from which to extrapolate monitoring data to unsurveyed EU areas and environmental factors which may be potentially affected;
c) reduce the overall monitoring and analysis efforts by setting up an EU-wide coordinated monitoring data analysis system.

1.3 Definitions

Data coordination for the purpose of this document refers to the collection, reporting, storage and exchange of GMO monitoring data from different sources. *Data coordination* requires an infrastructure (staff, the necessary hard- and software) and may take place at different stages of GMO monitoring (data collection methods → spatio-temporal design of data collection → data collection → data storage → data processing and analysis →data exchange).
Data harmonisation refers to the process of setting common standards for GMO monitoring. These standards may be set at different stages of GMO monitoring such as methods and spa-

[1] Council Decision of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 280, 18.10.2002, p. 27

tio-temporal design for data collection; data quality; data and file types and structure; data storage and analysis; and data exchange.

GMO monitoring data relates to
a) case-specific monitoring and general surveillance data collected by applicants and third parties and
b) data from external agro-environmental monitoring programmes according to recital 44 of the Directive.

Data coordination and harmonisation may refer to both types of monitoring data.
An explanation of the many acronyms used in this document is provided in Annex 1.

1.4 Monitoring Working Group (MWG) terms of reference

"*The possibility of EU-wide coordination and harmonisation of data resulting from post-market monitoring of GMOs*" was identified as an objective under the terms of reference for the MWG. The following approaches were also identified under the terms of reference as a means to achieving the aforementioned objective:

- *the working group shall gather, from all relevant sources within and outside of the European Community, information on monitoring concepts, plans and methodologies, as well as databases already developed by international or national bodies (e.g. the OECD, European Enforcement Project), research institutions, non governmental organisations, including notifiers, particularly taking into account previous activities of the Member States, including experience gathered through national monitoring programmes;*

- *the needs and possibilities of an EU-wide coordination of data resulting from post-market monitoring of GMOs on the basis of existing legislation and initiatives as well as capacities (information networks, reporting activities, registers, databases, etc.) in this field shall be identified and proposals for future coordinated activities elaborated accordingly.*

1.5 Preparatory work of the MWG: Concepts for the coordination and harmonisation of monitoring data exchange regarding GM crops

A document entitled *'Concepts for the coordination and harmonisation of monitoring data exchange regarding GM crops'* was drafted in May 2006 by the MWG and was adopted by the CAs in July 2006 (http://ec.europa.eu/environment/biotechnology/index_en.htm). The document was subsequently presented to the MWG in October 2006. This document set out the existing state of GMO monitoring, data coordination and agro-environmental monitoring programmes in the MS and the EU and proposed three options for central data coordination, harmonisation and analysis.

- National GMO Monitoring Information Systems
- Central EU-wide GMO Monitoring Information Systems
- Combination of National and EU-wide GMO Monitoring Information Systems

The CAs indicated that they were in favour of the third and final option - this option aims at integrating national monitoring Information Systems in parallel with an EU-wide monitoring Information System for the purposes of coordinating and harmonising monitoring data received from the applicants and external agro-environmental monitoring programmes. It should be noted that European Food Safety Authority (EFSA) supports the idea of a reporting and scientific analysis mechanism in the EU[2].

Following adoption of the 'Concepts for the coordination and harmonisation of monitoring data exchange regarding GM crops' by the CAs in July 2006, the MWG was asked to prepare a second technical concept document. The purpose of this second document is to review and propose existing EU agro-environmental monitoring programmes and data infrastructure schemes relevant for GMO monitoring and to explain in more detail how to implement a combination of National and EU-wide GMO Monitoring Information Systems.

This second technical concept document should again be delivered to the CAs for adoption and determination of the subsequent steps necessary to implement coordination and harmonisation of monitoring data.

[2] *Opinion of the Scientific Panel on Genetically Modified Organisms on the Post Market Environmental Monitoring (PMEM) of genetically modified plants, The EFSA Journal (2006) 319, 1-27*

2. Current state of GMO Monitoring, data coordination and agro-environmental monitoring programmes in the MS and the EU

Currently, there is no GM crop approved for cultivation purposes in the EU under the Directive (Status: February 2008).Currently, the commercial cultivation of GM crops in the EU is restricted to MON810. As this GMO was approved under Directive 90/220/EC no obligations were imposed to monitor this crop. However, with regard to events to be approved under Directive 2001/18/EC and Regulation (EC) 1829/2003, the granting of an approval will entail an obligation to monitor adverse environmental effects.
Concepts for GMO monitoring are still at an initial stage and the primary focus has been at a national level. Presently, there has been little focus on data coordination and the harmonisation of monitoring concepts on an EU-wide basis.

EU MS have various agro-environmental monitoring programmes in place - some of which have a long history of data collection – that are being considered in the context of general surveillance of GMOs. However, no programme identified to date, would currently meet the needs of a GMO monitoring programme without some adaptation. Certain aspects of these agro-environmental monitoring programmes, may be applicable to GMO monitoring.

National agro-environmental monitoring programmes are often driven by EU-obligations (Directives and Regulations) with the result that environmental parameters need to be monitored. In addition to these, NGOs in a voluntary capacity often monitor environmental parameters at EU level. Some of these monitoring programmes may be relevant to GMO monitoring including data coordination and harmonisation, for instance:

a) the Habitats Directive on the conservation of natural habitats and of wild fauna and flora (92/43/EEC[3]);
b) the Water Framework Directive (2000/60/EC[4]);
c) the Birds Directive on the conservation of wild birds (79/409/EEC[5]);
d) the Council Regulation 1698/2005/EEC on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and
e) monitoring of birds or other species by NGOs.

For some of the Directives mentioned, data coordination infrastructure hereafter referred to as 'data infrastructure schemes', have been developed with potential relevance to GMO monitoring including data coordination and harmonisation, namely:

a) European environment information and observation network (EIONET)
b) Infrastructure for Spatial Information in the European Community (INSPIRE)
c) Regulatory information systems in the context of GMOs

[3] *Official Journal L 206 , 22/07/1992 P. 0007 - 0050*
[4] *Official Journal L 327 , 22/12/2000 P. 0001 - 0073*
[5] *Official Journal L 103 , 25/04/1979 P. 0001 - 0018*

d) EU-wide monitoring methods and systems of surveillance for species and habitats of Community interest (EuMon)

Information on EU monitoring programmes and data infrastructure schemes are evaluated in this document with respect to their relevance to GMO monitoring.

3 Existing EU agro-environmental monitoring programmes relevant for GMO monitoring

3.1 Monitoring under the Habitats Directive (92/43/EEC)

3.1.1 General information of monitoring programme

3.1.1.1 Aim of monitoring programme

The aim of the Habitats Directive[6] is to monitor the incidental capture and killing of protected animal species and to undertake surveillance of the conservation status of the natural habitats and species.

3.1.1.2 Year of commencement

The Habitats Directive is in place since 1992. The first national monitoring reports (covering 1994 to 2000) were only status reports about the establishment of the programmes (without monitoring data).

3.1.1.3 Implementation of programme

Later stage: the implementation report (2001-2006 report) focuses on the setup of a systematic monitoring programme and active management measures and their impact on conservation status, while the next report (covering 2007-2012) will report on the conservation status of natural habitats and species.

