2008 GERMAN NETWORK MONITORING

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TABLE OF CONTENTS

1. SCOPE OF THE REPORT 3

2. INTRODUCTION 3

3. LEGAL NOTES 6

4. CROP PLANTINGS OF MON 810 IN GERMANY IN 2008 8

5. EVALUATION OF AVAILABLE INFORMATION OF SUITABLE EXISTING NETWORKS 10

5.1 Networks included in General Surveillance 10

5.2 Results of Analysis of Selected Networks: Category 1 11

5.2.1 Monitoring of Game species in Germany: Deutscher Jagdschutz-Verband e.V. (The German Hunting Association) 11

5.2.2 Monitoring of Common Birds: Dachverband Deutscher Avifaunisten e.V. (DDA) (Federation of German Avifaunists) 14

5.2.3 Monitoring of Butterfly population dynamics in Germany: Tagfalter-Monitoring Deutschland 16

5.2.4 Monitoring of Bees Germany: Deutsches Bienenmonitoring (German Honey Bee Monitoring Network) 19

5.2.5 Monitoring of soil in Germany: Boden-Dauerbeobachtung 22

5.3 Results of Analysis of Selected Networks: Category 2 24

5.3.1 Monitoring for indicators of biodiversity in agriculture: Daten zue Umwelt 24

5.3.2 Plant protection services: Informationssystem Integrierte Pflanzenproduktion (ISIP) 26

5.3.3 Register for cultivation of GM crops: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit 27

6. OVERALL CONCLUSIONS OF GERMAN NETWORK MONITORING 28

7. REFERENCES 29

APPENDIX 1 **2007 Monitoring Report: MON 810 Cultivation**
Czech Republic, France, Germany, Portugal, Slovakia, Poland, Romania, and Spain

APPENDIX 2 **2008 Annual General Surveillance Report for MON 810 undertaken on a voluntary basis**

1. SCOPE OF THE REPORT

This report addresses the analysis of selected networks as part of the implementation of General Surveillance of MON 810 in Germany.

2. INTRODUCTION

In April 1998, after a review of the risk assessment conducted for MON 810 in the notification C/F/95/12/02 by France, acting as the *rapporteur* country, by the competent authorities of the member states, and by the Scientific Committee on Plants, the European Union decided, in Commission Decision 98/294/EC, to approve the placing on the market of MON 810 in accordance with Directive 90/220/EEC (Commission Decision, 1998).

In 2005, Monsanto initiated, on a voluntary basis, a general surveillance monitoring program in anticipation of the mandatory requirement for post market environmental monitoring in all applications or renewals for deliberate release submitted under Directive 2001/18/EC and Regulation (EC) No. 1829/2003 (including the renewal of the MON 810 consent (Commission Decision, 1998)).

The objective of general surveillance is to identify the occurrence of unanticipated adverse effects of the genetically modified plants on human health or the environment that were not anticipated in the risk assessment. The main challenge of general surveillance is determining whether *1)* an unusual effect has been observed (*i.e.* an alteration that results in values that are outside the normal variation range given the constant change and flux of the agriculture, the agricultural practices, the rural environment and the associated biota in the European Union), *2)* the effect is adverse, and *3)* the adverse effect is associated with the GM plant or its cultivation (EFSA, 2006).

Taking the above factors into consideration, the general surveillance monitoring program implemented by Monsanto for MON 810 consists of four elements:

- a Farmer Questionnaire designed to assess any unusual observations in the areas where the product is cultivated;
- data collected from scientific publications or reports relating to the cultivated product and its environmental safety;
- company stewardship activities designed to ensure and maintain the value of the product;
- alerts on environmental issues by authorities, existing networks and the press that may reflect potential adverse effects associated with the product.

Results of the general surveillance monitoring, along with results of Insect Resistance Management are provided to the European Commission on an annual basis (**Attachment 1**). In addition, Monsanto also reports annually on general surveillance activities associated with the handling and use of viable MON 810 maize grain imported into the EU (**Attachment 2**). In both cases, if the investigation establishes that MON 810 is the cause of an adverse effect, Monsanto shall immediately inform the European Commission. Monsanto, in collaboration

with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, shall define and implement management measures to protect human health or the environment, as necessary.

