



National Institute for Public Health  
and the Environment  
*Ministry of Health, Welfare and Sport*

The background of the cover is a photograph of a traditional Dutch windmill with a stone body and wooden lattice sails. The windmill is situated on a grassy hill. In the foreground, there is a vast field of bright yellow rapeseed flowers. Several young trees with green leaves are scattered around the base of the windmill. The sky is a pale blue with some light clouds.

# General Surveillance of genetically

**General Surveillance of genetically modified plants**

*Possibilities for implementation in the Netherlands*



National Institute for Public Health  
and the Environment  
*Ministry of Health, Welfare and Sport*

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Possibilities for implementation in the Netherlands

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## Colophon

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## **Abstract**

### **General Surveillance of genetically modified plants in the Netherlands**

European legislation stipulates that the commercial cultivation of genetically modified (GM) crops should be monitored (General Surveillance, GS) to check whether unexpected, adverse effects on the environment could occur. The general idea in the EU is that the focus of GS should be on aspects such as biodiversity and a healthy soil. Since unexpected effects are difficult to track, it has not been clear how GS should be set up. Therefore, initially, GS will make use of already existing monitoring networks.

### **Suitable networks**

Within this context, the RIVM investigated which networks could be used for the general surveillance of genetically modified crops in the Netherlands. These were the Ecological Monitoring Network that follows the development of flora and fauna in the Netherlands, and the Biological Indicator System of Soil Quality that keeps track of soil quality. In addition, satellite observations can be used to detect changes in vegetation. It is possible that GM crops will be cultivated on a commercial scale in the Netherlands in the near future.

### **Research method**

This research was commissioned by the Dutch Ministry of Infrastructure and the Environment, and offers guidance with regard to existing networks. Firstly, existing networks in the Netherlands were systematically documented. Thereafter, they were examined based on criteria that ensures the long-term collection of reliable and relevant data for GS on biodiversity and soil quality. Subsequently, the possibilities of detecting unexpected environmental effects through GS was investigated. The report drawn up from this research can also be used to set up a GS system in other EU member states, or to come to an integrated European GS system.

#### **Keywords:**

Post-market monitoring, General Surveillance, genetically modified crops, GMO's, monitoring networks



## Rapport in het kort

### General Surveillance van genetisch gemodificeerde planten in Nederland

Volgens Europese regelgeving is het nodig om te monitoren of commerciële teelt van genetisch gemodificeerde gewassen onverwachte, schadelijke effecten heeft op het milieu (General Surveillance, GS). Het algemene idee in de EU is dat de nadruk ligt op het behoud van bijvoorbeeld biodiversiteit en van een gezonde bodem. Aangezien onverwachte effecten moeilijk op te sporen zijn, is het niet duidelijk hoe GS vorm moet krijgen. Daarom wordt in eerste instantie aangesloten bij bestaande monitoringnetwerken.

### Geschiede netwerken

In dat verband heeft het RIVM onderzocht welke van deze monitoringnetwerken geschikt zijn voor General Surveillance van genetisch gemodificeerde planten in Nederland. Dat blijken vooral het Netwerk Ecologische Monitoring, dat de ontwikkeling van de Nederlandse flora en fauna in kaart brengt, en het Bodembioologische Indicator systeem, dat de bodemkwaliteit volgt. Daarnaast kunnen satellietbeelden worden gebruikt om veranderingen in vegetatie aan te tonen. Mogelijk worden in Nederland in de nabije toekomst genetisch gemodificeerde planten op commerciële schaal geteeld.

### Werkwijze onderzoek

Het onderzoek is uitgevoerd in opdracht van het ministerie van Infrastructuur en Milieu (IenM) en biedt handvatten voor keuzes tussen de netwerken. Hiervoor zijn eerst bestaande monitoringnetwerken in Nederland geïnventariseerd. Daarna zijn deze getoetst aan criteria die er zorg voor dragen dat de netwerken over een lange periode betrouwbare data voor GS verzamelen, die betrekking hebben op de biodiversiteit en een gezonde bodem. Daarna is getoetst of met de GS daadwerkelijk schadelijke milieueffecten opgespoord zouden kunnen worden. Het rapport kan ook worden gebruikt om een GS-systeem in andere EU landen op te zetten, of voor een geïntegreerd EU-systeem.

### Trefwoorden:

Post-market monitoring, General Surveillance, genetisch gemodificeerde planten, GGO's, monitoring netwerken



## Preface

This report reflects the research and discussions that have taken place in the Netherlands from 2007 till this moment on the subject of General Surveillance (GS) and the potential implementation of GS in the Netherlands.

The research projects that are described in this report have been commissioned by the RIVM (SOR project EIA, within the framework of S/607001/001/EE) and by the Ministry of Infrastructure and the Environment.

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## Summary

When GM crops are commercially cultivated, under EU Directive 2001/18/EC, a General Surveillance (GS) system has to be in place in order to be able to detect any unexpected adverse effects of genetically modified (GM) crops, i.e. that were not predicted in the risk assessment of the GM plant. However, no predetermined focus, clear monitoring goals, or precise indications have been set about what to survey in GS. Furthermore, direct and indirect effects may manifest themselves in the long or short term, including outside the GM cultivation area.

The holder is responsible for the GS of the cultivation areas - and a wider area - of GM plants (2001/18/EC). Outside the cultivation area of GM plants, e.g. at national level, it could be argued that the national competent authority also has a responsibility for GS. EU Directive 2001/18/EC and guidance by EFSA do not specify in detail how such a national GS system should be set up. It is suggested to make use of existing networks that were developed for other purposes. Detailed and practical plans for GS based on such networks are not yet in place. This report provides an overview of existing monitoring networks and other surveillance systems in the Netherlands together with a critical discussion of their potential use for GS.

This report can serve as a basis for the implementation of GS systems in the Netherlands, but could also be of use to other EU member states or to arrive at an integrated European GS system.



# 1 Introduction

The area cultivated with genetically modified (GM) crops in the world is increasing rapidly. In 2010, the total area amounted to 148 million hectares in 29 countries ([www.isaaa.org](http://www.isaaa.org)). The major part of these GM crops consists of herbicide-tolerant crops and insect-resistant crops that produce an insecticidal toxin from *Bacillus thuringiensis* (Bt). In Europe, there is public concern regarding the cultivation of GM crops. Partly due to this concern, it was decided that approved GM events should be subject to post-market monitoring in the EU.

Post-market monitoring consists of two types of monitoring: Case-Specific Monitoring (CSM) and General Surveillance (GS). CSM focuses on specific uncertainties identified in the environmental risk assessment (ERA) that may still exist after a decision has been taken, giving authorisation for cultivation, or which is intended to further confirm assumptions made in the environmental risk assessment of a specific GM plant. CSM is thus only required if such uncertainties have been identified in the environmental risk assessment and will not be required for each GM plant approved for cultivation. The aspects taken into account in the environmental risk assessment and how these relate to CSM and GS are described in more detail in the text box on page 8.

By contrast, each GM plant requires GS after authorisation is given for cultivation (and/or import and processing). GS is described in Annex VII to Directive 2001/18/EC as *'largely based on routine observation ('look-see' approach) and should be used to identify the occurrence of unforeseen adverse effects of the GMO or its use for human health and the environment that were not predicted in the risk assessment'* (EC, 2001). There is no scientific basis for the occurrence of such effects, but the possibility of their existence has been raised because they cannot be ruled out. GS is thus intended to meet the need to investigate the possibility of such unexpected effects occurring.

As GS is intended to observe the potential effects of GM plants that are unknown, and could not have been predicted, based on the risk assessment of the GM plant, GS does not have a predetermined focus and, in principle, does not relate to a specific GM-crop combination (Bartsch et al., 2006; Sanvido et al., 2005, 2007, 2009). If there were to be unforeseen effects of GM plants, these effects could become manifest in the long or short term, inside or (as a result of uncontrolled spreading of the GMO or its products) outside the GM cultivation area which may then be observed in either the 'above ground' ecosystem or in the 'below ground' soil ecosystem. Since GS does not have a predetermined focus, it is necessary to first define what needs to be protected, i.e. what the environmental protection goals are. It is clear that the protection goals to be met by GS are the same as the protection goals of the environmental risk assessment. In general, monitoring networks for the purpose of these protection goals, such as biodiversity, water or soil quality, are already in place. It has been suggested that these existing monitoring networks could be used for the purpose of GS (EC, 2002; COGEM, 2005; EFSA 2006, 2011), and in this report we will look at these monitoring networks.

### ***Environmental risk assessment of GMOs, Case-Specific Monitoring and General Surveillance***

Before a GM plant is approved for commercial cultivation, an assessment is made of potential environmental risks resulting from its cultivation. This environmental risk assessment (ERA) is based on data and tests supplied by the notifier, available scientific literature, expert knowledge and experience from previous GM cultivations. The ERA is case-by-case and the effects of the GM plant are compared with the effects of non-GM parental plants. The data requirements, aspects to be taken into account in the risk assessment, and the principles of this assessment are laid down in EU Directive 2001/18/EC (EC, 2001) and in the guidance of the European Food Safety Authority (EFSA, 2010). Aspects that are always considered in the environmental risk assessment of every GM plant include:

- the potential of the GM plant to become more persistent or invasive;
- the potential for outcrossing with wild relatives and potential adverse effects of the GM plants resulting from this outcrossing and their offspring;
- potential adverse effects on non-target organisms, including humans and animals; and
- potential adverse effects on biogeochemical cycles in the soil.

Cultivation will only be permitted where potential negative effects of the GM plant compared to those of the non-GM parental lines are considered to be negligible. With certain GM plants, uncertainties may remain in the ERA. This will depend on the specific crop/trait combination. In such cases, a case-specific monitoring plan *may* become a condition for the authorisation to cultivate in the EU. This plan specifically describes what information will be required to reduce the uncertainties and, consequently, what will be monitored, how this will be done, and over what period. General Surveillance does not depend on the outcome of the ERA and the specific crop/trait combination. Therefore a GS plan is *always* part of the authorisation.

Discussions on GS began in the Netherlands in 2005. Under Directive 2001/18/EC, the permit holder is responsible for GS. Further to the recommendations of COGEM (2005), the responsible Ministries in the Netherlands decided that - given the fact that GS does not have a predetermined focus - no new monitoring systems would be set up. Under Directive 2001/18/EC, there are important arguments for the competent authority (CA) to hold some responsibility for GS, especially when it concerns GS at national level. From a logical point of view, it was considered unreasonable to leave GS outside the cultivation area (e.g. at national level) to the permit holders. Effects could also occur in the long term, after areas have been cultivated with a number of different GM crops, from several different permit holders. Another argument was that GS should be carried out in an objective manner and over a longer period in order to detect changes in time, and would be better managed under the auspices of the CA.

This report reflects the discussions that have taken place in the Netherlands on the potential implementation of a GS system. Over the years, several recommendations or choices were made, some of which may seem arbitrary, but these were often made for practical reasons. The report tries to explain the rationale behind these decisions. The starting point was the development of a national GS system based on existing monitoring networks. Although there is, as yet, no commercial GM cultivation in the Netherlands, it was decided to start setting up such a GS system to obtain baseline data. The GS system was not considered a monitoring network specifically to find effects of GM plants, but rather as a general system that would be capable of detecting adverse effects, should they occur. Ideally, GS should function not only as a general warning system but, more specifically, as an early warning system.

The aim of this report is to examine the feasibility of using existing monitoring networks and other available data, or data sources developed for other purposes, for GS in the Netherlands. This report first describes the available networks in the Netherlands. Thereafter, it sets out the rationale for the use of these networks/systems for GS and how they can be adapted for GS. The report ends with suggestions on how to implement a GS system based on the networks analysed. The report's conclusions consider the feasibility of using these networks as part of a national GS system for the Netherlands. The report may also serve as a basis for the implementation of GS systems in other EU member states, or an integrated European GS system.





## 2 **Criteria for monitoring networks and other sources for GS**

A GS system should be based only on networks that meet certain criteria. These criteria are described below.

### **Criteria for networks to be suitable for GS**

#### ***Data collected by the networks should be relevant to GS***

Although GS does not have a predetermined focus, not all data collated by networks may be relevant for the purposes of GS. The underlying reasoning is that it is not likely that all organisms or ecosystems will be exposed to GM plants or their products. Therefore it makes more sense to focus on networks that compile data on terrestrial organisms than on organisms in aquatic ecosystems far away from cultivation areas, like major lakes or the North Sea.

#### ***Data should be validated***

The data collected should be validated in order to assess the reliability of these data. Data validation means that data are checked for potential mistakes when the data are entered in a database and the probability of the data is also verified.

The method of data collection is also important in determining the reliability and quality of the data. Data collection should ideally follow a standard or validated protocol. This also has the advantage that data collected from different locations and at different times can be compared. In this way, any changes in numbers of organisms within one year or between years can be determined.