3.1.2 Observed features/indicators

3.1.2.1 Type of features/indicators observed

Annex I (habitats types) and II, IV and V (species) of the Habitats Directive lists the features to be observed, namely:
- The conservation status of natural habitats (e.g. coastal habitats, dunes, freshwater habitats & forests), and
- The conservation status of animals (vertebrates and invertebrates) & plants.

3.1.2.2 Criteria for selection of features/indicators

Criteria for selecting natural habitats and animals are specified in Annex III of the Habitats Directive and described in more detail by the Habitats Committee in DocHab-04-03/03rev3[7]: for instance range size and trend, future prospects (for both habitat types and species), population size and trend, suitable habitat size (species) area covered and specific structures and functions (habitat types).

3.1.3 Observed areas

3.1.3.1 Land surface types

Land types and water bodies (see 3.1.2.1)

[6] Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora.
[7] EC, 2005: "DocHab-04-03/03 rev.3", NOTE TO THE HABITATS COMMITTEE, from 15 March 2005 (DG Env. B2/AR D(2004))

3.1.3.2 Biogeographic regions

Habitat types inside special protection areas as specified in Natura 2000 as well as outside these designated areas.

3.1.3.3 Total area for which conclusions are drawn

All special protection areas as specified in Natura 2000, as well as areas outside these designated areas.

3.1.4 Sampling/observation design

3.1.4.1 General approach of sampling/observation design

It is up to the MS to establish a system to monitor the incidental capture and killing of the animal species and to undertake surveillance of the conservation status of the natural habitats and species. Each MS can adopt their own sampling and field methods in order to fulfil the specifications of DocHab-04-03/03rev.3.

3.1.4.2 Frequency of sampling/observation

MS can adopt specific observation frequencies depending on e.g. extent/abundance of habitats/species in different regions and threat status of species and habitat types (DocHab-04-03/03rev.3).

3.1.4.3 No. of sampling/observation sites

Each MS proposes a list of sites indicating which natural habitat types (Annex I) and which species (Annex II, IV and V) that are native to the territory the sites host.

3.1.4.4 Representativeness of no. of sampling/observation sites

Criteria for selecting sites eligible for identification as sites of Community importance and designation as special areas of conservation are set up (Annex III of Habitats Directive). Representativeness is required, as monitoring data must allow assessment of the conservation status of each species and habitat type within the biogeographic region. MS can adopt their own criteria to assure representativeness.

3.1.4.5 Size of sampling/observation sites

MS can develop their specific criteria to assign sampling areas (DocHab-04-03/03rev.3).

3.1.4.6 Sampling sites vary or remain constant in time

Generally, constant. In exceptional cases sites might be added.

3.1.5 Methodology of data coordination

For the raw data collection and reporting on the national level one coordinating national CA is assigned. The CA aggregates the data. Every six years, MS draw up a report - in a format established by the Commission - on the implementation of the measures taken under the Habitat Directive. The report includes information on the conservation status, measures taken and evaluation of the impact of those measures on conservation status of natural habitats types and species. The Commission prepares a composite report based on the MS reports. This report

includes an evaluation of progress achieved and, in particular, of the contribution to Natura 2000.
The generalised data are also provided to the EEA every six years. For reporting, the EEA Reportnet standards are used.

3.1.6 Data analysis

3.1.6.1 Aim of data analysis

Evaluation of the conservation status of habitats and species and the impact of measures taken under the Habitats Directive.

3.1.6.2 Type of data analysis

Statistical analyses are not yet developed, but numbers of the populations and conservation status evaluation scores (favourable, unfavourable inadequate, unfavourable bad, unknown) are required (as specified in DocHab-04-03/03rev3).

3.1.6.3 Baseline/threshold values

MS are encouraged to include favourable reference values for habitats and species within the biogeographic regions (DocHab-04-03/03 rev.3).

3.1.7 Data harmonisation efforts/extent

3.1.7.1 Sampling or observation methods

While MS are free to choose their means and methods of gathering data and to adapt monitoring methods to regional differences, the data finally reported to the Commission need to be comparable and compatible in order to allow for analysis at an EU scale. Initiatives on harmonisation of monitoring methods (incl. research projects like EuMon) and exchange of practices are being discussed.

3.1.7.2 Data quality management

Information of data quality must be provided (good, moderate, poor).

3.1.7.3 Data coordination

- Data are compiled at national level. For purposes of reporting to the Commission a general reporting format is provided (DocHab-04-03/03 rev.3).
- EEA Reportnet standards are applied for the reporting to the EEA.
- The data are integrated in (EIONET). In the future, the monitoring data will be integrated within INSPIRE.

3.1.8 Data availability

3.1.8.1 Public access to data

Final reports are published by the Commission and are made available on the following website: http://ec.europa.eu/environment/nature/knowledge/rep_habitats/index_en.htm

3.1.8.2 Host of data repository at EU level

The EEA (EIONET)

3.1.8.3 Availability of data

Monitoring data in the MS exist already from former monitoring obligations (prior to Habitats Directive). From 2001 on, monitoring data and reports are available and published in the 2001-2006 implementation report of the Commission. New Commission reports will become available every six years.

3.2 Monitoring under the Water Framework Directive (WFD) (2000/60/EC)

3.2.1 General information of monitoring programme

3.2.1.1 Aim of monitoring programme

The aim of the monitoring under the WFD[8] is to:
- Establish a comprehensive overview of water status within each river basin district (RBD) of the EU;
- Supplement and validate risk assessment procedure for surface waters;
- Assess long-term changes in natural conditions potentially resulting from anthropogenic activity;
- Assess the impact of water pollution;
- Assess changes in status of water bodies in response to the application of measures for improvement;
- Estimate pollutant loads transferred across international boundaries;
- Efficient and effective design of future monitoring programmes;
- Intercalibration of methodologies and data between MS, and
- Quantifying reference conditions (where they exist) for surface water bodies.

3.2.1.2 Year of commencement

Water status monitoring is being carried out for a number of decades in the framework of several sectoral Directives. The WFD entered into force in 2000. The 2001-2006 monitoring report focuses on the description of established programmes. In 2004/2005 a first estimation of the MS water status was carried out.

3.2.1.3 Implementation stage of programme

Later stage: For the period 2007-2012 more detailed monitoring reports, including monitoring data, will be provided by the MS.

3.2.2 Observed features/indicators

3.2.2.1 Type of features/indicators observed

For rivers e.g.
(a) the quality elements/features, for instance: Biological elements (aquatic flora, benthic invertebrate fauna, fish fauna), hydromorphological elements supporting the biological elements (hydrological regime, river continuity, morphological conditions), chemical and physico-chemical elements supporting the biological elements;
(b) general elements (thermal conditions, oxygenation conditions, salinity, acidification status, nutrient conditions) and
(c) specific pollutants.

[8] Directive 2000/60/EC of 23 October 2000 establishing a framework for Community action in the field of water policy

3.2.2.2 Criteria for selection of features/indicators

The criterion is the explanatory power of the indicator for assessing the ecological status of previously defined quality elements (see 3.2.2.1) per water body type.

3.2.3 Observed areas

3.2.3.1 Land surface types

Water bodies: rivers, lakes, transitional waters, coastal waters and groundwater.

3.2.3.2 Biogeographic regions

25 ecoregions for rivers and lakes

3.2.3.3 Total area for which conclusions are drawn

All RBD in the EU.