On 27 April 2007, the German Competent Authority, the Federal Office of Consumer Protection and Food Safety (BVL; Bundesamt für Verbraucherschutz und Lebensmittelsicherheit), temporarily suspended the authorisation to distribute MON 810 maize seeds for commercial planting in Germany. The suspension remained valid until Monsanto, as authorisation holder, submitted an appropriate monitoring plan for MON 810 cultivation in Germany to the BVL. An agreement on this monitoring plan was the basis for the lifting of the German suspension.

While Farmer Questionnaires remain the central element of the monitoring plan for MON 810, the use of available information from defined existing networks was an additional and new element that was proposed for incorporation into the general surveillance. Results and analysis of the 2008 Farmer Questionnaires will be incorporated in the 2008 Cultivation Monitoring Report, and will be provided to the European Commission in July 2009.

Following discussions and agreement with the BVL[1,2,3], with respect to the national implementation of the monitoring of MON 810, two categories of networks were selected to contribute to the General Surveillance of MON 810 in Germany. Five networks were selected in the first category as being suitable to provide information on a relevant monitoring character; game species, common birds, butterfly population dynamics, bees and soil. The second category of networks provides information on relevant influencing characters which play a critical role in determining the context in which the plants (GM or not GM) will be cultivated, and therefore set the context of the monitoring. These networks include monitoring for indicators of biodiversity in agriculture (this network also includes indicators related to soil organisms and soil functions), plant protection services and the register for cultivation of GM crops, and will be consulted on an *ad hoc* basis to cross check information generated by other aspects of the monitoring program. Additional networks such as the meteorological services or other networks monitoring for pollution levels could also be included where it was judged that this would be relevant. German networks selected for consideration in the general surveillance monitoring are considered adequate and proportionate to the area and acreage planted to MON 810 in Germany (see **Section 4; Table 1**).

In collaboration with the BVL, Monsanto agreed to analyse publicly available resources of these networks on an annual basis, as one component of general surveillance, to help assess whether any potential adverse effects have occurred as a result of MON 810 cultivation. If sound scientific indications of adverse effects are observed, raw data will be requested from

[1] Monsanto to BVL, 31 August 2007
[2] Monsanto to BVL, 9 November 2007
[3] Monsanto to BVL, 4 December 2007

the networks in order to conduct a more thorough investigation to determine if the effects are related to the cultivation of MON 810.

This report represents the results of Monsanto's analysis of these network reports in 2008, and is provided to the BVL in advance of the 2008 MON 810 Cultivation Monitoring Report. It is important to note that for the 2008 season, the acreage cultivated to MON 810 maize in Germany represented no more than 0.2% of the total acreage of maize planted in Germany (see **Section 4; Table 1**) and 0.026% of the total arable land in Germany. It was therefore not expected that MON 810 could influence any of the parameters of the selected networks, especially when looking at all tangible factors that are known to influence agricultural environments. However, it remains that this exercise is important, as it has allowed the testing and development of the concept of assessing networks for general surveillance in anticipation of larger acreage of MON 810.

3. LEGAL NOTES

The legal basis of this report is the agreement with the BVL as outlined in the BVL's letter to Monsanto of 5 December 2007. BVL and Monsanto agreed on the monitoring measures in order to avoid court proceedings regarding the suspension of the authorisation to distribute MON 810. Monsanto maintains its opinion that there was no legal ground for this suspension, as there were no reasons for considering that MON 810 constitutes a risk to human health or the environment. Also, *Section 20 (2)* GenTG does not authorise member states to impose monitoring measures according to the Directive 2001/18/EC, as those monitoring measures only apply for a new notification or a renewal of an existing notification, but not for existing authorisations to distribute a GMO.