#### ***Data collection should take place on a regular basis***

GS should preferably make use of data collected on a regular basis, e.g. annually. Networks that collect data only once per decade may be considered less suitable for GS because any effects will only be observed at a late stage.

#### ***Networks should be stable***

To be able to track changes over time, the network needs to be stable. Networks that only collect data for a limited period of time are therefore not suitable for GS. It will not be straightforward, and may even be impossible, to transfer data from one network to another which has a different approach. Since the stability of a network is often dictated by financial support, the funding stability of a network is also important.

#### ***Data collection should cover the entire national (or biogeographical) territory***

GS is intended to detect unforeseen changes which may extend beyond the actual cultivation areas of GM plants. Former cultivation areas also need to be included in a GS system. For this reason, networks that collect data at a biogeographical or at a national level would be preferable. A small country like the Netherlands can be considered as one biogeographical region.



### 3 Inventory of networks or other data sources for GS in the Netherlands

A first inventory of the main monitoring networks in the Netherlands was made by the Dutch Commission on Genetic Modification (COGEM, 2005). This report draws on the COGEM inventory and explores other sources of information which may potentially be useful for GS.

This chapter provides an overview of all networks and data sources, and briefly indicates whether or not they would meet the requirements for networks as indicated in the previous chapter (chapter 2). Therefore, the same structure as in chapter 2 (sections 2.1 to 2.5) has been followed for each network and data source. A summary is given in Table 1.

Information sources that are already in place for the purpose of GS at EU level are described at the end of this chapter.

#### **Ecological Monitoring Network (NEM)**

- Protection goal is biodiversity;
- Aim is to monitor the development of Dutch flora and fauna within the scope of international nature policy frameworks, like the Birds and Habitats Directive;
- Data collected include numbers of organisms of Dutch flora and fauna; data are relevant for GS;
- Measurements conducted by trained and organised volunteers (PGOs, i.e. *particuliere gegevens-beherende organisaties*) and by provincial networks; the data are validated;
- Monitoring of most species groups takes place on an annual basis
- NEM is stable;
- NEM covers the entire national territory;
- For further information see: [www.netwerkeecologischemonitoring.nl](http://www.netwerkeecologischemonitoring.nl).

#### **Biological Indicator System of Soil Quality (BISQ, Dutch: Bobi)**

- Protection goal is soil quality;
- Aim is to monitor soil quality in the context of the Convention on Biological Diversity (CBD, 1992);
- Data collected are numbers of soil organisms and micro-organisms: data are relevant for GS;
- Measurements are carried out by scientists; data are validated;
- Sampling takes place once a year; each location is sampled once every six years;
- BISQ is a stable network;
- Sampling in BISQ covers the entire national territory;
- For further information see: <http://www.rivm.nl/bibliotheek/rapporten/607604009.html>.

#### **Network for Water Quality (Dutch: MWTL, Monitoring Waterstaatkundige Toestand des Lands)**

- Protection goal is water quality;
- Aim is to monitor chemical, physical and biological parameters of water quality in the context of national and international legislation and agreements, such as the European Water Framework Directive, the Dutch Water Act, etc;

- Data collected are numbers of water organisms (e.g. plankton, mussels fish, birds, water plants); some of the data may be relevant for GS;
- Measurements made by Directorate-General for Public Works and Water Management (Rijkswaterstaat) or other parties, by organised volunteers (PGOs) and scientists; data are validated;
- Measurements generally take place annually;
- MWTL is a stable network;
- MWTL covers the entire national territory (water);
- For further information see: [www.rijksoverheid.nl/documenten-en-publicaties/rapporten/2011/12/30/mwtl-meetplan-waterdienst-2012-monitoring-waterstaatkundige-toestand-des-lands-milieumeetnet-rijkswateren.html](http://www.rijksoverheid.nl/documenten-en-publicaties/rapporten/2011/12/30/mwtl-meetplan-waterdienst-2012-monitoring-waterstaatkundige-toestand-des-lands-milieumeetnet-rijkswateren.html).

### **Earth Observation Systems**

- Protection goal: none specified;
- Aim is the production of remote sensing images by satellite systems that can be used for many purposes, including measuring developments in vegetation dynamics;
- Measuring vegetation changes may be useful for GS if the system is sensitive enough;
- Data on vegetation dynamics (as indicated by a vegetation index) have to be analysed and validated by scientists;
- Depending on the satellite system, images with different resolutions (5 to 250 m<sup>2</sup>) are taken at different intervals (every day to one every 16 days);
- Satellite systems can be considered a stable information source;
- Satellite systems cover the entire national territory;
- For further information see: [http://www.alterra.wur.nl/UK/research/Specialisation+Geo-information/Earth Observation/About/](http://www.alterra.wur.nl/UK/research/Specialisation+Geo-information/Earth%20Observation/About/).

### **National Flora and Fauna Database** (Dutch: NDFF, Nationale Database Flora en Fauna)

- Protection goal is biodiversity;
- Aim is to store and make available validated distribution data from a wide range of environmental monitoring schemes, together with opportunistic data (i.e. occasional observations by volunteers);
- Data collected are numbers of organisms (flora and fauna); data are relevant for GS;
- Data are validated;
- Most data are collected on an annual basis, but not necessarily at the same locations;
- The NDFF is stable;
- Data contained in the NDFF cover the entire national territory;
- For further information see: [www.natuurloket.nl](http://www.natuurloket.nl).

### **Agricultural Surveillance**

- Protection goal is agricultural quality;
- Aim is to detect plant diseases and inspect plant quality;
- Data collected are numbers of diseased potato plants and data on potato plant quality; data may be relevant for GS;
- Data are collected by qualified inspectors of the Plant Protection Service (Dutch: PD), the Netherlands General Inspection Service for Agricultural Seeds and Seed Potatoes (Dutch: NAK) and from the Food and Consumer Product Safety Authority (Dutch: VWA). Data are validated;

- Data are collected on an annual basis; depending on the purpose of the survey several times a year, but not always at the same locations;
- Agricultural surveillance can be considered a stable information source;
- Data collection is restricted mainly to potato fields, disease hot spots or is randomly carried out;
- For further information see: [www.VWA.nl](http://www.VWA.nl) and [www.naktuinbouw.nl](http://www.naktuinbouw.nl).

### **Survey of bees**

Initiated by the international scientific network Coloss (prevention of bee colony losses, [www.coloss.org](http://www.coloss.org))

- Protection goal is bee health;
- Aim is to find causes for the sudden and dramatic death of honey bees in the EU;
- Data collected are numbers of bees: data are relevant for GS;
- Data collection by NCB (Netherlands Centre for Bee research); data are validated;
- Data collection on an annual basis, at least for the duration of the project (until 2012);
- Survey is on a temporary basis; no stable network;
- Survey covers all active Dutch beekeepers;
- For further information see: [www.beemonitoring.org](http://www.beemonitoring.org).

### **European Invertebrate Survey Organisation** (Dutch: EIS, Stichting EIS - Nederland)

- Protection goal is biodiversity of insects and other invertebrates;
- Aim is to increase knowledge on insects and other invertebrates and to protect these groups;
- Monitoring for most species groups appears to take place on an annual basis;
- Data collection by PGOs, volunteers not organised in PGOs, or other networks; not clear how data collection takes place;
- Most data are validated and stored in the NDFF;
- Network is stable;
- It is not clear if data are collected nationwide;
- For further information see: [www.eis-nederland.nl](http://www.eis-nederland.nl).

Based on the criteria indicated in chapter 2, several networks meet all the specified criteria (NEM, BISQ, Earth Observation Systems and NDFF). For NDFF, it was considered that the data entered in this database are useful but consist mainly of NEM data. The network on water quality (MWTL) was considered only partly useful for GS since the focus of this network is mainly on organisms in larger water bodies (i.e. rivers, lakes, and the sea). In addition, some measurements, like those for waterfowl and other birds, already form part of NEM. The remaining networks or data sources were not further considered in detail, either because they will operate only for a limited period of time, or they do not cover the entire territory of the Netherlands, or the data are not collected in accordance with validated protocols.

For these reasons only NEM, BISQ and Earth Observation Systems were further investigated for the purpose of GS.

*Table 1. Summary of existing monitoring networks or other data sources in the Netherlands and their compliance with the suggested criteria for networks for the purpose of GS as indicated in chapter 2.*

*Networks/data sources shown in bold were further evaluated for use in GS.*

Network/ Source	Protection goal	Data relevant for GS	Data validated	Frequency of data collection	Network stability	Coverage
<b>NEM</b>	<b>Biodiversity</b>	<b>yes</b>	<b>yes</b>	<b>annual</b>	<b>OK</b>	<b>NL</b>
<b>BISQ</b>	<b>soil quality</b>	<b>yes</b>	<b>yes</b>	<b>sampling is annual; each location is sampled once every 6 years</b>	<b>OK</b>	<b>NL</b>
MWTL	water quality	partly, relevant data included in NEM	yes	Annual	OK	NL water
<b>Earth Observation systems</b>	<b>none</b>	<b>yes, if vegetation dynamics are measured, and if scale is fine enough</b>	<b>yes, by analysing data for vegetation dynamics</b>	<b>images taken once per day - once every 16 days</b>	<b>OK</b>	<b>NL</b>
Agricultural surveillance	agricultural quality and plant health	yes	yes	annual	OK	Limited to agricultural areas, mostly potato
NDFF	biodiversity	yes, includes data from NEM	yes	differs per species	OK	NL
COLOSS	bee health	yes	yes	annual	temporary project	NL
EIS	invertebrate biodiversity	yes	yes, after uptake in NDFF	probably	OK	NL?

#### **Sources that are already in place in the EU and used for GS**

After authorisation has been given for commercial cultivation in the EU, the permit holder has to meet certain obligations before the GM crop may actually be grown. These obligations are summarised in the box below. Owing to these obligations, there are also some information sources available that can be used for the purpose of GS. The sources and some examples are listed on the following page.

**Obligations upon the permit holder after authorisation for cultivation has been given**

When consent is given for commercial cultivation of GM plants in the EU, the permit holder has to meet certain requirements before the GM crop can actually be grown. Growers in all member states have to report all the locations where the GM crops will be grown in that specific member state (MS) every year. In addition, as part of the GS plan, farmers have to complete a survey every year, concerning any unusual observations (farmer questionnaire). These questionnaires are collected by the permit holder and summarised in their annual monitoring reports sent to the European Commission (EC) and all member states. These annual monitoring reports also contain a summary of the peer-reviewed literature published on the specific GM crop. If an adverse environmental effect of the GM crop is detected, the permit holder has to report this immediately to the EC, who will subsequently inform the member states.

- **National register of locations for commercial GM crop cultivation**  
Under Directive 2001/18/EC, each member state has to establish a register which records the locations of where GM crops are or have been commercially grown. These registers are public. In the Netherlands, growers of GM crops have to report these locations every year before 1 February to the National Service for the Implementation of Regulations (Dutch: *Dienst Regelingen*: [www.invloket.nl](http://www.invloket.nl)). These locations are subsequently made public in a register that can be found in the Netherlands at: [http://www2.hetinvloket.nl/Kaarten\\_VROM/index.html](http://www2.hetinvloket.nl/Kaarten_VROM/index.html).
- **Farmer questionnaire**  
When GM crops are cultivated, a subset of farmers has to report any unusual effects observed in their fields compared to non-GM crops. This is done by means of a questionnaire. An example can be found at: [www.ec.europa.eu/food/food/biotechnology/docs/2009\\_Farmer\\_Questionnaire.pdf](http://www.ec.europa.eu/food/food/biotechnology/docs/2009_Farmer_Questionnaire.pdf).
- **Reports from permit holders**  
When European authorisation is given and GM cultivation of the GM crop takes place in Europe, the permit holder has to file annual reports with the EC. These reports include results from post-market monitoring (including GS) and literature searches of peer-reviewed papers that are related to potential environmental effects of the specific GM crop. Member states also receive these reports from the EC. Examples can be found at: [www.ec.europa.eu/food/food/biotechnology/index\\_en.htm](http://www.ec.europa.eu/food/food/biotechnology/index_en.htm).
- **Literature systems**  
There is quite some research available on the potential effects of GM crops in relation to food safety, feed safety and environmental safety. Data are published in peer-reviewed journals and elsewhere. These journals are accessible through the libraries of research institutes. Abstracts of relevant papers and relevant sites can also be accessed through the International Centre for Genetic Engineering and Biotechnology (ICGEB, [www.icgeb.org](http://www.icgeb.org)), for example.