3.2.4 Sampling/observation design

3.2.4.1 General approach of sampling/observation design

It is a stratified arbitrary sampling design since all EU ecoregions, different RBDs and water body types are covered. WFD Guidance Doc. No.7[9] gives more precise information on sampling methodology. For surface water bodies three different monitoring intensities are foreseen in terms of frequency, monitoring points and quality elements/features: a) surveillance monitoring (for water bodies with good status), b) operational monitoring (for bodies identified as being at risk of failing to meet their environmental objectives), and c) investigative monitoring (for bodies where the reason for any exceedances is unknown).

3.2.4.2 Frequency of sampling/observation

The Directive allows MS to tailor monitoring frequencies according to the conditions and variability within their own waters. However, frequencies should be chosen so as to achieve an acceptable level of confidence and precision. WFD Guidance Doc. No.7 gives more precise information in terms of the minimum of monitoring frequencies on all the quality elements (e.g. 6 months for phytoplankton, 3 years for macro-invertebrates).

3.2.4.3 No. of sampling/observation sites

37.000 monitoring sites for surface waters and 42.000 for groundwater in the EU.

3.2.4.4 Representativeness of no. of sampling/observation sites

Representativeness is a requirement of the WFD.

3.2.4.5 Size of sampling sites

Variable water volumes and areas depending on sampled features, methodology and habitat. The minimum area to be monitored are water catchments > 10 km².

3.2.4.6 Sampling sites vary or remain constant in time

Constant, unless new monitoring sites are defined in case of decreased water status or unknown exceedances.

[9] http://www.waterframeworkdirective.wdd.moa.gov.cy/guidance.html

3.2.5 Methodology of data coordination

For the raw data collection and reporting at the national level, one coordinating national CA is assigned. The CA aggregates the data and generalises the precise measuring points for the purpose of protection of privacy.
The generalised data are provided via monitoring reports to the EEA every six years. For reporting, the EEA Reportnet standards are used. The Commission prepares a composite report based on the MS reports.

3.2.6 Data analysis

3.2.6.1 Aim of data analysis

Assess changes in status of water bodies in response to natural variations and the application of measures for improvement.

3.2.6.2 Type of data analysis

Although the WFD Guidance Doc. No.7 specifies that "The process of selecting water bodies and monitoring stations should entail statistical assessment techniques, and should ensure that the overview of water status has an acceptable level of confidence and precision", so far no statistical analysis is carried out due to the lack of data. The WFD Guidance Doc. No.7 specifies good practice for sampling intervals and frequencies to attain results with desired confidence. Examples for statistic calculations are provided (for instance for means, trends and data aggregation).

3.2.6.3 Baseline/threshold values

MS may establish reference (baseline) conditions based on existing high status water bodies and against which other water bodies have to be compared. Normative threshold values are given for classifying the respective ecological status on a 5-step scale.

3.2.7 Data harmonisation efforts/extent

3.2.7.1 Sampling or observation methods

The WFD and WFD Guidance Doc. No.7 recommend standardised sampling methodologies (ISO, CEN). Only few methods, however, have been standardised within the MS. The different methodologies used within the MS make the analysis of overall results difficult, but an intercalibration is still possible.

3.2.7.2 Data quality management

WFD Guidance Doc. No.7 describes good practice for the monitoring design (no. of sites, temporal frequency of measurements) to achieve results with acceptable error probability. Standardised methods, quality control techniques (ISO 5667-14) and quality control tests at regular intervals are suggested. The WFD Guidance Document No.7, however, is not binding to the MS.

3.2.7.3 Data coordination

- The data intercalibration and coordination between bordering states sharing RBDs demand many efforts because of differing sampling methodologies. For international RBDs one responsible CA is assigned.
- EEA Reportnet standards are applied for the reporting.

- The data are integrated within EIONET and the Water Information System for Europe (WISE). In the future, the WFD monitoring data will be integrated within INSPIRE.

3.2.8 Data availability

3.2.8.1 Public access to data

The access to the raw data is restricted. Local raw data can be obtained on request.
The monitoring reports to the EEA and the composite report of the Commission are accessible by the public and are made available on the following website: http://cdr.eionet.europa.eu/.

3.2.8.2 Host of data repository at EU level

The EEA (EIONET)

3.2.8.3 Availability of data

Monitoring data of water quality parameters in the MS exist from former monitoring obligations (prior to WFD) concerning water. From 2007 on more detailed monitoring reports will be available. Commission reports are available every six years.

3.3 Monitoring under the Birds Directive (79/409/EEC)

3.3.1 General information of monitoring programme

3.3.1.1 Aim of monitoring programme

Report on the protection, management and control of wild bird species annexed in the Birds Directive[10].

3.3.1.2 Year of commencement

1982

3.3.1.3 Implementation of programme

Implemented

3.3.2 Observed features/indicators

3.3.2.1 Type of features/indicators observed

Naturally occurring birds, their eggs, nests and habitats are observed.

3.3.2.2 Criteria for selection of features/indicators

Not specified

3.3.3 Observed areas

3.3.3.1 Land surface types

Sea and land areas

[10] Birds Directive 74/409/EEC of 2 April 1979 on the conservation of wild birds.

3.3.3.2 Biogeographic regions

Geographical sea and land area, as regards the breeding, moulting and wintering areas and staging posts along their migration routes. Special attention is paid to wetlands. The Birds Directive does not apply to Greenland.

3.3.3.3 Total area for which conclusions are drawn

All protection areas

3.3.4 Sampling/observation design

3.3.4.1 General approach of sampling/observation design

Not specified

3.3.4.2 Frequency of sampling/observation

Not specified, but updates need to be provided every 3 years.

3.3.4.3 No. of sampling/observation sites

The MS classify the most suitable territories in number and size as special protection areas for the conservation of these species.

3.3.4.4 Representativeness of no. of sampling/observation sites

Not specified

3.3.4.5 Size of sampling/observation sites

The MS classify the most suitable territories in number and size as special protection areas for the conservation of these species.

3.3.4.6 Sampling sites vary or remain constant in time

Not specified

3.3.5 Methodology of data coordination

Every 3 years, the MS forward a report to the Commission on the implementation of national provisions taken (no monitoring data). The Commission prepares a composite report based on the MS' reports.

3.3.6 Data analysis

Not specified in the Birds Directive

3.3.7 Data harmonisation efforts/extent

No data harmonisation efforts yet

3.3.8 Data availability

3.3.8.1 Public access to data

Final reports are available to the MS (only authorities).

3.3.8.2 Host of data repository at EU level

No data repository

3.3.8.3 Availability of data

No raw data available, only reports.

3.4 Monitoring under the Council Regulation (EC) No. 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)

3.4.1 General information of monitoring programme

3.4.1.1 Aim of monitoring programme

Monitoring of the rural development programmes.

3.4.1.2 Year of commencement

The strategic monitoring programme will start in 2010 and end on 1 October 2014.

3.4.1.3 Implementation of programme

Early implementation stage

3.4.2 Observed features/indicators

3.4.2.1 Type of features/indicators observed

A limited number of common indicators relating to the baseline situation. Relevant environmental indicators comprise biodiversity (population of farmland birds), water quality (pollution by nitrates and pesticides) and soil (erosion risk, organic farm area).

3.4.2.2 Criteria for selection of features/indicators

Explanatory power for assessing impact of rural development programmes

3.4.3 Observed areas

3.4.3.1 Land surface types

Rural areas

3.4.3.2 Biogeographic regions

Not specified, but covers major agricultural areas of the EU.