The monitoring measures as described below meet all the requirements from the agreement of 5 December 2007. This applies to the four elements of the general surveillance monitoring program (farmer questionnaires, scientific publications or reports, company stewardship, alerts on environmental issues) as well as to the use of available information from defined existing networks. The networks in the first category (monitoring of game species, common birds, butterfly population dynamics, bees, and soil) and in the second category, were agreed between BVL and Monsanto. Monsanto has agreed to analyse, on an annual basis, the reports published by the networks to establish whether any potential adverse effects as a result of MON 810 cultivation can be identified. The monitoring only refers to the publicly available information of the networks. Therefore, the consideration of the networks is not dependent on the willingness or ability of networks to cooperate or contribute to the monitoring of MON 810. In the agreement of 5 December 2007, both sides agreed on the suitability and relevance of the data collected by the networks. Therefore, any doubts regarding the suitability of the networks or their willingness to cooperate would not lead to a breach of the monitoring requirements.

In addition, the agreement of 5 December 2007 and Monsanto's monitoring plan also fulfil the requirements of the Directive 2001/18/EC, Annex VII to this directive and the corresponding provisions in the National Gene Technology Law (*Section 16c* GenTG). Firstly, it is worth emphasising that a case-specific monitoring (*fallspezifische Beobachtung, § 16c Abs. 2 Nr. 1 GenTG*) is neither required nor possible with regard to MON 810. The objective of the case-specific monitoring is to confirm that any assumptions regarding the occurrence and impact of potential adverse effects of the GMO, or its use in the environmental risk assessment are correct. Its main objective is to determine the significance of any adverse effects identified in the risk assessment. As in the risk assessment of MON 810 no such effects have been identified, there is no room for a detailed case-by-case monitoring at all. In fact, in the case of MON 810 only a general surveillance (*allgemeine Beobachtung, § 16c Abs. 2 Nr. 2 GenTG*) is required. As the EFSA Guidance Document on Monitoring (EFSA, 2006) states, general surveillance applies where no adverse effect has been identified in the environmental risk assessment. The objective of general surveillance is to detect unanticipated adverse effects. According to the opinion of the EFSA GMO Panel, general surveillance should generally oversee the geographical regions where GM plants are

grown, without having any specific hypothesis on adverse effects on human health or the environment. As general surveillance is not hypothesis-driven, it is not conducted using directed experimental approaches (EFSA, 2006, p. 43, 45).

Furthermore, the EFSA Guidance Document on Monitoring (EFSA, 2006) clarifies that the evaluation of the consistency and reliability of existing monitoring networks is part of the monitoring process. Monitoring plans therefore should not be viewed as static, but may be modified or adapted by the applicant responsible for the GMO. It follows from the above that a potential need for modifications of a monitoring plan would not lead to a breach of the monitoring requirements. Finally, the EFSA Guidance Document clarifies that there are no provisions regarding the time frame for reporting the results of the monitoring. This also applies for the agreement between BVL and Monsanto of 5 December 2007. It is worth mentioning that according to the Guidance Document, the annual reports only should contain a confirmation that monitoring has been carried out according to the given consent together with a summary of major preliminary results. Comprehensive monitoring reports – like the report for MON 810 below and in **Attachment 1** - should be submitted periodically, e.g., every third year. Only in those reports should the observation and data collected be reported and analysed in detail. Against this background, the detailed report submitted by Monsanto below also fulfils the reporting requirements in every respect, as Monsanto is delivering this report long before the end of the suggested period.

4. CROP PLANTINGS OF MON 810 IN GERMANY IN 2008

MON 810 was planted on 3,173 hectares in Germany in 2008 (**Table 1**). MON 810 is principally cultivated in the north-east of Germany **(Figure 1**).