## 4 Methodological approach to the analysis of data from existing monitoring networks for the purpose of GS

As indicated in chapter 1, GS does not have a predefined focus because it is not known *whether* effects will occur, *where* they will occur and *what* these effects might be (positive or negative). In fact, it could be assumed that everything has to be measured, without any particular focus in the monitoring. As this is not a feasible option, it was considered what data would be relevant for the purpose of GS.

GS should be based on protection goals, like biodiversity, for which data are already collected, based on national and EU requirements. Experts agree (EFSA, 2011; Smit et al., 2012) that the approach for GS would be to measure the potential effects on these protection goals (i.e. biodiversity, soil quality, etc.), thereby making use of information sources which are already available, e.g. existing monitoring networks. As these monitoring networks have been designed for other purposes, they cannot supply statistical proof of potential effects of GM crops. What they can do, however, is to generate 'alerts' when changes in the protection goal (i.e. biodiversity, soil quality etc.) do occur. This is further described below.

In the event of such an alert, or that a change is observed which is found to be statistically significant, further analysis should demonstrate whether this change can be correlated with GM cultivation, or if it is related to other causes, such as changes in agricultural practice or climate change. Statistical methods are available to establish a potential significant correlation between a change in biodiversity on the one hand, and GM cultivation on the other hand. This is described in section 5.2, using a non-GMO example in which the effects on the soil nematode community can be significantly correlated with the amount of manure deposited.

### *Types of alerts*

The idea of GS is that a signal (alert) will be issued when an element of biodiversity (or a criterion like soil quality) is significantly affected. Different types of alerts can be issued. Firstly, trends in indicator species in the area where the GM crop is grown may differ significantly from trends in a reference area after the introduction of the GM plants. In these situations a type 1 alert can be issued (see Figure 1).

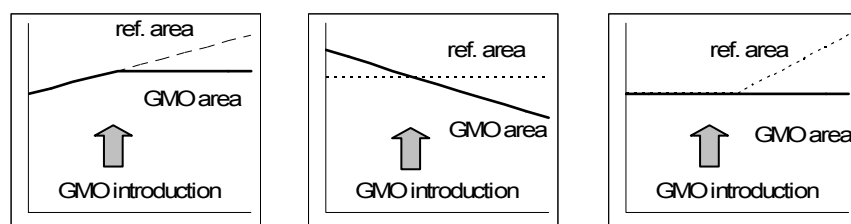
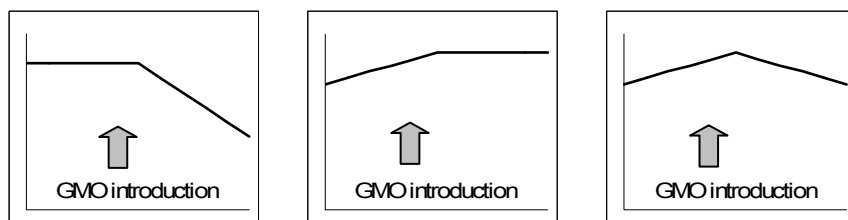


Figure 1. Hypothetical situations where a type 1 alert would be issued further to the introduction of GM plants where there is a change in the trend for indicator species in the area where the GM crop is grown (GMO area) compared to the trend for the same species in a reference area (ref. area).

Secondly, a type 2 alert can be issued when there is a statistically significant change in the direction of the trend for the indicator species after the introduction of GM plants (see Figure 2).



*Figure 2. Hypothetical situations where a type 2 alert would be issued following the introduction of GM plants where the trend direction for indicator species changes after the introduction of GM plant.*

The difference between type 1 and type 2 alerts is that for the latter the trend is not compared with the development of biodiversity in a reference area. This type of alert is necessary since it cannot be known in advance how far the potential influence of the GM crops (or their products) will extend. If this influence were to extend to the entire national territory, it would not be registered as a type 1 alert, since the influence will also affect the reference area. A type 2 alert can be seen as a first indication that something may have happened. While a type 1 alert may be a stronger indication that this could be due to the introduction of GM plants (see also section 5.1 for an example).

If a type 1 or 2 alert is issued the next step would be to determine whether there is logical explanation for this alert. Only if no such explanation or correlation can be found for the detected changes in biodiversity (or soil quality), there will be a suspicion that these changes could be correlated to GM cultivation, in which event statistical methods can be used to establish whether or not there is a significant correlation between these changes and GM cultivation (see also section 5.2).

## 5 Feasibility of GS using selected networks

Based on the results of chapter 3, it was decided to examine in more detail the Ecological Monitoring Network (NEM), the network on soil quality (BISQ) and the use of satellite systems for the purpose of GS, taking into account the methodological approach as set out in chapter 4.

### 5.1 Ecological Monitoring Network

The NEM monitors the status of Dutch flora and fauna in relation to policy goals based on the legislative requirements. Policy goals are used that focus on species, as in the Birds and Habitats Directive, or the policy on farmland birds. Policy goals can also focus on protection areas (Natura2000) or the effects of eutrophication, acidification and the decline in the water table.

The NEM is joint undertaking between PBL (the Netherlands Environmental Assessment Agency), CBS (Statistics Netherlands), the Provincial Authorities, and two Dutch Ministries (Economic Affairs, Agriculture, Nature and Innovation, and Infrastructure and the Environment). Data are collected on an annual basis by experienced volunteers organised in PGOs, and by provincial networks in accordance with standard protocols that can be found on the NEM website. Data are collected on species abundance or on species distribution. In the latter case only the presence or absence of a species is determined. The PGOs manage and validate the data. Data are further validated by the CBS and eventually entered in the National Flora and Fauna Database (NDFF).

Data on species abundance are statistically analysed by CBS, using log linear regression with TRIM, software specially developed for the NEM (Pannekoek and van Strien, 2001). These analyses result in annual indices and longer term national or regional trends per species. Data analysis on the distribution of species is done by the PGOs. The output of the NEM can be found on the PGO and CBS websites and at [www.compendiumvoordeleefomgeving.nl](http://www.compendiumvoordeleefomgeving.nl).

The NEM provides species monitoring for the following species groups:

- Reptiles
- Amphibians
- Mammals (bats and some diurnal mammals)
- Water birds (non-breeding)
- Breeding birds
- Birds on resting places
- Fish (only in polders and small streams)
- Butterflies
- Dragonflies
- Vegetation (plus trends for many individual species)
- Lichens
- Mushrooms
- Beetles (only distribution of some species in the Habitats Directive)
- Molluscs (only distribution of some species in the Habitats Directive)

#### *NEM and approach for GS*

Working closely with PBL and CBS, the feasibility of GS using NEM data for GS was examined. During the many discussions and brainstorming sessions, experts made a number of recommendations for an approach to GS in the Netherlands.

*Changes in species abundance reflect changes in biodiversity*

GS based on changes in the abundance of species provides a good indication of changes in biodiversity. Monitoring changes in abundance will be more sensitive than monitoring changes in the presence or absence of species.

*Indicators for GS*

It was considered that indicators could be selected for GS which would function as a 'red flag' for a group of organisms. These indicators would be for groups of selected species. It was agreed that a choice of indicators would be selected for species groups that could come into contact with certain crops, i.e. birds, plants, butterflies and diurnal mammals. The choice of indicators is summarised in Table 2. An extensive list of the individual species is given in Appendix 1.

*Table 2. Criteria and choice of species to be used as indicators for GM maize and potato.*

<b>Groups of organisms</b>	<b>Criteria</b>	<b>Potato</b>	<b>Maize</b>
<b>Plants</b>	Wild relatives	General state of flora	General state of flora
<b>Birds</b>	Potential interaction with crop	Farmland birds (Dutch: <i>akker- en weidevogels</i> )	Farmland birds, seed-eating birds
<b>Birds of prey</b>	Interaction through food web	Birds of prey occurring in agricultural fields, owls	Birds of prey occurring in agricultural fields, owls
<b>Diurnal mammals *</b>	Potential interaction with crop	Hare, roe deer	Hare, roe deer
<b>Butterflies **</b>	- Butterfly larvae feeding on crop - Species that are part of the food web	Potato is a crop where very few butterflies occur	Maize is a crop where very few butterflies occur
<b>Red List species</b>	Endangered species that occur in cultivation area of crop (birds, butterflies)	Species in cultivation area of starch or eating potatoes	Species in area where green maize is cultivated

\* *Rabbits have been excluded because their population is too variable over time and fluctuations in this species' population are known to have many causes*

\*\* *Arthropods are not included since they are not covered by NEM*

*Inclusion of endangered species*

It was also considered important to include endangered species as the public and policymakers generally consider effects on these species (e.g. extinction) to be more important than effects on common species. Therefore, species have been selected that are on the Netherlands' Red List or are likely to be placed on this list in the near future, as they are considered 'endangered' according to IUCN criteria ([www.iucnredlist.org](http://www.iucnredlist.org)). The species will be selected, based on their prevalence in the regions where maize and potato are grown (and where GM maize and potato will be cultivated in the future). Red List species that are almost extinct have not been included due to lack of data (see below).

*Species groups excluded from GS*

Species groups that are covered by NEM, but were excluded for GS, were reptiles, amphibians, bats, fish, dragonflies, lichens, fungi and molluscs. It was reasoned that, given their habitat and behaviour, these species (with the exception of certain fungi) are less likely to come into contact with GM plants (or their products) as the species monitored do not normally occur in agricultural areas.

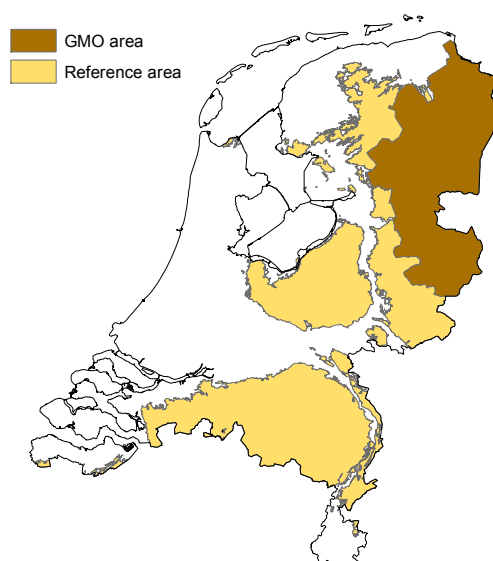
*GS at national or regional levels*

GS should essentially take place at national level. However, if effects of GM crops should occur, measurements at national level will not be sensitive enough. Therefore, it was recommended to focus on agricultural regions, i.e. the specific regions in the Netherlands (NL) where agricultural crops are normally cultivated. The focus would be on those regions where maize and starch potato are cultivated as these are the first GM crops which are expected to be introduced into the Netherlands (e.g. insect-resistant Bt maize, amylose-free potato and disease-resistant potato). An indication of the cultivation areas for starch potato and maize are shown in Figure 3.

*Comparing GM cultivation area with a reference area*

Effects of GM crops can be detected by comparing cultivation areas with a reference area (type 1 alert, see chapter 4). A cultivation area is considered as the area where GM crops will be grown in the future. A reference area is the area where the crop is not cultivated, or less extensively cultivated. Ideally, a reference area will have the same environmental conditions (including non-GM crop cultivation) as the area where the GM crop is cultivated. This situation can be approximated by selecting sampling points just within the influence of GM crops and points just outside this influence as a reference. However, there is no existing knowledge available on the extent of the influence of GM crops. Therefore, it was recommended to assess the effects of GM crops on a regional scale, e.g. to compare regions where there is extensive cultivation of the crop (i.e. cultivation area) with regions where there is little or no cultivation (i.e. reference area) (see Figure 3). A probable consequence of this will be that differences will be found that are caused by factors other than the GM crops (false alert). To reduce the number of these 'false alerts', a reference area should be chosen which is comparable to the cultivation area in terms of environmental conditions. For starch potatoes, for example, it is expected that GM starch potatoes will be grown on the sandy soils in the north-eastern part of the country, and thus only sandy soils in the rest of the country should be included in the reference area (Figure 3). The number of false alerts can be further reduced by carefully comparing baseline trends from the cultivation area with those of the reference area before the introduction of GM crops.

Any remaining false alerts will not be a problem in GS. As GS does not have a predefined focus, it is better to issue a false alert than to miss a potential GM effect. Conversely, it cannot be ruled out that differences between the cultivation and reference areas may mask GM-induced effects in the cultivation area.



*Figure 3. Indication of the cultivation areas for starch potatoes in the Netherlands. The dark areas indicate the main growing areas for starch potatoes (e.g. sandy soil in the northeast of the Netherlands) where GM starch potatoes are expected to be cultivated (GMO area). The areas with yellow shading represent sandy soils in the rest of the country that can be used as a reference area (reference area).*

#### *Few sampling points for rare species*

For rare species, like Dutch Red List species, the number of NEM plots where the species are monitored is often too small to calculate reliable trends. Moreover, some species, like butterflies, are not often found in agricultural areas, especially Red List butterflies. Therefore it was recommended not to limit the comparison only to sampling points in the agricultural area under cultivation and reference areas, but to include sampling points from natural areas as well.