3.4.3.3 Total area for which conclusions are drawn

Area for which EAFRD investments are granted

3.4.4 Sampling/observation design

3.4.4.1 General approach of sampling/observation design

Not specified

3.4.4.2 Frequency of sampling/observation

Rural areas applying for the programme are checked regularly

3.4.4.3 No. of sampling/observation sites

Not specified

3.4.4.4 Representativeness of no. of sampling/observation sites

5 to 10% of the sites are checked

3.4.4.5 Size of sampling/observation sites

Not specified

3.4.4.6 Sampling sites vary or remain constant in time

Some sampling sites may vary, others may remain constant for a number of years

3.4.5 Methodology of data coordination

For the first time in 2010 and than each second year (till 2014) each MS will submit to the Commission, a summary report setting out the progress made in implementing its national strategy plan and objectives and its contribution to the achievement of the Community strategic guidelines. Every two years (till 2015) the Commission will present a report summarising the main developments, trends and challenges relating to the implementation of the national strategy plans and the Community strategic guidelines.

3.4.6 Data analysis

No data analysis specified

3.4.7 Data harmonisation efforts/extent

No data harmonisation efforts yet, except for the reports

3.4.8 Data availability

3.4.8.1 Public access to data

Public access to evaluations of rural development programmes

3.4.8.2 Host of data repository at EU level

No data repository specified

3.4.8.3 Availability of data

Starting from 2010 until 2015.

3.5 Pan-European Common Bird Monitoring Scheme (PECBMS)

3.5.1 General information of monitoring programme

3.5.1.1 Aim of monitoring programme

Monitoring the state of Europe's common birds. The main aim of the scheme is to use common birds as indicators of the general state of nature, using scientific data on changes in breeding populations across Europe.

3.5.1.2 Year of commencement

Programme was started in January 2002.

3.5.1.3 Implementation of programme

First phase of the project: in 2003, 18 countries supplied information on 24 common farmland birds (Gregory *et al*., 2005[11]).
Second phase of the project: in 2007, 20 countries supplied information on 124 common bird species (PECBMS, 2007[12]).

3.5.2 Observed features/indicators

3.5.2.1 Type of features/indicators observed

The indicators observed are a group of birds:
- common farmland birds (33)
- common forest birds (28)
- habitat generalists or specialists of other habitat types (such as urban habitats) (63)

3.5.2.2 Criteria for selection of features/indicators

In total 124 bird species are selected for observation. Selection was based on species being (1) abundant and widespread (> 50.000 breeding pairs) and (2) characteristic of farmland or forest (or common generalist) - characteristic species are those where > 50% of the regional population utilises a particular habitat for breeding or feeding.

3.5.3 Observed areas

3.5.3.1 Land surface types

All sites from national count schemes are selected for observation, including European farmland (agricultural land and farmland) and woodland (including woods, parks and gardens).

3.5.3.2 Biogeographic regions

Observations are done within the biogeographic regions: Atlantic, boreal, continental and Mediterranean.

3.5.3.3 Total area for which conclusions are drawn

20 European countries are organised in PECBMS in 2007.

3.5.4 Sampling/observation design

3.5.4.1 General approach of sampling/observation design

There is no standardised sampling design applied across European States. Some of them use a stratified random design.

3.5.4.2 Frequency of sampling/observation

Observations are carried out annually (between 1 to 12 visits to each site per year)

3.5.4.3 No. of sampling/observation sites

[11] Gregory, R.D., van Strien, A., Vorisek, P., Gmelig Meyling, A.W., Noble, D.G., Foppen, R.P.B and Gibbons, D.W. (2005) Developing indicators for European birds. Phil. Trans. R. Soc. B., 360, 569-288.
[12] PECBMS (2007) State of Europe's Common Birds, 2007. CSO/RSBP, Prague, Czech Republic, 2007.

Survey plots tend to be widely distributed at national level, covering many bird species and habitats with reasonable representation.

3.5.4.4 Representativeness of no. of sampling/observation sites

More or less representative for the participating 20 EU countries

3.5.4.5 Size of sampling/observation sites

It is more or less harmonised

3.5.4.6 Sampling sites vary or remain constant in time

Sampling sites remain constant in time.

3.5.5 Methodology of data coordination

The PECBM scheme uses data from large-scale monitoring schemes based on volunteer fieldwork. Not the raw data, but national processed data computed with standard software, are collected by the PECBMS.

3.5.6 Data analysis

3.5.6.1 Aim of data analysis

Analysis of common European bird species trends.

3.5.6.2 Type of data analysis

The computer package TRIM (TRends and Indices for Monitoring data; http://www.ebcc.info/trim.html). It is used to calculate national species indices and to combine these in supranational indices for each species. It analyses time-series of counts with missing observations using Poisson regression. Supranational indices are then combined to create indices for groups of species (indicators).

3.5.6.3 Baseline/threshold values

The baseline for most of the EU is the species occurrence in 1990.

3.5.7 Data harmonisation efforts/extent

3.5.7.1 Sampling or observation methods

The national schemes differ in methods and survey design (Gregory *et al.*, 2005). These differences do not influence supranational results because the indices are standardised before being combined.

3.5.7.2 Data quality management

Extended data quality control includes checks on whether data are available from countries and whether a species national index is representative of the national population. Similar checks have been performed at all other levels, including regional indicators.

3.5.7.3 Data coordination

The PECBM scheme collates national data from EU countries in a harmonised way.

3.5.8 Data availability

3.5.8.1 Public access to data

The yearly reports are publicly available on the website of the European Bird Census Council (EBCC: www.ebcc.info).

3.5.8.2 Host of data repository at EU level

PECBMS

3.5.8.3 Availability of data

Information on species-specific national population sizes for a particular year from 2003 on can be obtained from the European Bird Database (www.ebcc.info).

4 Existing Data Infrastructure Schemes in the EU relevant for GMO monitoring data

4.1 European Environment Information and Observation Network (EIONET)

4.1.1 General information of the data infrastructure scheme

4.1.1.1 Aim of EIONET

EIONET is a partnership network of five European Topic Centres (ETCs) designated by the EEA and national membership institutions (ca. 900 experts from 37 countries in over 300 national environment agencies and other bodies dealing with environmental information). It aims to provide timely and quality-assured data, information, and expertise for assessing the state of the environment in Europe.

4.1.1.2 Commencement of EIONET

EIONET was established in 1994.

4.1.1.3 Implementation stage of EIONET

Implemented

4.1.2 Covered features/indicators

4.1.2.1 Type of features/indicators covered

The EEA reports on a Core Set of 30 (mostly aggregated) environmental Indicators (CSI[13]). The indicators are observed by topic and coordinated by five ETCs covering
a) air quality, emissions and climate change greenhouse gases,
b) water (nutrients, water quality),
c) the terrestrial environment (agriculture, land use and cover, soil),
d) waste and material flows, and
e) nature protection and biodiversity (species diversity, threatened species and protected areas).
Some of the ETCs are working under Directives covered in chapter 3.

4.1.2.2 Criteria for selection of features/indicators

The EEA has defined the DPSIR (Driving forces - Pressure - State - Impact – Response) framework to assist in the development of indicators. The indicators shall provide policy relevant information on Europe's terrestrial environment and enable to review and evaluate the effectiveness of existing policies. Other criteria are analytical soundness and measurability.

4.1.2.3 Interval for updates

Varies depending on indicators covered and reporting obligation frequency.