Table 1. Area of MON 810 maize cultivated in Germany from 2005 – 2008

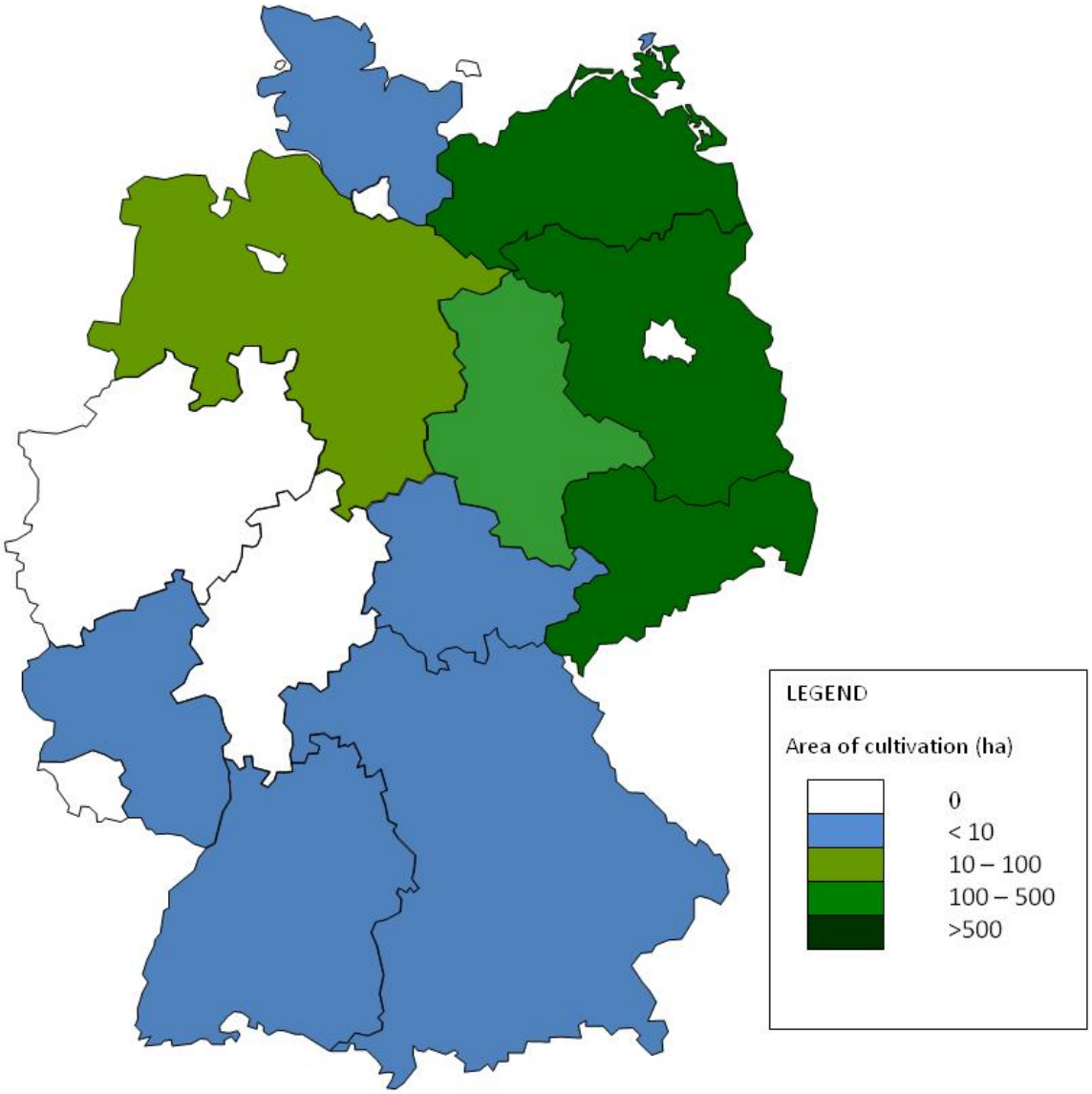
	2005	2006	2007	2008
MON 810 area (hectares)	342	947	2,685	3,173

While the acreage planted to GM maize in Germany since its introduction has slightly increased from year to year, it is important to note that the total acreage planted to maize in Germany has also increased in the period between 2005 and 2008; the percentage of GM maize planted in Germany is still negligible when compared to the total acreage of maize cultivated in Germany, *i.e.* no more than 0.2% (**Table 2**), or the total arable land, *i.e.* 0.026%.