Another way to incorporate rare species in GS is to look at the number of species per sampling point instead of the abundances of separate species. By doing so, even a Red List species that is only present at one sampling point will be taken into account in the observations. In this way a trend can be calculated, based on the mean number of Red List species whereby the same comparisons can be made as with Multi-species Indices (MSIs, see below).

#### *Indices and Multi-Species Indices*

Missing counts in NEM data are statistically replaced (imputed) by TRIM to enable aggregation of counts to higher levels (e.g. cultivation area, reference area, national level). For the selected indicator species, total numbers in the sampling point are calculated per region per year. These numbers are converted to indices by setting the first year (e.g. the first year with GM crops) at 100 and expressing the following years as a percentage of the first year (e.g. an index of 50 means a halving of the population compared to the first year; an index of 200 represents a doubling of the population).

Apart from indices per species, indices for a group of species are also calculated (Multi-Species Index, MSI) by calculating the geometric mean of the yearly indices of the species. Calculating the geometric mean enables a doubling of one

species (index rises from 100 to 200) to be offset by the halving of another (decline from 100 to 50), as the geometric mean of 200 and 50 is 100. MSIs are considered a good indicator of the development in the whole species group. This is a well-established method for monitoring the development of a group of species (Buckland et al., 2011; Gregory et al., 2005; van Strien et al., 2011). MSIs are less sensitive than indices of individual species because species can compensate for one another in MSIs. A change in MSI therefore represents a stronger signal than a change in the indices of individual species. Alerts will, of course, only be issued when enough species within a group change in the same direction. For GS the groups and the individual species within these groups are indicated in Table 1 and Appendix 1.

#### *Calculation of trends with TrendSpotter*

TRIM imputes missing values and calculates overall trends over time series' of individual species. Although TRIM can also calculate separate trends for the last few years in a time series, trends for the last few years will not usually be statistically significant. This restricts the use of TRIM for early warning purposes. Therefore, the programme TrendSpotter can be used to assess the possible effects of GM crops. TrendSpotter (Visser, 2004) calculates flexible trends in time series and also calculates a confidence interval (CI). A flexible trend can be compared with a running mean across time points in which the value of the trend (height of the trend line) is specifically determined by the yearly values at that particular moment and those of the surrounding years, without the influence of years that are further away in time. In other words, TrendSpotter is sensitive to detecting trends in the short term (shorter than TRIM) and would therefore be useful for GS, which is intended to function as an early warning system. TrendSpotter also calculates the difference in trend values between the previous year and each of the preceding years, including the CI for this difference. Therefore it is possible to indicate for each year whether the population number in that year is significantly higher or lower than the year before (Soldaat et al., 2007).

#### *Potato as a test case for GS*

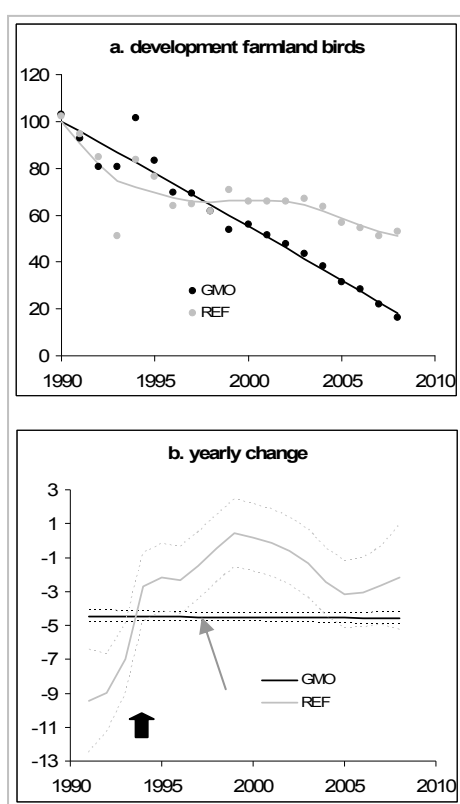
Potato was chosen as a test case. Trends in the selected indicator species for potato were analysed for the past 15 years to determine whether these could be used for GS, as trends should neither fluctuate too much nor be too stable if potential changes are to be detected. A further reason to collect data on the selected indicator species was to create a starting point for GS, as there is currently no GM cultivation in the Netherlands. The preliminary analysis of the trends in selected indicator species for the past 15 years proved to be useful for the purpose of GS (e.g. trends were neither too variable nor too stable), and it was agreed to continue with the selected species. Based on this first pilot, a more extensive second pilot was started to determine which statistical analysis method would be most suitable for the purpose of GS.

#### *Example of a type 1 alert*

Chapter 4 describes two types of alerts. A type 1 alert would be issued in the event of a change in the trend direction of a species or species group following the introduction of a GM crop, compared to the trend direction of this species or species group in a reference area. Figure 4a shows the development in farmland birds (six species) in the cultivation area (where GM crops may be grown in the future) and in the reference area in the period from 1990 to 2008. Data points are MSI values; the lines indicate the trends as calculated by TrendSpotter. With the output of TrendSpotter, the percentage of yearly change and the confidence interval can be calculated (Soldaat et al., 2007). In Figure 4b this has



been done for trends in farmland birds from Figure 4a. In this figure, the horizontal lines represent the annual change in the mean trend of farmland birds in the cultivation area where the GM crops will be grown (GMO) and the confidence interval. The value of -4 means that the trend value is four index points lower in that specific year compared to the year before. The other lines represent the mean trend in farmland birds in the reference area. In years where the CIs do not overlap, the mean yearly change significantly differs statistically between the cultivation area and the reference area. For farmland birds this occurs in the first years and in the middle part of the time series, and thus type 1 alerts would be issued.



*Figure 4a Development in farmland birds in the cultivation area (GMO, i.e. where cultivation of the GM crop is expected) and in the reference area (REF, i.e. where no (or less) cultivation of the GM crop is expected) from 1990 to 2008 in NL (indices, 1990=100).*

*Figure 4b The mean yearly change in index points of these birds and the 95% confidence interval (CI) in the two areas as determined by TrendSpotter (type 1 alert). The bold lines indicate the mean yearly change, the dotted lines are the CIs. If the CIs do not overlap, there is a statistically significant difference and a type 1 alert would be issued. The grey arrow indicates when a type 1 alarm would be issued after potential introduction of a GM crop (black arrow).*

As an example, let us suppose that in Figure 4 GM plants were introduced in 1994 or 1995 (indicated by a black arrow). From the figure, it can be seen that a few years later the yearly change differs between the two areas (the confidence intervals (CIs) no longer overlap in Figure 4b), which could be an effect of the introduction. Note, however, that there was already a difference in the preceding years, indicating that other factors than the GM crop can cause differences in trends. This method will therefore be particularly useful in

indicating an effect of GM plants where the trends are similar in both areas before the introduction.

#### *Example of a type 2 alert*

A type 2 alert would be issued whenever the trend direction of a species or species group changes following introduction. As indicated above, the difference compared with a type 1 alert is that the trend in the cultivation area is not compared to a reference area. To give an example, the annual change in the trend for the hare is plotted in Figure 5. A value of -10 means that the trend value is ten index points lower in that specific year compared to the year before. When the CI is below 0, there is a statistically significant reduction compared to the year before; above 0, there is an increase. It can be seen in Figure 5 that there is a statistically significant decline between 1997 and 2001, while there is a period until 2006 where there is no statistically significant difference in trend direction (CI includes 0), except for 2006. If the trend change from 1997 or 2007 had followed further to the introduction of a GM crop, type 2 alerts would have been issued (Fig. 5b).

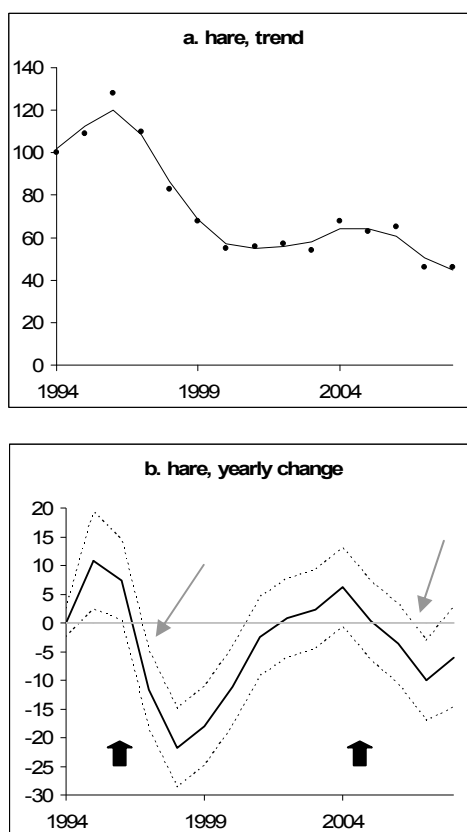


Figure 5a Trend for the hare in the cultivation area.

Figure 5b Mean annual change (in index points) in the cultivation area, and the confidence interval as determined by TrendSpotter (type 2 alert).

Where the CI is below 0 (the horizontal line) there has been a statistically significant decrease in the hare in the cultivation area compared to the preceding year. The grey arrows indicate when a type 2 alarm would be issued after potential introduction of a GM crop (black arrow).

The method described above is sensitive to relatively large changes in numbers of selected species or species groups. Whether an effect will be found or not will depend on a combination of (1) the magnitude of the change in trend, and (2) the annual fluctuation in the species or species group. A small change in trend will be detected at an early stage if the species (or species group) does not show very much year-on-year variation. By contrast, with large annual fluctuations, a significant change in trend will only be observed after a longer period of time. The method is not specific to the effects of GM plants, but is useful for all potential ecological stressors. The method is relatively insensitive to incidental changes because the alert system is based on changes in trends, which will become manifest only when the increase or decrease is sustained over a few years. In conclusion, the analysis of NEM data as described here would appear to be promising for the purposes of GS.

## 5.2 Biological Indicator System of Soil Quality

### *Description of BISQ*

The Bobi or BISQ network (Rutgers et al., 2009) is a nationwide monitoring programme which samples some 300 locations with different land uses and soil types. Each location is sampled in a six-year cycle. The programme was set up after the Convention on Biological Diversity was ratified by the Dutch government. BISQ was developed in 1997 at the request of the former Dutch Ministry of Housing, Spatial Planning and the Environment to assess the quality and resilience of the soil ecosystem (Bloem et al., 2006). The link between biodiversity and soil function is represented in BISQ from the point of view that the soil food web provides an opportunity to link diversity to specific functions, i.e. the life support functions. BISQ enabled the most important life support functions of the soil to be identified, i.e. decomposition of organic matter, nutrient cycling, soil structure formation, plant-soil interactions and ecosystem stability. Ecological processes were then linked to these functions and the dominant soil organism groups and ecological process parameters were determined and brought together in a practical indicator system to be used for national monitoring (Rutgers et al., 2009). BISQ has been incorporated in an already operational abiotic soil monitoring programme, the Dutch Soil Quality Network (DSQN). This network is based on 200 sites classified into various land use/soil type categories and represents approximately 75% of the total land surface area. The parameters measured by BISQ are given in Figure 6 and in Rutgers et al. (2009).

### *BISQ and GS*

In 2007, an RIVM project started to explore the options for GS of the soil ecosystem based on BISQ. The project consisted of several parts:

- Literature review of unexpected effects of GM plants in the soil ecosystem to identify potential indicators for GS;
- Discussion with experts on (a) the challenges of GS of the soil ecosystem, and (b) the use of BISQ for GS;
- Exploration of statistical tools to analyse data in existing networks (like BISQ) for GS.

### 5.2.1 Literature review

#### *Reported unexpected effects of GM crops*

As a first step, a literature review was carried out (Smit et al., 2010, 2011) to identify unforeseen effects of GM crops on soil functions or organisms. The idea was that functions of organisms that were proven to be affected by GM crops

could subsequently be selected as indicators for GS. Peer-reviewed scientific papers describing effects of GM crops were assessed, but revealed only a few unexpected effects of GM crops on the soil system. Effects that were found were transient and smaller than the effects caused by normal agricultural practices such as crop rotation, tillage or the application of plant protection agents.

#### *Potential indicators for GS*

Although the literature review did not reveal any unexpected GM effects, a number of processes and organisms were shown to be slightly affected by GM crops (Smit et al., 2010, 2011). Organic matter degradation, organic content and related parameters (e.g. microbial C content) responded to GM crops and thus may be indicators for GS since organic matter degradation is one of the most important soil functions. The nematode community is also recommended as an indicator for GS because of its response to GM crops, as indicated in the literature. Nematodes are essential organisms in the soil food web and sensitive to disturbances. Arbuscular mycorrhizal fungi can also be considered as an indicator because they are an important group of soil micro-organisms due to their ability to form associations with plants and improve plants' nutrient uptake. The few publications there are on the effects of GM crops do not give a clear picture regarding their response. However, there are currently no routinely applicable methods for the specific detection of arbuscular mycorrhiza. The same applies to micro-array analysis for assessing microbial diversity of a broad range of bacterial and fungal species in soil. Such an application would be very useful for GS when sufficiently developed for routine application.