[13] http://themes.eea.europa.eu/IMS/CSI

4.1.3 Covered areas

4.1.3.1 Land surface types

All types

4.1.3.2 Biogeographic regions

All European biogeographic regions

4.1.3.3 Total area

EU

4.1.4 Methodology of data coordination

For information flow to the EEA the 'Reportnet' is used which is a group of web applications and processes developed by the EEA to support international environmental reporting. Each EEA-MS has designated an institution, the so-called National Focal Point (NFP) that coordinates the collection of environmental information at national level and one National Reference Centre (NRC) for each of the five environmental topics.

4.1.5 Data analysis

The EEA collates and analyses the majority of data sets.

4.1.6 Data harmonisation efforts/extent

4.1.6.1 Sampling or observation methods

The harmonisation of sampling methodologies is regarded as necessary by EIONET: there is a continuing harmonisation process.

4.1.6.2 Data quality management

Data quality is assured due to national validation and due to the high input standards set by the EEA. EEA uses ISO19113 quality assessments for geospatial data.

4.1.6.3 Data coordination

EIONET uses the DublinCore Metadata Element Set to describe the data, but it also uses EIONET specific metadata elements. EIONET provides an extensive information technology infrastructure (referred to as e-EIONET) for coordinating data. Software, data structures, and exchange formats are standardised.

4.1.7 Data availability

4.1.7.1 Public access to data

The EEA services, data sets and reports are open to the public. However, for some data sets the access is restricted to public authorities such as the NFPs and the NRCs.

4.1.7.2 Host of data repository at EU level

The EEA.

4.1.7.3 Temporal availability of data

Spatial data sets of some features extend back many years before the establishment of EIONET in 1994.

4.2 Infrastructure for Spatial Information in the European Community (INSPIRE)

4.2.1 General information of the data infrastructure scheme

4.2.1.1 Aim of INSPIRE

INSPIRE[14] is an EU initiative under Directive 2007/2/EC establishing an Infrastructure for Spatial Information in the European Community with the aim to create a European geodatabase with integrated spatial information services.

4.2.1.2 Commencement of INSPIRE

The INSPIRE Directive entered into force in 2007.

4.2.1.3 Implementation stage of INSPIRE

Later stage: The process for developing the INSPIRE Directive took six years until 2007. Implementing rules are to be adopted by the MS in 2008. Commencement of operating metadata will be 2010 for Annex I and II themes (basic information and geodata already existing) and 2013 for Annex III themes (special geodata).

4.2.2 Covered features/indicators

4.2.2.1 Type of features/indicators covered

Annex I – III of the Directive 2007/2/EC lists the features (themes) addressed, for instance land cover, soil, land use, environmental monitoring facilities, biogeographic regions, habitats and biotopes, species distribution.

4.2.2.2 Criteria for selection of features/indicators

Availability of spatial data

4.2.2.3 Interval for updates

Varies depending on features covered.

4.2.3 Covered areas

4.2.3.1 Land surface types

All types

4.2.3.2 Biogeographic regions

All biogeographic regions

4.2.3.3 Total area

EU

[14] http://www.ec-gis.org/inspire/

4.2.4 Methodology of data coordination

Within the MS a contact point (authority) having the appropriate infrastructure must be designated for coordinating the information flow across the different governmental levels. Data sets are stored locally in the MS. The same contact point forwards information from the MS to the EIONET, using the EEA Reportnet standards. At EU level the Commission is responsible for data coordination.

4.2.5 Data analysis

Not foreseen within the INSPIRE services

4.2.6 Data harmonisation efforts/extent

4.2.6.1 Sampling or observation methods

It is not the intention of INSPIRE to harmonise sampling methodologies for the data sets. However, there is a continuing process for harmonising the various INSPIRE themes to be covered.

4.2.6.2 Data quality management

MS must provide metadata of high quality and metadata must contain information on the quality of the spatial data sets. Metadata are implemented according to ISO norms.

4.2.6.3 Data coordination

Harmonising data coordination is the main objective of INSPIRE. Data services and networks are established using common interfaces according to ISO norms. The frequency of updating spatial data sets shall be harmonised.

4.2.7 Data availability

4.2.7.1 Public access to data

The INSPIRE services shall be available to the public. However, some data sets will be restricted to public authorities where international relations, intellectual property rights, confidentiality of personal data, protection of the environment etc. may be affected.

4.2.7.2 Host of data repository at EU level

The EEA (EIONET).

4.2.7.3 Temporal availability of data

Metadata of the various features will be available from 2010 but can extend back many years.

4.3 Regulatory Information Systems in the context of GMOs under 2001/18/EC

4.3.1 General information of the data infrastructure scheme

4.3.1.1 Aim of regulatory information systems

Directive 2001/18 specifies the obligation to exchange and publish information related to the authorisation of GMOs between the European Commission, the MS and the public. The RIS[15] provides complete workflow and document management during the lifecycle of a GMO authorisation.

4.3.1.2 Commencement of regulatory information systems

The RIS commenced in 2003

4.3.1.3 Implementation stage of regulatory information systems

Later stage: test phase

4.3.2 Covered features/indicators

4.3.2.1 Type of features/indicators covered

The GMO Register will contain various types of information from the notification of a GMO (see Commission Decision 2004/204/EC[16]), for instance details concerning the notifier, general information on the GMO, detection methods, and supply of samples. The GMOREGEX will contain all information related to the workflow of the GMO authorisation process, for instance the dossiers, the consent by the lead CA, the Commission Decision and time-related actions.

4.3.2.2 Criteria for selection of features/indicators

Not applicable

4.3.2.3 Interval for updates

Varies depending on respective step in the notification process

4.3.3 Covered areas

4.3.3.1 Land surface types

None

4.3.3.2 Biogeographic regions

None

4.3.3.3 Total area

EU

[15] The RIS includes the informatioin systems GMOREGEX (http://bgmo.jrc.ec.europa.eu/home/ict/gmoregex.htm) and the the Directive 2001/18 GMO Register project (http://bgmo.jrc.ec.europa.eu/home/ict/dir-2001-18.htm).

[16] Commission Decision 2004/204/EC of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council

4.3.4 Methodology of data coordination

The GMORegIS (GMO Regulatory Information Systems) portal developed by the Joint Research Centre (JRC) provides the central access point. The CAs provide the information via a data interface to the GMO Register which collects the metadata and publishes non-confidential data on the internet (http://biotech.jrc.it).

4.3.6 Data analysis

The GMOREGEX system provides tools for analysis and statistical reports on the contents of the GMO Register.

4.3.6 Data harmonisation efforts/extent

4.3.6.1 Sampling or observation methods

Not applicable

4.3.6.2 Data quality management

Applicants must provide standardised information and metadata for the summary notification information format (SNIF) according to Commission Decision 2002/813/EC[17] and for the GMO Register according to Commission Decision 2004/204/EC.

4.3.6.3 Data coordination

Data coordination is fully harmonised, since one central metadata portal is used (GMO-RegIS). Workflow management is automated. The Dublin Core standards for the GMOs (thesaurus for metadata) are used. The GMORegIS is fully interoperable concerning semantic, syntax and transfer/communication protocol.

4.3.7 Data availability

4.3.7.1 Public access to data

The RIS shall be available to the public, as well as to MS and the Commission. The RIS will contain two sets of data, one accessible to the public and the other accessible only to the MS, the Commission, and EFSA.

4.3.7.2 Host of data repository at EU level

JRC of the European Commission in Ispra.