Table 2. Comparison of MON 810 maize and conventional maize cultivated in Germany from 2005-2008

	2005	2006	2007	2008
MON 810 (hectares)	342	947	2 685	3 173
Conventional maize (hectares)	1 705 658	1 742 053	1 871 397	2 081 520
MON 810 area as percentage of total maize cultivated in Germany (%)	0.02	0.05	0.14	0.15

Source : http://www.bvl.bund.de/cln_007/nn_491980/DE/06_Gentechnik/07_Anbau/01_Standortregister/HG-Auswertung_Stareg.html



http://194.95.226.237/stareg_visual_web/localeSwitch.do?language=en&page=/data.do

Figure 1. National distribution of Bt maize in Germany in 2008 visualised by the Federal Institute of Consumer Protection and Food Safety (BVL)

5. EVALUATION OF AVAILABLE INFORMATION OF SUITABLE EXISTING NETWORKS

5.1 Networks included in General Surveillance

Monsanto Europe has committed to analyse on an annual basis, information of the networks in Category 1 listed below to establish whether any potential adverse effects as a result of MON 810 cultivation can be identified. In general, networks listed in Category 2 are consulted only on an *ad hoc* basis to cross check information generated by other aspects of the monitoring program.

Category 1: Networks providing information on relevant monitoring characters

- Monitoring of game species in Germany:
  Deutscher Jagdschutz-Verband e.V. (The German Hunting Association)

- Monitoring of common birds:
  Dachverband Deutscher Avifaunisten e.V. (DDA) (Federation of German Avifaunists)

- Monitoring of butterfly population dynamics:
  Tagfalter-Monitoring Deutschland

- Monitoring of bees in Germany:
  Deutsches Bienenmonitoring (German Honey Bee Monitoring Network)

- Monitoring of soil in Germany:
  Boden-Dauerbeobachtung

Category 2: Networks providing information on relevant influencing characters

- Monitoring for indicators of biodiversity in agriculture:
  Daten zur Umwelt

- Plant protection services
  Informationssystem Integrierte Pflanzenproduktion (ISIP)

- Register for cultivation of GM crops
  Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Publicly available information such as published (annual) reports from the networks, websites, online databases, newsletters, letters, emails were used or accessed to collect information. Letters and emails of invitation were sent to the network coordinators to discuss the principles of the general surveillance. In some cases direct contact was established with the coordinators of the network. The information was subsequently evaluated to establish whether any potential adverse effect as a result of the MON 810 cultivation could be identified.

5.2 Results of Analysis of Selected Networks: Category 1

5.2.1 Monitoring of Game species in Germany: Deutscher Jagdschutz-Verband e.V. (The German Hunting Association)

The German Hunting Association (Deutscher Jagdschutz-Verband e.V.) established the German Wildlife Information System, WILD (Wildtier-Informationssystem der Länder Deutschlands) in 2001. The WILD system was set up as a long-term project to run for 10 years from January 2003 for the country-wide collection of information about the occurrence, number, and development of game populations throughout Germany. Project and background information is presented in the project handbook[4].

Data in WILD are collected by counting game species in so-called reference areas. Data from 2003 – 2007 were assembled and assessed for six reference species; the European Hare (*Lepus europaeus* Pallas), Red Fox (*Vulpes vulpes* L.), Badger (*Meles meles* L.), Carrion Crow (*Corvus c. corone* L.), Hooded Crow (*Corvus c. cornix* L.), and Partridge (*Perdix perdix* L.)[5] (Bartel *et al.,* 2004, 2005, 2006, 2007 and Grauer *et al*., 2008).

Six regions across Germany were distinguished: Northwest (Nordwestdeutsches Tiefland), Northeast (Nordostdeutsches Tiefland), West (Westdeutsches Mittelgebirge), East (Ostdeutsches Mittelgebirge), Southwest (Südwestdeutsches Mittelgebirge/Stufenland), and the Alpine area (Alpenvorland) (Figure 1, Grauer *et al*., 2008[6]). Since its inception, the project has established more than 800 reference areas, in the regions listed above, evenly distributed all over Germany.

- ***European Hare***

Population densities of the European hare were calculated by spotlight trip censuses by local hunters (Strauß *et al.,* 2008). The census is carried out in spring and autumn.