### **5.2.2 Expert workshop**

#### *Adverse effects and protection goals*

The literature review was used as a basis for a workshop with national and international experts in the field of soil ecology, molecular biology and on GS (Smit et al., 2009, 2012). At this workshop, the major issues regarding GS that were identified earlier by the Dutch soil experts were discussed, including the proposed indicators. Concerning these issues, all the participants agreed that it is not possible to detect adverse effects with GS because the term 'adverse' implies that effects have to be qualified or judged, which is more of a societal issue than a scientific one. It was concluded that it is necessary to define what needs to be protected (protection goals). Soil quality was proposed as an overarching protection goal. The concept of ecosystem services was introduced for linking measurable parameters to soil functions in order to determine soil quality (Figure 6)

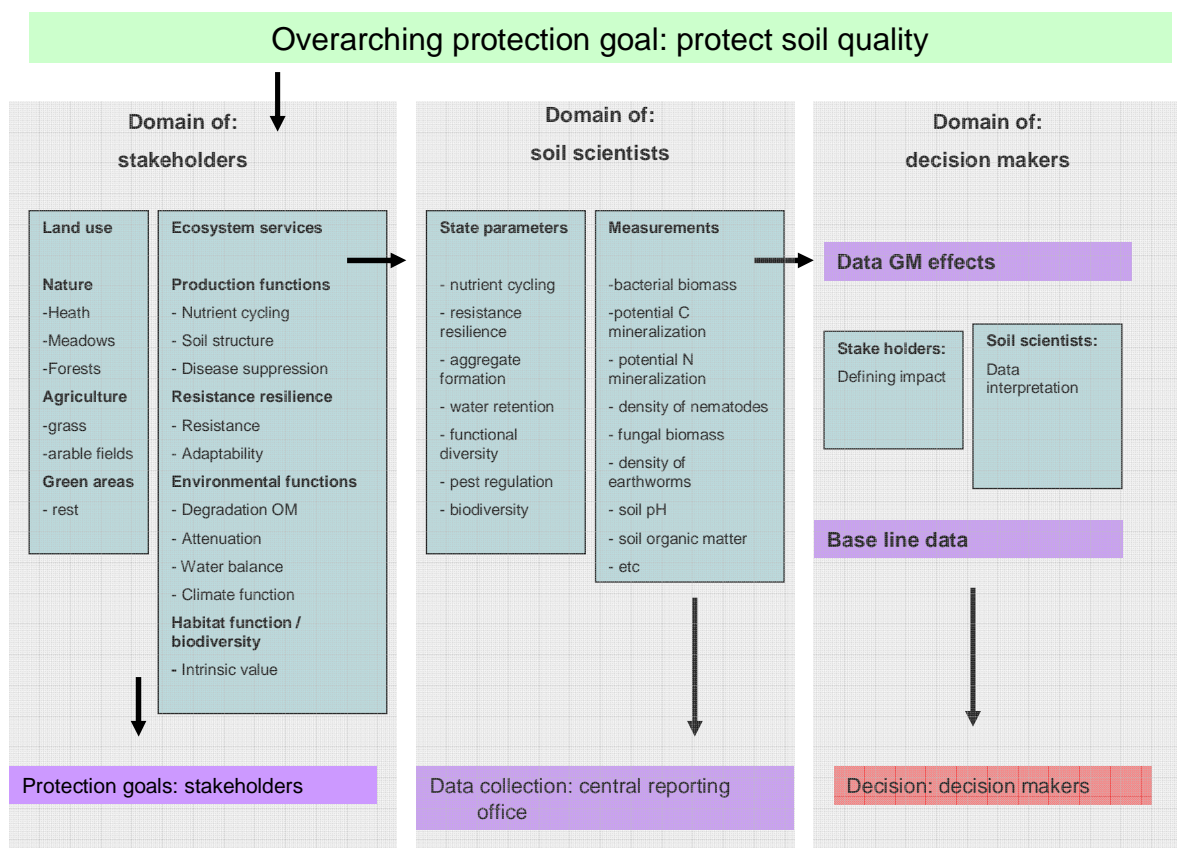


Figure 6. Diagram of stakeholder participation model that could be used for GS. This is an adapted form of the system described by Rutgers et al. (2009).

#### *Ecosystem services and stakeholder participation*

Classification of an effect as adverse or not largely depends on the use of the soil or land, and the land users are those that have to make this judgement. For this purpose, a stakeholder participation model (Rutgers et al., 2009) was adopted consisting of three domains: the land users, the soil scientists and the decision-makers. Each of these domains has its own specific interests. As a first step, land users such as farmers, local authorities and managers of nature reserves will be involved in determining which ecosystem services they regard as most important to be considered in the GS system. Soil scientists will then select indicators to assess the status of the selected ecosystem services and provide scientific data for regulatory authorities to decide whether unanticipated effects as a consequence of GM cultivation have indeed occurred.

#### *Data collection and monitoring*

The second part of the workshop focused on data collection, relevant monitoring programmes and the sensitivity and resolution of the monitoring. The BISQ initiative was considered the best source for generating data for GS of the soil in the Netherlands. It was indicated that BISQ may have to be adapted for General Surveillance by increasing the sampling frequency and the locations. This may prove to be too expensive since analysis of all parameters at one location already amounts to € 3000. If all parameters are to be analysed annually at 300 locations this would cost € 900,000 a year. However, costs can be reduced

by selecting parameters and by developing different sampling scenarios. For example, by focusing on a few robust indicators such as labile organic matter (potentially mineralisable nitrogen) and nematodes, the cost could be reduced to € 140,000 a year. Alternatively, more focused sampling could be applied (inside and outside cultivation areas). Sampling intensity could be stepped up for GS depending on the scale of future GM crop cultivation. Three scenarios are envisaged (Smit et al., 2009, 2011).

### **5.2.3 Exploration of statistical tools to analyse data of existing networks (like BISQ) for GS**

#### *BISQ and statistical analysis for GS*

The last part of the project looked at the use of statistical tools and systems to make existing monitoring networks – originally developed for other purposes – suitable for GS (Vonk et al., in preparation). The approach taken and the results of this study are described below.

Data from BISQ have been used to illustrate how statistical methods and models can be implemented for the purpose of GS. The methods are used to be able to pick up signals from unknown stressors (such as GM crops) from a large data set without any prior knowledge of the possible effects of either the stressor or its spatial distribution (GS step 1). Subsequently, these changes can be linked either to the cultivation of GM crops or to other causes (GS step 2).

#### *Example of statistical approach for GS*

In the example described below, the Observational and Simulated Evidence (OSE) approach (Mulder et al., 2003) is used to show a basic approach to identify effects from a (previously unknown) stressor in Dutch soil systems, and the value of additional ecological information to identify differences between sites and the probable causes of these changes.

In this study by Mulder et al. (2003) changes were observed in the diversity and abundance of the nematode community in soils of Dutch farms, and it was found that these changes could only partly be explained by the abiotic conditions in the soils. By including a previously unidentified stressor, namely livestock density, which encompasses the amount of cattle, pig and poultry manure applied to grasslands, a larger part of the observed variation in the nematode community could be explained. The farming intensity (amount of manure applied) had a direct effect on the nematode community structure and on the functioning of the soil. The same approach can also be applied to correlate changes in the nematode community due to other stressors, e.g. GM crops.

#### *Description of the model*

A short description is given below of the procedures applied to BISQ data to identify the possible influence of the stressor (Livestock Units, LSU) and to distinguish between LSU effects and other environmental conditions, like temperature, rainfall, pH, phosphate concentration (for a more detailed description see Mulder et al., 2003).

The presence or absence of nematode taxa is determined (as binary data) in BISQ. However, binary data are highly case-sensitive for taxa occurrences; therefore, the binary nematode response at the originally scored taxonomic level (presence/absence of taxa) was rounded up and merged at trophic levels for either bacterial or hyphal-feeding habits. In this way, the sensitivity of the model to the presence/absence of individual species is minimized, and replaced by 'feeding habit' data, which are more robust in impact diagnostic analyses.

Merging nematodes at trophic levels also provided more ecological insight into their functioning in the soil. The ratio between bacterial feeding and hyphal feeding nematodes (the nematode channel ratio, NCR), reflects the relative importance of two pathways in the flux of matter and nutrients in the soil, i.e. the bacterial pathway and the fungal pathway. The ratio between the bacterial pathway and the fungal pathway is also a measure of the microbial competition in the soil.

After the data pre-treatment, a statistical model was applied to analyse the data and explore possible associations between the stressor (LSU) and the response of the nematode community, expressed as the nematode channel ratio (NCR).

### Results

The various parameters to describe or summarise nematode distribution patterns in managed grasslands were not fully explained by variables like pH and organic matter. However, the analyses showed that there was a statistically significant link between the effect on the shift in the functional characteristics of the nematode community on the one hand, and the variability in the Livestock Units on the other, despite the influence of all other factors (such as pH and organic matter) on the nematode community (Mulder et al., 2003; Mulder et al., 2011). This correlation is illustrated with GIS maps (Figure 7). The correlation between the effect on the nematode channel ratio (NCR) representing the nematode community the one hand, and the amount of manure deposited (LSU) on the other hand, can be visualized by comparing the colours in the GIS maps.

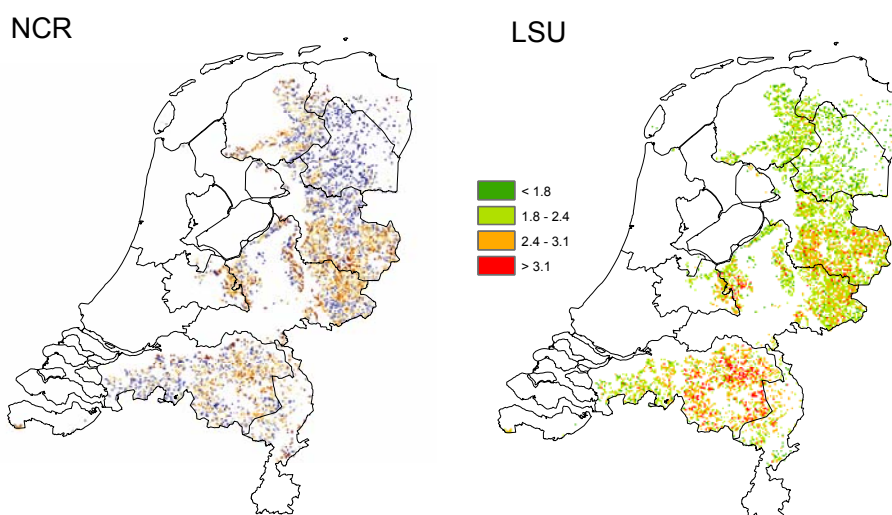


Figure 7. GIS analysis of Dutch grasslands and pastures on sand (Left). Variability of the nematode channel ratio (modelled NCR classes) as response variable over sites. (Right) Distribution of the potential stressor variable 'livestock density' (observed LSU classes). One livestock unit (LSU) is given here as the amount of dairy cattle excreting an average of  $41 \text{ kg P ha}^{-1} \text{ yr}^{-1}$ . The NCR ranges from 0.85 (blue pixels, low farming pressure) up to 0.91 (orange pixels, high farming pressure). Comparison (Mantel comparison) between the colours (indicating NCR and LSU classes) shows a robust and significant correlation between the nematode microbivores and the amount of deposited manure.

### *Correlation between observed effects and cultivation of GM crops*

If such an unanticipated effect on the nematode community would have occurred due to the cultivation of GM crops, in principle, the same statistical methods would be able to trace this.

If an effect is detected, other obvious causes should first be explored before looking into the potential correlation between observed effects and GM cultivation. If no correlation with obvious causes can be found, a number of 'GM related parameters' could be incorporated, such as crop type data, distance of the sampling point to GM crop fields, time elapsed since a GM crop was grown there, etc. These data are available as there is a register of locations where GM crops are or have been grown (see chapter 3).

## **5.3 Earth Observation Systems**

The use of Earth Observation Systems (EOS) for GS was studied by Alterra (Roerink and Danes, 2010). A summary is given below.