4.3.7.3 Temporal availability of data

Metadata sets will extend back to 1991.

[17] Council Decision 2002/813/EC of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market

4.4 EU-wide monitoring methods and systems of surveillance for species and habitats of Community interest (EuMon)

4.4.1 General information of the data infrastructure scheme

4.4.1.1 Aim of EuMon

EuMon[18] is a research consortium under the Sixth Framework Programme for coordination and standardisation of biodiversity monitoring across Europe. EuMon provides a European-wide database of already existing biodiversity monitoring programmes and methods for species and habitats of Community interest. The long-term objective is to enable wide access to data and to come to a harmonised approach towards long-term indicator-based monitoring in Europe. Monitoring data are not collected.

4.4.1.2 Commencement of EuMon

The project commenced in 2004. In 2006 an internet database of European species and habitats monitoring regimes was launched that is successively complemented.

4.4.1.3 Implementation stage of EuMon

Later stage: To date information from 552 monitoring schemes are available extending to 402 species and 150 habitats. The final project report to the EU with recommendations for application of common standards for monitoring designs and methodologies will be in August 2008.

4.4.2 Covered features/indicators

4.4.2.1 Type of features/indicators covered

Species and habitats preferably of community interest (Birds Directive and Habitats Directive).

4.4.2.2 Criteria for selection of features/indicators

Availability of monitoring programmes and methods.

4.4.2.3 Interval for updates

The EuMon metadata are continuously updated.

4.4.3 Covered areas

4.4.3.1 Land surface types

All types

4.4.3.2 Biogeographic regions

All biogeographic regions

4.4.3.3 Total area

EU

[18] http://eumon.ckff.si/index1.php

4.4.4 Methodology of data coordination

The project is coordinated at the Centre for Environmental Research UFZ-Leipzig-Halle. 15 partners from different MS provide deliverables to EuMon. Data sets on existing monitoring programmes are stored at the Centre for Cartography of Fauna and Flora, Slovenia.

4.4.5 Data analysis

Not foreseen in EuMon.

4.4.6 Data harmonisation efforts/extent

4.4.6.1 Sampling or observation methods

The aim of EuMon is to describe how monitoring methods can beharmonised. There is no continuing process for harmonisation.

4.4.6.2 Data quality management

The contributors to the database have to provide precise metadata (40-50 items) on existing monitoring programmes.

4.4.6.3 Data coordination

Only metadata on existing monitoring programmes are coordinated. The information system uses common interfaces.

4.4.7 Data availability

4.4.7.1 Public access to data

An internet database of monitoring schemes is publicly available [19].

4.4.7.2 Host of data repository at EU level

Centre for Cartography of Fauna and Flora, Slovenia.

4.4.7.3 Temporal availability of data

The database only includes existing monitoring programmes some of which may store data sets extending back many years.

[19] http://eumon.ckff.si/monitoring/search.php

5 Overall evaluation of existing monitoring programmes and data infrastructure schemes

5.1 Agro-environmental monitoring programmes

Five existing European agro-environmental monitoring programmes have been studied for purposes of their evaluation for their potential usefulness in monitoring of GMOs. These include monitoring under

- The Habitats Directive,
- The Water Framework Directive (WFD),
- The Birds Directive,
- The Council Regulation on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and
- Birds in the framework of the Pan-European Common Bird Monitoring Scheme (PECBMS).

Table 1 presents an overview of this evaluation.

5.1.1 Monitoring under the Habitats Directive

The features observed under the Habitats Directive, which are the conservation status of predefined natural habitats and species in the EU, could partly be of use for GMO monitoring. Guidance is provided on how to set up the monitoring sampling/observation design and data evaluation. Statistics for the raw data collected are not yet developed. No standardised methodologies are recommended. National data are reported to the Commission every six years by the use of a standard format and stored on EIONET. The 2007-2012 report will, for the first time include an evaluation (without monitoring data) of the conservation status of habitats and species. It is not yet clear whether and to what extent the national raw data are accessible.

5.1.2 Monitoring under the Water Framework Directive (WFD)

Some of the river quality elements (e.g. biological elements) monitored under the WFD could be useful in the context of GMO monitoring. Guidance on how to set up the monitoring sampling/observation design and data analysis is provided. Although it is recommended to use standardised methodologies, only few are used within the MS. Techniques for statistical analysis of raw data are developed. Raw data are collected and processed at national level. Aggregated national monitoring data are reported to the EEA using EEA reporting standards every six years and stored on EIONET. Monitoring data have been made available since 2007. Access to national raw data is restricted, but can be obtained on request.

5.1.3 Monitoring under the Birds Directive

The monitoring of birds - with focus on protection areas - under the Birds Directive could partly be of use for GMO monitoring. Little information is available on sampling/observation designs used and on data analysis carried out. Raw data have been collected at national level since 1982 and reported every 3 years to the Commission. There is no access to raw data.

5.1.4 Monitoring under the European Agricultural Fund for Rural Development (EAFRD)

Monitoring under the EAFRD has a strong focus on agricultural land. The highly aggregated indicators that are monitored are only of minor relevance for GMO monitoring, except for the

population of farmland birds. The implementation of the monitoring programme is still at an initial stage. No information is available on sampling/observation designs to be used and on data analysis done. Reports (without monitoring data) will become available every two years from 2010 till 2014.

5.1.5 Monitoring under Pan-European Common Bird Monitoring Scheme (PECBMS)

The monitoring of birds under the PECBMS could partly be of use for GMO monitoring. For the PECBMS, raw data are collected and processed at national level. Standardised sampling methods and statistics (TRIM programme) are used to process the data. Although different sampling/observation methodologies are used within the MS under PECBMS, overall analysis of the national data is still possible. Aggregated national monitoring results have been made available annually at the EBCC (European Bird Census Council) website since 2003.

5.2 Data infrastructure schemes

Four European data infrastructure schemes have been studied and evaluated with respect to their relevance to GMO monitoring. These are

- the European Environment Information and Observation Network (EIONET),
- the Infrastructure for Spatial Information in the European Community (INSPIRE),
- the Regulatory Information Systems (RIS) in the context of GMOs under Directive 2001/18, and
- EuMon, which is a project under the Sixth Framework Programme.

Table 2 presents an overview of this evaluation.

5.2.1 European Environment Information and Observation Network (EIONET)

The EIONET of the EEA is the most developed and readily available information system for environmental data coordination at EU level. It consists of a network of so-called National Focal Points that coordinate the collection of environmental information at national level to be reported to the EIONET using harmonised data sets and reporting procedures. It stores various existing environmental data dating back many years. It will incorporate data from monitoring under the Habitats Directive, the Water Framework Directive and other EU reporting obligations. In addition, it includes data quality management and interoperability with MS information systems. EIONET is considered most appropriate for the coordination and harmonisation of GMO monitoring data.

5.2.2 Infrastructure for Spatial Information in the European Community (INSPIRE):

INSPIRE is an EU initiative establishing an infrastructure for harmonised spatial information available in the MS. Many spatial data of monitored indicators harmonised within INSPIRE are relevant to GMO monitoring. INSPIRE if functional will include the highest standards with regards to data harmonisation in the EU. It is both technically and with regards to content, interlinked with EIONET. It is intended to harmonise monitoring data from the WFD and the Habitats Directive. In the EU the INSPIRE approach is unique. The INSPIRE data harmonisation and administrative implementation procedure including the administrative network, can be taken as an example as to how GMO monitoring data may be coordinated and harmonised. Specific GMO monitoring data have been included for harmonisation under

the INSPIRE framework and are currently part of the INSPIRE data sets that have to be specified in more detail.