### *Description of Earth Observation systems*

Remote sensing, also called earth observation, refers to obtaining information about objects or areas on the earth's surface, using electromagnetic radiation (light) without being in direct contact with the object or area. Remote sensing is performed by satellite systems that differ in their revisit time (1-16 days) and their resolution (5-100 metres), (see Table 3). Remote sensing is increasingly used to acquire information about environmental processes such as agricultural crop growth, land cover changes, deforestation, vegetation dynamics, water quality dynamics, urban growth, etc. In the context of GS, it was considered whether remote sensing could contribute to the detection of unexpected effects on vegetation due to GM cultivation. For this, Roerink and Danes (2010) began a project to study the feasibility of using EOS for GS, focusing on vegetation. Several vegetation indicators can be derived from satellite images. To monitor the temporal behaviour of vegetation throughout a year, at least monthly cloud-free observations are necessary. The number of available images depends on the revisit time and cloud cover. Given the large number of days with cloud cover in the Netherlands, this can only be achieved with a satellite revisit time of one or two days.

*Table 3. Overview of satellite imagery that can be used to monitor vegetation dynamics.*

Satellite	Resolution	Revisit time	Cost
Landsat	30 m	16 days	€ 0.02 per km <sup>2</sup>
SPOT	10-20 m	8 days	€ 0.53 per km <sup>2</sup>
MODIS	250 m	daily	free downloadable
NOAA/AVHRR	1000 m	daily	free downloadable
RapidEye	5 m	5.5 days	€ 0.95 per km <sup>2</sup>
DMC	32 m	daily	€ 0.12 per km <sup>2</sup>

### *Vegetation Index*

Several vegetation indices have been developed over the years. The Normalized Difference Vegetation Index (NDVI) is most suitable for the purpose of GS. The NDVI index ranges between 0 and 1 and has no physical meaning. However, it is easy to measure and is very sensitive to temporal and spatial changes in vegetation, such as changes in vegetation type (see Figure 8). Another advantage is that it is not sensitive to weather conditions, such as temperature.



### *MODIS images*

The MODIS system was selected for analysis at national level. MODIS has the highest resolution (250 m) of the freely available remote sensing images and still has a daily revisit time. MODIS also provides composite images from the 16-days-maximum-NDVI product. The 16-days-maximum-NDVI composite images have the advantage of excluding cloud-affected data. Only when all the 16 days in a composite image are cloudy, the image is cloud-affected. Unfortunately, this occurs regularly in the Netherlands and it is therefore necessary to filter out the cloud-affected data. Additionally, the 16-day composites use a mask to filter out the sea. This mask is known to be inconsistent which makes the results near the coastline (within 15 km) unreliable. Despite the shortcomings of the composite images, the 16-days-maximum-NDVI product also saves time with pre-processing and provides 23 images a year, which is sufficient for use in time series analyses. The NDVI composite product was therefore downloaded and used during this study. Where the outcomes were not satisfactory, it was decided to use the original daily images instead of the 16-day composites.

### *Time series analysis*

The use of time series analysis on remote sensing images offers good prospects for year-to-year monitoring of the earth's surface. However, there are two serious drawbacks which have to be dealt with: (i) time series analysis of remote sensing data produces huge amounts of data to be processed and analysed, and (ii) the presence of erroneous data, like cloud-affected images or missing pixels.

The selected HANTS (Harmonic Analyses of Time Series) algorithm (Roerink et al., 2000) deals with the second of these drawbacks and has three benefits:

- Reduction in data volume. The method allows the volume of data to be reduced by a factor of at least 5 without loss of information.
- Exclusion of erroneous data. The method can exclude cloud-affected images and missing pixels from the analysis.
- Objective and quantitative description of vegetation dynamics. The time series of NDVI remote sensing images can be described with Fourier components (amplitude and phase).

HANTS has been used successfully for various applications, such as cloud screening, removal and replacement, land cover classification, vegetation dynamics and climate variability assessment.

### *Proof of principle*

As a proof of principle, it was decided to compare images from two years that differed in conditions, e.g. 2003 and 2007. The idea was to see if any differences in vegetation could be observed and if so, the nature and extent of the differences. MODIS satellite images are available from 2000 onwards.

MODIS 16-days-maximum-NDVI composite images were used to characterise vegetation dynamics for these years. To explain the differences between the different years, the following additional information sources were used:

- Meteorological data (recorded by the Royal Netherlands Meteorological Institute at De Bilt);
- LGN (Netherlands land cover map);
- Aerial photographs taken in 2003 and 2007;
- Expert knowledge.

After masking all land-use classes except nature, it became possible to zoom-in on extreme vegetation phenology differences between years. Figure 8 shows five different areas, or 'hot spots', where there were extreme differences between the HANTS components in the different years. These hot spots were located in the Veluwe (three hot spots), the Biesbosch and the Oostvaardersplassen, all

relatively large natural areas in the Netherlands. After identifying the hot spots, it was attempted to find a plausible explanation for the unusual change in the vegetation phenology by analysing higher resolution aerial photographs dating from 2003 and 2007 in combination with the LGN land cover map.

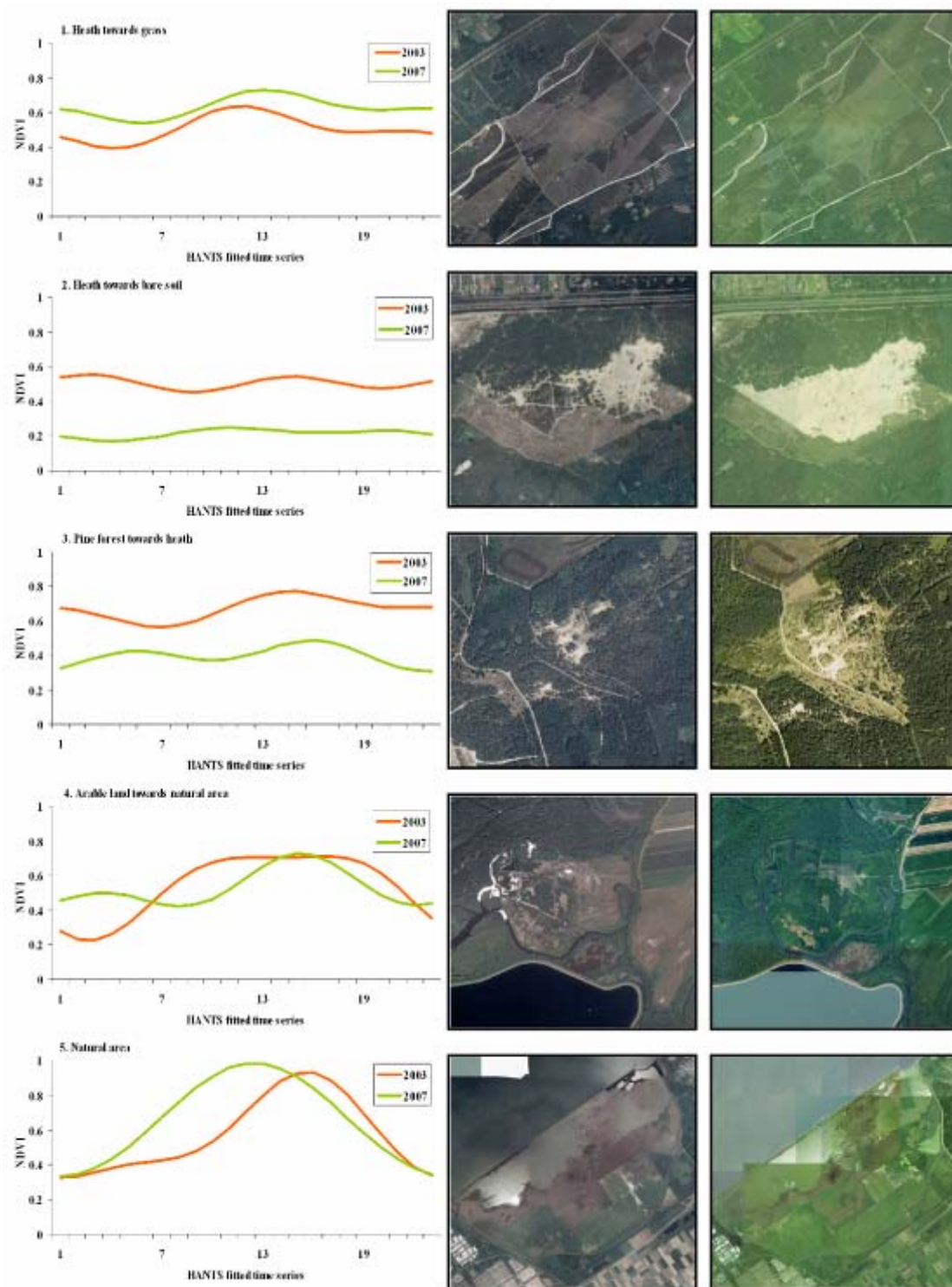


Figure 8 Temporal NDVI profile and corresponding aerial photographs from 2003 (pictures left) and 2007 (pictures right) showing hot spots of unusual effects on vegetation

The first three hot spots were identified in the Veluwe and were selected for their extreme differences between the average NDVI in 2003 and 2007. In two cases the average NDVI in 2003 was higher than in 2007, and in the third case the opposite occurred. The aerial photographs clearly reveal that human intervention is the cause of the sudden change in average NDVI values. These were nature conservation activities, such as heath removal from drifting sands and the cutting of pine trees. For the hot spot where the average NDVI in 2007 was higher than 2003, it is more difficult to find a plausible reason. From the aerial photographs it is apparent that there has been no human intervention, as in the other cases. However, from the LGN land cover map it becomes clear that the land cover is heath, which is sensitive to rapid succession without intervention activities, e.g. grazing by sheep.

From the analyses it could be concluded that the HANTS method described here would be suitable to identify unusual effects in vegetation. However, it has some drawbacks:

#### *Masking of water bodies*

The automatic water masking procedure is not very accurate and sometimes also excludes coastal areas. In this way a maximum of about 10 to 15 pixels (~3 to 4 km) near the coastline can be masked as water. Remarkably, the masking is only incorrect for shorelines on the eastern border of water. Consequently, strange effects in HANTS curve fitting frequently occur due to missing NDVI values. To overcome this problem, it could be decided to use the daily images instead of the 16-day composites. These daily images do not have a water mask+ however, the use of daily images would require far more processing time.

#### *Spatial resolution*

The MODIS input images and therefore also the resulting HANTS output have a resolution of 250 m (i.e. 6.25 ha). This is not sufficient to detect changes at field level, especially given the relatively small plot sizes and heterogeneous land cover in the Netherlands. To detect changes within small natural areas or agricultural plots, a resolution of 30 m (0.09 ha) or more will be necessary. However, to apply the same analysis to, e.g. RapidEye satellite images (5 m resolution) would be expensive and processing-intensive, and it would generate such large volumes of data that it becomes practically impossible to apply it on the scale of the Netherlands or Europe. However, it could also be argued that by using satellite images with a higher spatial resolution, like RapidEye, GS would be more suitable as an early warning system. To reduce the volume of data, the images could be limited to certain specific areas in GM cultivation areas and in the reference areas. This would also reduce the cost of using high resolution images (0.95 per km<sup>2</sup>). In this case it would also have to be established for RapidEye what vegetation effects can be detected, i.e. its sensitivity, and whether this system would still be feasible in the event of large scale cultivation of GM crops in the Netherlands.

#### *Conclusions*

The MODIS method described here can monitor relatively large changes only in natural areas, as arable farming involves major changes in vegetation type every year and is therefore always classified as 'extreme' changes in vegetation. GS essentially also requires that agricultural areas are monitored, so in case this method would be used for the monitoring of agricultural areas, a similar method needs to be specifically developed for that purpose.



## 6 Recommendations for future implementation of GS in the Netherlands

This report aims to present an overview to develop a practical approach to a GS system for the Netherlands based on the use of existing monitoring networks and other available data sources. In this chapter, recommendations are made for the implementation of GS in the Netherlands based on the networks described and discussed in more detail in chapter 5. It is further considered how and by whom observed effects can be correlated with the cultivation of GM crops.

### 6.1 Networks

#### *NEM*

The first monitoring system described was the NEM. This network appears to be very promising as a basis for GS in the Netherlands due to the data collected for the purpose of the environmental protection goal of 'biodiversity', the stability of the network and the frequency of sampling. More importantly, data selection and statistical analysis can be tailored to the purpose of GS, and the proof of principle using existing data described in chapter 5.1 demonstrates its suitability for GS. The NEM and its sub-networks are currently partly financed by the Ministry of Infrastructure and the Environment (Dutch Competent Authority, responsible for GS); therefore, data for GS can be obtained without incurring additional costs. Continued funding of the NEM is therefore also important for GS. The NEM data provide a suitable basis for an early warning system for potential GM effects.

#### *BISQ*

The BISQ network with the protection goal of 'soil quality' was also considered in terms of its applicability for GS. Like NEM, BISQ complies with the criteria for networks as defined in chapter 2 (see Table 1). Soil quality is considered an important protection goal by the European Commission (as indicated by [http://ec.europa.eu/environment/soil/pdf/report\\_conf.pdf](http://ec.europa.eu/environment/soil/pdf/report_conf.pdf) and [http://eusoils.jrc.ec.europa.eu/library/maps/biodiversity\\_atlas](http://eusoils.jrc.ec.europa.eu/library/maps/biodiversity_atlas)). If it were to be decided that the soil ecosystem should be part of GS in the Netherlands, BISQ would be the obvious network for this. Although sampling in BISQ takes place every year, each sampling site is examined only once every six years. This may be less suitable as an early warning system. However, it takes several years before changes in management are detectable in the soil. It could be decided to sample each sampling site on a yearly basis. It could also be argued that measuring the complete set of BISQ indicators for GS is too expensive, especially if this complete set is to be measured at all sites on a yearly basis. The selection of a few robust indicators from BISQ could provide a practical solution at a fraction of the cost of the full set of indicators. An alternative would be to limit sampling to sites within and directly outside GM cultivation areas. However, this will only be feasible if GM cultivation is limited (Smit et al., 2012). BISQ may therefore be suitable for GS in an adapted form (selection of indicators, increase in sampling frequency).

New tools are being developed (like chips that represent major functional groups of the soil ecosystem) that could be integrated in BISQ. Further development is necessary to make these new tools cost-effective and applicable as a standard method.

### *EOS*

Earth Observation Systems could be used to observe effects on vegetation in natural areas as a consequence of GM cultivation. Effects on vegetation could occur due to GM crop invasion, thereby affecting biodiversity. Alternatively, vegetation could be affected due to the GM crop having an adverse effect on soil functioning (i.e. on soil fertility), thereby hampering subsequent vegetation growth. In this case, EOS could, to a certain extent, offer a substitute to BISQ or be used alongside BISQ. The use of Earth Observation systems (EOS) was explored and found –in principle– to be feasible for GS in natural areas, but not in agricultural areas due to the high turnover of crops (e.g. crop rotation and changes in land use). Observation can be provided on a national scale with a resolution of 250x250 m (6.25 ha) using freely available data. However, this is not sensitive enough to be able to act as an early warning system. Higher resolution can only be obtained at a higher price, e.g. by using another satellite system and by limiting the observation area. To detect changes within a small natural area or in an agricultural plot, a resolution of no more than 30 metres (preferably lower) would be required.

### *Sensitivity of networks*

Another important issue is the sensitivity of the networks, e.g. what effects can be detected using data from NEM, BISQ or EOS in the Netherlands for GS. For NEM, the system is designed to detect yearly trend changes with a minimum of 5% change in numbers of individuals of selected species (or species groups) per year. This means that, in general, a 5% increase or decrease in numbers per year can be detected. The sensitivity may be higher or lower depending on the species (or species groups) measured, i.e. the variation.

For the indicators measured in BISQ the normal variation in soil (variation coefficient) is about 20%. This means that, generally speaking, only increases or decreases of more than 20% can be detected. This will also depend on the natural variation in the specific indicator at the field site which could be more than 20% (up to 30-50%), in which event the sensitivity will be lower.

Sensitivity is determined by the numbers of replicates. With sufficient replicates it is possible to detect changes of 10%.

As already mentioned above, for EOS the sensitivity of detecting vegetation changes will depend on the satellite system used. Relatively large changes in natural areas can be observed using MODIS. To detect more smaller changes in a resolution of 30 metres or less is necessary.

In the United Kingdom, a sub-group of the Advisory Committee on Releases to the Environment (ACRE) recently took a similar approach, i.e. investigating the use of existing Environmental Surveillance Networks (ESNs) as one tool for General Surveillance (GS), and in particular the ability of such networks to detect changes in environmental parameters. The sub-group advises that, overall, the use of the UK's existing ESNs for the purpose of post-market environmental monitoring (PMEM) in England is plausible. However, it recommends that the ability of each selected ESN to detect change has to be carefully considered as this may be limited. The likelihood of detecting change is influenced by a number of factors including the number and location of sampling points and the level of GM uptake (i.e. scale of GM cultivation). When finalised, the full report will be available on the ACRE website ([www.defra.gov.uk/acre](http://www.defra.gov.uk/acre)). In response to the findings of the sub-group, the Department for Environment, Food and Rural Affairs (DEFRA) has commissioned additional analyses to develop simple linear models. These will be used to estimate the ability of ESNs to detect

changes over time, or the differences in such changes between sites that differ in some respects, taking into account a number of factors including the scale and duration of the survey and the abundance of organisms. This model may also be used to estimate the number of sites required to achieve a certain level of capability, and in turn provide guidance on how the existing networks can be extended to provide additional capability and examine the cost-effectiveness of such extensions. Further details on the approach are available on the DEFRA website (DEFRA, 2012). The outcome of this approach will also be useful for the implementation of a GS system in the Netherlands.

## 6.2 Measured effects in relation to GS

### *What effects should be measured?*

GS is intended to observe unforeseen *adverse* effects. The question is therefore what does 'adverse' mean in relation to GS? In relation to the soil, Smit et al. (2012) defined adverse effects as effects that cause an '*irreversible or long term disturbance of key ecosystem functions that may result in changes in biodiversity*'. In the expert workshop (see section 4.2.2, Smit et al., 2009, 2012), it was decided that the classification of an effect as 'adverse' is not a scientific issue, but should be determined by relevant members of society (including policymakers). The classification of an effect as adverse or not largely depends on the use of the soil or land, and it is the land users (including 'users' of natural areas) who have to make this judgement. Therefore, the concept of ecosystem services is used to determine effects on the soil and whether they are adverse or not.

For measurements in ecosystems in general, like those carried out by the NEM, adverse effects could be interpreted as a significant change in trend in numbers of individuals in selected groups of species, thereby affecting biodiversity. The European Food Safety Authority (EFSA) considers an adverse effect as causing irreversible damage to a protection goal (EFSA, 2011). The effect should be biologically significant in which the intensity of the effect should be considered, as well as the intrinsic and economic value of the populations of species and the reversibility of the damage (EFSA, 2011). Therefore, it is not easy to define what is considered adverse and will depend on the protection goals of that specific country. These protection goals are determined by policymakers (Sandivo et al., 2011).

Irrespective of the definition of 'adverse', the first step in observing an adverse effect is the detection of an effect itself, and subsequently determining whether this effect is adverse and/or unusual. This report describes how effects can be detected, using data from existing monitoring networks such as NEM and BISQ (or with EOS). An effect can be defined as an observation that significantly differs from the baseline (COGEM, 2005). This stresses the importance of baseline data to use as a reference for effects. For the purposes of GS we define 'significantly' as *statistically* significant. This could be an observation that is statistically significant from the baseline (before GM cultivation took place), or that is statistically significantly different from a reference area (described as a type 1 alert under the NEM based approach). There may also be statistically significant effects that could occur only at a local level which could be overlooked when data are analysed for a larger region. These local effects could also be useful as an early warning sign to be taken into account when there is a suspicion that this could be linked to GM cultivation. This could be judged by a Task Force consisting of experts with different areas of expertise, as described by COGEM (2005). This Task Force will be discussed in more detail below.



### *Correlation with GM cultivation*

If a statistically significant effect is determined, the next step will be to find a logical cause for this effect. Only where the effect cannot be explained by factors that originate from agriculture in general, or from specific natural or climatic factors, there could be a correlation with GM cultivation. The GM register could be of use in establishing a potential correlation. Under Directive 2001/18/EC, each EU country should establish a register which records all locations where commercial GM cultivation takes place. As described above, growers have to register the plots where GM plants are cultivated on an annual basis. This means that there will be a history of GM locations that can be referred to when an unusual effect is observed. Using this information on GM locations, a statistical method as described in section 5.2 can be applied to establish whether or not there is a correlation. Where such a correlation between the effect and the GM crop (or crops) can be established, a causal relationship has to be demonstrated between the effect and the specific GM with case-specific research or monitoring. The outcome of this '*a posteriori*' case-specific research, or monitoring will provide the input for a renewed environmental risk assessment (ERA) of this specific GM. In such cases, GS will detect an effect that was not envisaged or was overlooked in the original risk assessment and in this way contributes to the quality and completeness of the ERA of GM crops. In the event that adverse effects can be correlated with a specific GM crop, Directive 2001/18/EC prescribes that this has to be reported directly to the European Commission and all member states, and immediate measures have to be taken to protect human health and the environment. Establishing a potential correlation between a significant effect and GM cultivation was considered to be the task of experts.

### *Central Reporting Office and Task Force*

In the expert workshop (Smit et al., 2012), it was concluded that a Central Reporting Office (CRO) needs to be established where all surveillance data are collected and stored in a central database. This CRO would also be responsible for the organisation of the data collection and the stakeholder participation process. COGEM (2005) recommended setting up a GS Task Force for GM crops consisting of experts on the subject of monitoring networks, GM crops, soil quality (including land users), water quality and nature conservation. This Task Force could meet every year to discuss observed effects, determine whether they are adverse or not and draw conclusions on the potential correlation with GM crops. They would report to the Competent Authority (CA) under Directive 2001/18/EC. Based on this report, together with a possible recommendation by COGEM concerning this report, adequate measures could be taken by the CA. The CRO as described above, could be linked to this Task Force.

## **6.3 Concluding remarks**

Under Directive 2001/18/EC the permit holder is responsible for post-market monitoring and thus for GS. In other words, the company that places GM crops on the market is obliged to perform GS. In our view GS, especially outside the cultivation areas, should be organised at national level in each member state to ensure proper data access and comparability, continuity, and the opportunity to create a database to enable long term impact assessments. This becomes all the more relevant if a number of GM crops produced by different companies are put on the market, which would mean that several companies would have to set up GS in different countries for different periods of time (i.e. the period that a specific GM crop is on the market). Such an approach is inherently inefficient, lacks continuity and does not provide a good basis for comparing data.

*Combination of networks for GS*

Taking into account the above, it can be decided whether and how to implement a GS system based on existing networks or systems at national level, like the networks NEM, BISQ and EOS in the Netherlands. This decision will have to be taken by the Dutch policymakers. This national GS system can be independent of the GS of the cultivation area itself, which will remain the primary responsibility of the permit holder. Dutch policymakers may opt for just one network, or for a combination of the selected networks. Combining a NEM and BISQ-based GS approach could be considered, for example, in which event the GS system will cover unusual effects affecting both biodiversity and soil quality. NEM could also be chosen as the only network for GS, as NEM seems to be more suitable to use as an early warning system. EOS (together with a suitable resolution) could be applied to detect vegetation changes in protected natural areas.

The other systems and networks described in chapter 2 could be used to complement a particular GS approach. The farmer questionnaires will provide an important source of information, as it may be assumed that unforeseen effects of GM cultivation will most likely originate at the source (fields with GM cultivation). These questionnaires can be obtained for GM crops grown in other EU member states. If there are indications of an adverse effect, this could prompt more specific surveillance in areas where this specific GM is grown (or has been grown) in the Netherlands. The same applies to annual reports and findings published in peer-reviewed literature, where there are indications of adverse effects. Other valuable sources are the inspections carried out by the Plant Protection Service (PD) for the prevention of plant diseases. In relation to biodiversity of other species that are not measured by NEM, data on distribution could be obtained from the NDFF database. For bees, results from the monitoring that now takes place in relation to bee death initiated by the Coloss research programme could be used.

All these additional data sources should be used with care and can only serve as a means to focus on specific areas or species (for example on bees) where there is an indication of an unusual effect. They cannot provide a basis for a GS system in the Netherlands as they cannot provide the specific analyses required for the purpose of GS. One should be aware that the use of many information sources could also increase the number of false alerts (see chapter 4), thereby making the GS system less sensitive and more expensive.

We consider GS to be a safety net that will detect adverse effects, should they occur as a result of GM cultivation in the EU. Ideally, GS can serve as an early warning system. On a European level, this may be difficult to achieve when the development of national GS systems is left up to the individual member states, as not all of them have similar monitoring networks in place, or networks that are suitable for GS. For this reason, it would be preferable to make use of a harmonised European system for data exchange that already exists at European level and which could be adapted for the purposes of GS. The use of earth observation systems with a suitable resolution at European level, or focused on specific protected areas within the EU, is one example. Alternatively, European databases that have already been set up for data exchange could be explored in terms of their use for GS. A platform like Lifewatch, for example, which is involved in the collection and exchange of European biodiversity data ([www.lifewatch.eu](http://www.lifewatch.eu)), could be further used to extend and coordinate such an initiative.