5.2.3 Regulatory information systems (RIS) in the context of GMOs under Directive 2001/18

The RIS provide an EU-wide functional GMO-related infrastructure. The RIS are optimised with regard to data interoperability (semantic, syntax and data transfer). The RIS if functional will provide compulsory elements during the authorisation process of GMOs and will contain the entire workflow information for all involved stakeholders from the start of the application until the approval. However, the RIS are not designed to include GMO monitoring data. For the process of GMO monitoring, data coordination and harmonisation linkages and potential amendments to the RIS especially with regard to the workflow could be made.

5.2.4 EU-wide monitoring methods and systems of surveillance for species and habitats of Community interest (EuMon)

The EuMon research project is in the process of establishing an EU-wide database on existing biodiversity monitoring programmes across Europe. The aim of EuMon is to induce a harmonised approach towards long-term indicator-based monitoring in Europe with a particular focus on biodiversity. The aim thus corresponds to the coordination and harmonisation requirements of GMO monitoring. EuMon is the most extensive information platform of programmes that may be involved in GMO monitoring at both national and EU level. Focussing primarily on wild habitats and species, however, it is not all-encompassing in terms of indicators relevant for GMO monitoring.

Table 1: Evaluation of agro-environmental monitoring programmes in the EU

	Applicability for GMO monitoring (+partly applicable, +- potentially applicable, - not applicable*)				
	Habitats Directive	WFD	Birds Directive	EAFRD	Monitoring of Birds
General information of the monitoring programme					
aim of monitoring programme	+	+	+	+-	+
commencement of monitoring programme	-	-	-	-	-
implementation stage of monitoring programme	+-	+-	+	-	+
Observed features/indicators					
type of features/indicators observed	+	+	+	+-	+
criteria for selection of features/indicators	+	+	-	-	+
Observed areas					
land surface types	+	+-	+	+	+
biogeographic regions	+	+	+	+	+
total area	+-	+-	+-	+	+
Sampling/observation design					
general approach of sampling/observation design	+	+	-	-	+
frequency of sampling/observation	+	+	+-	+-	+
no. of sampling/observation sites	+	+	+-	+-	+
representativeness of no. of sampling/observation sites	+	+	-	+-	+-
size of sampling/observation sites	+	+	+-	-	+-
constant or variable sampling/observation sites	+	+	+-	+-	+
Methodology of data coordination	+	+	-	+-	+-
Data analysis					
aim of data analysis	+	+	-	-	+
type of data analysis	+-	+	-	-	+
baseline/threshold values	+	+-	-	-	+
Data harmonisation efforts/extent					
sampling or observation methods	-	+-	-	-	+
data quality management	+-	+-	-	-	+

data coordination	+	+	-	+-	+
Data availability					
public access to data	+-	+-	+-	+-	+-
host of data repository at EU level	+	+	-	-	+
temporal available data	+-	+-	-	-	+

* + partly applicable, with minor changes; +- potentially applicable in the future either with or without considerable changes; - not relevant or not possible to adapt to GMO monitoring

Table 2: Evaluation of existing platforms and data infrastructure schemes in the EU

	Applicability for GMO monitoring (+partly applicable, +- potentially applicable, - not applicable*)			
	EIONET	INSPIRE	GMO regulatory inform. systems	EuMon
General information of the data infrastructure scheme				
aim of data infrastructure scheme	+	+	+	+
commencement of the data infrastructure scheme	-	-	-	-
implementation stage of scheme	+	+-	+-	+-
Observed features/indicators				
type of features/indicators observed	+	+	+-	+
criteria for selection of features/indicators	+	+-	+-	+-
interval for updates	+-	+-	+	+-
Observed areas				
land surface types	+	+	-	+
biogeographic regions	+	+	-	+
total area	+	+	-	+
Methodology of data coordination	+	+	+-	+-
Data analysis	+	-	-	-
Data harmonisation efforts / extent				
sampling or observation methods	+-	+-	-	+-
type of data analysis	+	+	+	+-
baseline/threshold values	+	+	+	+-

Data availability				
public access to data	+-	+-	+	+-
host of data repository at EU level	+	+	+	+-
temporal available data	+	+-	+-	+

* + partly applicable with minor changes; +- potentially applicable in the future either with or without considerable changes; - not relevant or not possible to adapt to GMO monitoring

6 Implementation of GMO monitoring data coordination and harmonisation in the MS and the EU

Five EU-wide agro-environmental monitoring programmes and four infrastructure schemes have been studied in order to elaborate on the implementation of a combination of national and EU-wide GMO monitoring information systems.

At EU level the monitoring activities under the WFD, the Habitats Directive and the PECBMS have been identified as being the most relevant for GMO monitoring given their aim, indicators observed, methods and spatio-temporal design for data collection, data analysis, data storage and data exchange facilities (see chapter 5).

These three EU-wide agro-environmental monitoring programmes predominantly use specific national monitoring methodologies and designs, which make an intercalibration of the collected data at EU level difficult. However, higher levels of data aggregation, intercalibration is still possible, since national monitoring methodologies are well described and the finally reported data are required to be comparable and compatible in order to allow analysis at EU scale. Furthermore, the process of data coordination under the WFD and Habitats Directive can be taken as an example of how monitoring activities at national level can be integrated within a monitoring design covering several or all European MS. Besides the obligation to report at national level, the nationally collected monitoring data is provided to a European infrastructure scheme. Under the PECBMS, data are collected and hosted by PECBMS itself. Data collected nationally under the WFD and the Habitats Directive are integrated into EIONET by the use of a standardised reporting format. EIONET is the central European focal point for a number of environmental monitoring reporting obligations and hosts the most developed data coordination scheme.
More in depth evaluation is required to determine the overall information value of these programmes for GMO monitoring purposes, since at present no agro-environmental monitoring programme is fully applicable for GMO monitoring. For instance, no raw data are provided yet on a regular basis at EU level and the monitored areas of the agro-environmental monitoring programmes will overlap only partially with areas cultivated with GMOs.
Hence, in the EU there is an existing network of both agro-environmental monitoring programmes and infrastructure schemes for coordinating monitoring data that to some extent could be applicable for GMO monitoring (see Figure 1 for their interrelationship). However, while most of the infrastructure schemes are already fully operational at EU level, most of the monitoring programmes are still in the process of implementation.

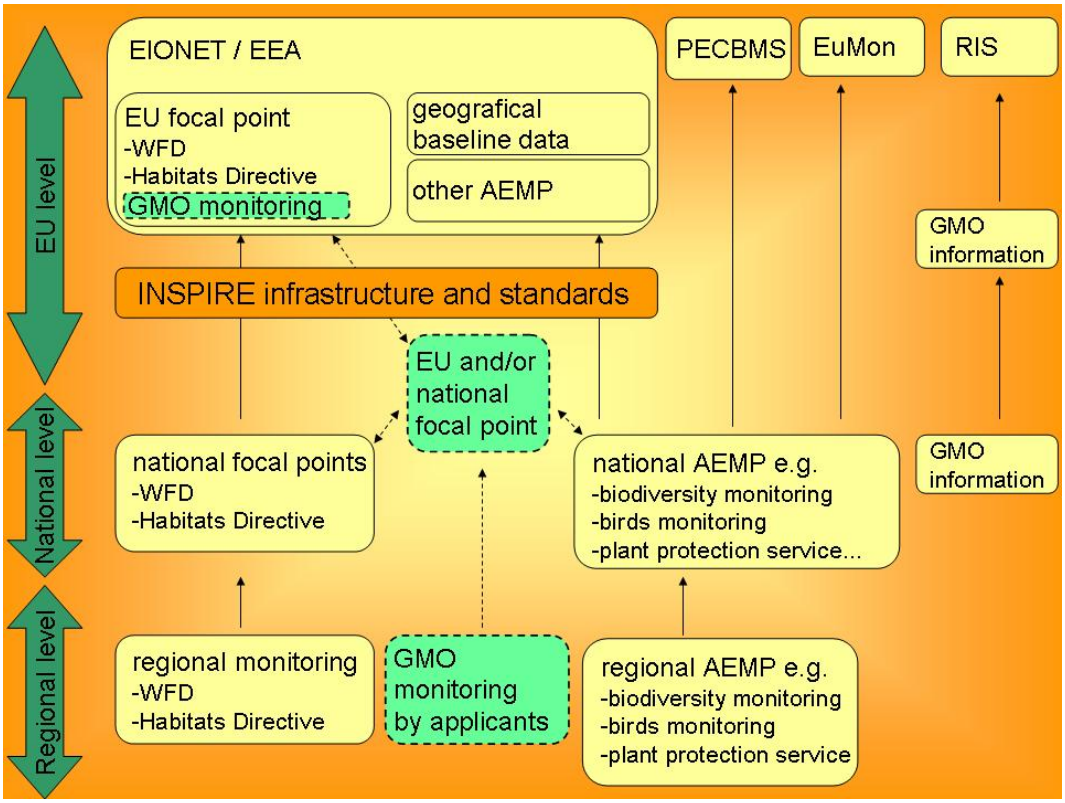

Figure 1: Interrelationships between existing EU-wide agro-environmental monitoring programmes and infrastructure schemes relevant to GMO monitoring and proposed structure for GMO monitoring data coordination

While individual efforts are undertaken by the EU-wide monitoring programmes and infrastructure schemes to harmonise their approaches, additional efforts are being undertaken at EU level to achieve harmonisation of monitoring data. In this context, EuMon and particularly the INSPIRE process are of importance. EuMon envisages harmonised approaches at the level of methods and data coordination to be used for long-term biodiversity indicator-based monitoring and access to data; INSPIRE aims at harmonising spatial data sets in the EU (including data collected under the WFD, the Habitats Directive and for the GMO monitoring). Spatial data harmonised under INSPIRE will also be coordinated and hosted by the EIONET.

On the basis of the study done, the MWG is of the opinion that an implementation of both national and EU-wide GMO monitoring activities in parallel is feasible, if this system is integrated into or makes use of a similar approach as the existing EU-wide network of programmes and infrastructure schemes involved in agro-environmental monitoring. The current infrastructure scheme of EIONET is most appropriate for this aim. The setting up and implementation of such a GMO monitoring system (preferably, including monitoring activities carried out by the notifiers as national and EU-wide agro-environmental monitoring programmes only partly cover GMO monitoring features), will need further administrative and scientific consultation. For example, the applicability and potential adaptation of the existing national and EU-wide monitoring programmes (e.g. in terms of observed features/indicators and methods) to meet the requirements for GMO monitoring, will need some further thought. Therefore, the MWG is of the opinion that a scientific consultation process is required to discuss the coordination and harmonisa-

tion of GMO monitoring data, access to raw data, data collection methods, spatio-temporal design for data collection, data quality, data storage and analysis as well as reporting formats for data exchange within the EU with the aim of achieving EU-wide standards. This scientific consultation process could be largely integrated with and follow similar coordination and harmonisation procedures as of INSPIRE, EIONET, WFD and Habitats Directive. These coordination and harmonisation procedures established over the years include regular meetings of the MS and the Commission responsible, the buildup of technical and staff infrastructure, and the work on documents providing common guidance to the stakeholders.
When initiating this process, administrative aid, funding and legal matters such as obligations to use technical and scientific standards, will also need to be considered. For example, the data coordination approach of EIONET using EU and national focal points for storing the GMO monitoring data and reports could be adopted. National and/or European bodies could then be responsible for the collation of GMO monitoring data from the applicants, of third parties and from existing monitoring programmes (Figure 1) and report to the EIONET. Therefore, the MWG recommends to specify in greater depth the details of and the conditions to participate in or make use of the existing monitoring programmes and infrastructure schemes in the EU.

7 Recommendations[20]

We recommend the establishment of a system for coordinating GMO monitoring data. This system could be based on the approaches used for monitoring under the WFD and the Habitats Directive as well as for data coordination under EIONET.

The following constitutes the next steps towards achieving this:

1. Consultation with existing monitoring/data coordination systems under the WFD, Habitats Directive and EIONET in order to determine in greater depth if monitoring programmes and infrastructure schemes already in use in the EU may be used for purposes of GMO monitoring and what elements would be required to contribute to GMO monitoring.

2. A common strategy and time schedule for implementing the process of GMO monitoring data coordination and harmonisation should be elaborated and agreed. The present administrative implementation procedure of INSPIRE should be considered as to how this process may take place.

3. A scientific consultation process is required to discuss coordination and harmonisation of GMO monitoring data, monitoring plans, methods, spatio-temporal design for data collection, data quality, data storage, data analysis and data exchange within the EU with the aim of establishing guidelines for a harmonised common approach for the MS.

4. The coordination and harmonisation of GMO monitoring data requires detailed legal obligations at the EU level for the involved stakeholders to participate in this process

Other aspects to be considered at an early stage will be costing, source of funding and administrative aid of the implementation process. Possible funding could be obtained from the budget of the IDA (Interchange of Data between Administrations). [21]

[20] Note: These recommendations form one package and should not be addressed one by one.

[21] IDA = Interchange of Data between Administrations: IDA is a European Commission driven strategic initiative using advances in information and communications technology to support rapid electronic exchange of information between Member State administrations. The objective is to improve Community decision-making, to facilitate operation of the internal market and to accelerate policy implementation.

Acronyms

CA	Competent Authority
DPSIR	Driving forces - Pressure - State - Impact – Response
EAFRD	European Agricultural Fund for Rural Development
EBCC	European Bird Census Council
EEA	European Environmental Agency
EFSA	European Food Safety Authority
EIONET	European Environment Information and Observation Network
ETC	European Topic Centre
EU	European Union
EuMon	EU-wide monitoring methods and systems of surveillance for species and habitats of Community interest
GMO	Genetically Modified Organism
GMORegIS	GMO Regulatory Information System
INSPIRE	Infrastructure for Spatial Information in the European Community
ISO	International Organisation for Standardisation
JRC	Joint Research Centre
LMO	Living Modified Organism
MS	Member States
MWG	Monitoring Working Group
NFP	National Focal Point
NRC	National Reference Centre
OECD	Organisation for Economic Co-operation and Development
PECBMS	Pan-European Common Bird Monitoring Scheme
RBD	River Basin District
SDIC	Spatial Data Interest Community
SNIF	Summary Notification Information Format
TRIM	TRends and Indices for Monitoring data
WISE	Water Information System for Europe
WFD	Water Framework Directive