### *Conclusions*

In conclusion, if the Netherlands' Competent Authority decides to implement a GS system, there are several networks that could be used for this purpose, alone or in combination. One option would be to choose a GS system based on NEM, a network with biodiversity, as its protection goal. Data selection and analysis can be adapted to make this network suitable for GS (see section 5.1). A second network that could contribute to a GS system is BISQ, which has soil quality as its protection goal (see section 5.2), in which event it could be considered to focus on a few robust indicators for soil quality and adjust the sampling frequency. Data obtained from earth observation systems with a high resolution could be used as an additional source for GS, to monitor vegetation in specific areas like protected natural areas around GM cultivation areas, for example. In addition, the GS system can be supplemented with other available information sources as described in chapter 2. This system would help to increase the chance of adverse effects being detected – should they occur. As mentioned earlier, the use of many information sources could also increase the number of false alarms, thereby making the GS system less sensitive. Linking these potential effects afterwards to GM cultivation will be a challenge. The approach described in chapter 5 (Mulder et al. 2003; Vonk et al., in preparation) could contribute to establishing a potential correlation. This correlation could be further examined by the Task Force on GM crops, previously referred to.

Like in the Netherlands, the approach to developing a GS system based on existing networks could also be applied in other member states, provided that there are networks in place to serve protection goals that are important to that specific member state.

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## List of abbreviations (Dutch/English)

ACRE	Advisory Committee on Releases to the Environment of GMO's (United Kingdom)
BISQ	Biological Indicator System of Soil Quality
BobI	Bodembioologische indicator
CA	Competent Authority
CBS	Centraal Bureau voor de Statistiek/Statistics Netherlands
CSM	Case-Specific Monitoring
COGEM	Commission of Genetic Modification (Netherlands)
COLOSS	Prevention of Colony Losses
CI	Confidence Interval
CRO	Central Reporting Office
DEFRA	Department for Environment Food and Rural Affairs (United Kingdom)
DSQN	Dutch Soil Quality network
EOS	Earth Observation System
EFSA	European Food Safety Authority
EIS	European Invertebrate Survey
GaN	Gegevensautoriteit Natuur/National Authority for Data concerning Nature
GMO	Genetically modified organism
GS	General Surveillance
HANTS	Harmonic ANalyses of Time Series
PBL	Plan Bureau voor de Leefomgeving/Netherlands Environmental Assessment Agency
LGN	Landelijk Grondgebruik Nederland/Netherlands soil cover map
LMF	Landelijk meetnet flora/National Flora monitoring network
LSU	Livestock Units
Ministry of IenM	Ministerie van Infrastructuur en Milieu/Ministry of Infrastructure and the Environment
Ministry of EL&I	Ministerie van Economische Zaken, Landbouw en Innovatie/Ministry of Economic Affairs, Agriculture and Innovation
MS	Member State
MSI	Multi-species Index
MWTL	Monitoring Waterstaatkundige Toestand des Lands
NAK	Nederlandse Algemene Keuringsdienst voor zaad en pootgoed van landbouwgewassen/Netherlands General inspection Service for Agricultural Seeds and Seed Potatoes
NCB	Nederlands Centrum voor Bijenonderzoek/Netherlands Centre for Bee research
NCR	Nematode channel ratio
NDFF	Nationale Database Flora en Fauna/National Flora and Fauna Database
NDVI	Normalized Difference Vegetation Index
NEM	Netwerk Ecologische Monitoring/Ecological Monitoring Network
NVWA	Nederlandse Voedsel en Warenautoriteit/Netherlands Food and Consumer Product Safety Authority



OSE	Observational and Simulated Evidence
PD	Plantenziektenkundige Dienst/Plant Protection Service
PGO	Particuliere Gegevensbeherende Organisatie/ Private Ecological datamanagement Organisation
TRIM	Trends and Indices for Monitoring data
RIVM	Rijksinstituut voor Volksgezondheid en Milieu/National Institute of Public Health and the Environment
RL	Red List

## Appendix I. Species groups (indicators)

On the list below all species indicated in **bold** are used for GS. Species were not taken into account in case there were not enough NEM data-points available (<6) in one of the areas (cultivation area or reference area), or in case the trends were considered to be unreliable for other reasons (e.g. standard errors are too large).

### Group 1: Red List butterflies

*(Red List species with the exception of severely threatened species)*

Aardbeivlinder	( <i>Pyrgus malvae</i> )
<b>Bont dikkopje</b>	<b>(<i>Carterocephalus palaemon</i>)</b>
Boswitje	( <i>Leptidea sinapis</i> )
Bruin blauwtje	( <i>Aricia agestis</i> )
Bruine eikenpage	( <i>Satyrrium ilicis</i> )
<b>Bruine vuurvliinder</b>	<b>(<i>Lycaena tityrus</i>)</b>
Duinparelmoervlinder	( <i>Argynnis niobe</i> )
<b>Gentiaanblauwtje</b>	<b>(<i>Phengaris alcon</i>)</b>
<b>Groot dikkopje</b>	<b>(<i>Ochlodes sylvanus</i>)</b>
Heideblauwtje	( <i>Plebejus argus</i> )
<b>Heivlinder</b>	<b>(<i>Hipparchia semele</i>)</b>
<b>Kleine ijsvogelvlinder</b>	<b>(<i>Limenitis camilla</i>)</b>
Kleine parelmoervlinder	( <i>Issoria lathonia</i> )
<b>Kommavliinder</b>	<b>(<i>Hesperia comma</i>)</b>
Sleedoornpage	( <i>Thecla betulae</i> )
Spiegeldikkopje	( <i>Heteropterus morpheus</i> )
Zilveren maan	( <i>Boloria selene</i> )

### Group 2: Red List birds

*(Red List species with the exception of severely threatened species)*

Blauwe kiekendief	( <i>Circus cyaneus</i> )
<b>Boerenzwaluw</b>	<b>(<i>Hirundo rustica</i>)</b>
<b>Bontbekplevier</b>	<b>(<i>Charadrius hiaticula</i>)</b>
<b>Boomvalk</b>	<b>(<i>Falco subbuteo</i>)</b>
Brilduiker	( <i>Bucephala clangula</i> )
Dwergstern	( <i>Sterna albifrons</i> )
Engelse kwikstaart	( <i>Motacilla flavissima</i> )
<b>Gele kwikstaart</b>	<b>(<i>Motacilla flava</i>)</b>
Graspieper	( <i>Anthus pratensis</i> )
<b>Grauwe klauwier</b>	<b>(<i>Lanius collurio</i>)</b>
<b>Grauwe vliegenvanger</b>	<b>(<i>Muscicapa striata</i>)</b>
<b>Groene specht</b>	<b>(<i>Picus viridis</i>)</b>
Grote karekiet	( <i>Acrocephalus arundinaceus</i> )
Grote mantelmeeuw	( <i>Larus marinus</i> )
Grote stern	( <i>Sterna sandvicensis</i> )
Grote zilverreiger	( <i>Casmerodius albus</i> )
<b>Grutto</b>	<b>(<i>Limosa limosa</i>)</b>
<b>Huismus</b>	<b>(<i>Passer domesticus</i>)</b>
<b>Huiszwaluw</b>	<b>(<i>Delichon urbica</i>)</b>
<b>Kerkuil</b>	<b>(<i>Tyto alba</i>)</b>
Kleine zilverreiger	( <i>Egretta garzetta</i> )
<b>Kneu</b>	<b>(<i>Carduelis cannabina</i>)</b>

Koekoek	<i>(Cuculus canorus)</i>
Kramsvogel	<i>(Turdus pilaris)</i>
<b>Kwartelkoning</b>	<b><i>(Crex crex)</i></b>
<b>Matkop</b>	<b><i>(Parus montanus)</i></b>
Middelste zaagbek	<i>(Mergus serrator)</i>
<b>Nachtegaal</b>	<b><i>(Luscinia megarhynchos)</i></b>
<b>Nachtzwaluw</b>	<b><i>(Caprimulgus europaeus)</i></b>
Oeverloper	<i>(Actitis hypoleucos)</i>
<b>Paapje</b>	<b><i>(Saxicola rubetra)</i></b>
<b>Patrijs</b>	<b><i>(Perdix perdix)</i></b>
<b>Pijlstaart</b>	<b><i>(Anas acuta)</i></b>
<b>Porseleinhoen</b>	<b><i>(Porzana porzana)</i></b>
Purperreiger	<i>(Ardea purpurea)</i>
<b>Raaf</b>	<b><i>(Corvus corax)</i></b>
<b>Ransuil</b>	<b><i>(Asio otus)</i></b>
<b>Ringmus</b>	<b><i>(Passer montanus)</i></b>
<b>Roerdomp</b>	<b><i>(Botaurus stellaris)</i></b>
Roodhalsfuut	<i>(Podiceps grisegena)</i>
Slechtvalk	<i>(Falco peregrinus)</i>
<b>Slobeend</b>	<b><i>(Anas clypeata)</i></b>
<b>Snor</b>	<b><i>(Locustella luscinioides)</i></b>
<b>Spotvogel</b>	<b><i>(Hippolais icterina)</i></b>
<b>Steenuil</b>	<b><i>(Athene noctua)</i></b>
Steltkluut	<i>(Himantopus himantopus)</i>
Strandplevier	<i>(Charadrius alexandrinus)</i>
<b>Tapuit</b>	<b><i>(Oenanthe oenanthe)</i></b>
<b>Tureluur</b>	<b><i>(Tringa tetanus)</i></b>
<b>Veldleeuwerik</b>	<b><i>(Alauda arvensis)</i></b>
<b>Visdief</b>	<b><i>(Sterna hirundo)</i></b>
<b>Watersnip</b>	<b><i>(Gallinago gallinago)</i></b>
<b>Wielewaal</b>	<b><i>(Oriolus oriolus)</i></b>
<b>Wintertaling</b>	<b><i>(Anas crecca)</i></b>
<b>Zomertaling</b>	<b><i>(Anas querquedula)</i></b>
<b>Zomertortel</b>	<b><i>(Streptopelia turtur)</i></b>
<b>Zwarte stern</b>	<b><i>(Chlidonias niger)</i></b>

### Group 3: Butterflies in agricultural areas

Bruin zandoogje	<i>(Maniola jurtina)</i>
Citroenvlinder	<i>(Gonepteryx rhamni)</i>
Dagpauwoog	<i>(Aglais io)</i>
Geelsprietdikkopje	<i>(Thymelicus sylvestris)</i>
Gehakkelde aurelia	<i>(Polygonia c-album)</i>
Groot koolwitje	<i>(Pieris brassicae)</i>
Hooibeestje	<i>(Coenonympha pamphilus)</i>
Icarusblauwtje	<i>(Polyommatus icarus)</i>
Klein geaderd witje	<i>(Pieris napi)</i>
Klein koolwitje	<i>(Pieris rapae)</i>
Kleine vos	<i>(Aglais urticae)</i>
Kleine vuurvinder	<i>(Lycaena phlaeas)</i>
Koninginnenpage	<i>(Papilio machaon)</i>
Oranje zandoogje	<i>(Pyronia tithonus)</i>
Oranjetipje	<i>(Anthocharis cardamines)</i>
Zwartsprietdikkopje	<i>(Thymelicus lineola)</i>

## Group 4: Breeding birds, birds of prey, owls in agricultural areas

<b>Buizerd</b>	<b><i>(Buteo buteo)</i></b>
<b>Grauwe kiekendief</b>	<b><i>(Circus pygargus)</i></b>
<b>Havik</b>	<b><i>(Accipiter gentiles)</i></b>
<b>Kerkuil</b>	<b><i>(Tyto alba)</i></b>
<b>Ransuil</b>	<b><i>(Asio otus)</i></b>
<b>Sperwer</b>	<b><i>(Accipiter nisus)</i></b>
<b>Steenuil</b>	<b><i>(Athene noctua)</i></b>
<b>Torenvalk</b>	<b><i>(Falco tinnunculus)</i></b>

## Group 5: Breeding birds in agricultural areas

<b>Ekster</b>	<b><i>(Pica pica)</i></b>
<b>Graspieper</b>	<b><i>(Anthus pratensis)</i></b>
<b>Kievit</b>	<b><i>(Vanellus vanellus)</i></b>
<b>Patrijs</b>	<b><i>(Perdix perdix)</i></b>
<b>Scholekster</b>	<b><i>(Haematopus ostralegus)</i></b>
<b>Veldleeuwerik</b>	<b><i>(Alauda arvensis)</i></b>

## Group 6: Diurnal mammals in agricultural areas

<b>Haas</b>	<b><i>(Lepus europaeus)</i></b>
<b>Ree</b>	<b><i>(Capreolus capreolus)</i></b>

## Group 7: Plants

<b>Graminaeae</b> in relation to GS of GM maize	<b><i>(Gramineae)</i></b>
<b>Solanaceae</b> in relation to GS of GM potato	<b><i>(Solanum nigr. ssp.nigrum)</i></b>
	<b><i>(Solanum dulcamara)</i></b>

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