The number of European Hare per 100 hectares were recorded across Germany from 2002 – 2007 (Figure 12, Grauer *et al.,* 2008[6]). Steady growth in the numbers of European Hare per 100 hectares were observed between 2002 and 2006, however a slight decrease was observed in 2007. Reasons for this slight decrease were discussed in Bartel *et al*., 2005 and were attributed to factors associated with habitat and other local regional factors such as predators (red fox, badger, birds of prey *etc*). It appears very unlikely that the cultivation of MON 810 was associated with this observed decrease, given that the net growth rate shows a difference in 2007 in the European Hare population across all regions, and MON 810 was grown primarily in Northeastern Germany.

The net growth rate in percent, as a result of reproduction, mortality and dispersal, was also estimated by accounting for the difference between spring population and autumn population density in any one year. Differences in densities can be seen on a regional level from year to

[4] http://medienjagd.test.newsroom.de/projekthandbuch_wild0808.pdf (Last accessed 19 March, 2009)
[5] During preliminary studies in 2001 and 2002, population densities of brown hare and partridge were studied.
[6] Grauer et al., 2008 - http://www.jagdnetz.de/wild?meta_id=1179 (Last accessed 19 March, 2009)

year (Figure 11, Grauer *et al.,* 2008[6]). Between 2002 and 2007, high densities were recorded in Northwest and Southwest Germany, which has a high incidence of intensively used agricultural landscapes as well as pastoral areas (Strauß *et al.,* 2008). Population densities appear significantly lower in East Germany than in Northwest Germany. This has been attributed to the differences between the regions linked to the size of the agricultural fields, which are larger in East Germany (a result of the agricultural system in the former German Democratic Republic) than Northwest Germany (Strauß *et al.,* 2008). Differences in densities could also be attributed to different habitat types, methodological errors, diseases (Strauß *et al.,* 2008), predators or weather conditions (Bartel *et al*., 2005).

- ***Red Fox***

Population densities of Red Fox from 2003 – 2007 were determined by den mapping, according to the method defined by the German hunting association. The dens of the Red Fox are counted and mapped by the local coordinator of the hunting district, and Red Fox density is calculated as the published male / female ratio of 2.5 and an average of 4.5 young foxes per hole (Bartel *et al*., 2005).

Some variability was observed within each of the six regions between 2003 and 2007 in the number of Red Fox dens per 100 hectares mapped, however no significant differences were observed over time (Figure 17, Grauer *et al*., 2008[7]). Differences across regions were observed; the highest densities of Red Fox dens were found in the hilly areas in mid-Germany, while lower densities were recorded in Northwest and Southwest Germany. This difference is likely explained by habitat preference of the Red Fox. Given that only very small amounts of MON 810 are cultivated in Northwest and Southwest Germany, it is very unlikely that this variation can be attributed to MON 810.

- ***Badger***

Badger populations were determined by mapping Badger setts. Between 2003 and 2007, some variability within regions was observed in Badger populations, but numbers did not seem to change significantly over time (Figure 21, Grauer *et al*., 2008[7]). Differences were also observed from region to region, with higher densities recorded in the west and lower densities in Northeast Germany. It should be noted that the sample size within the northwest region was too small for a proper analysis. While lower densities of Badger were observed in Northeast Germany, an area where MON 810 is cultivated, the variation is most likely due to habitat and food supply representative of these regions, two factors that have a major influence on distribution of Badgers.

- ***Carrion and Hooded Crow***

Crow density was mapped by estimating breeding pairs per square kilometer. The crow breeding pair densities are relatively stable in all regions over the years from 2003 to 2007

[7] Grauer et al., 2008 - http://www.jagdnetz.de/wild?meta_id=1179 (Last accessed 19 March, 2009)

(Figure 28, Grauer *et al*., 2008[7]), although some slight differences are attributed to lower number of spot checks (Grauer *et al*., 2008). Data showed considerable agreement with the German breeding birdrace entry data as published by Sudfeld *et al*., 2007 (see also Section 4.2.2).

- ***Partridge***

Area estimation for Partridges was evaluated. The method is based on a questionnaire which has been used by the WILD network since 2001 to assess the occurrence of Partridges in German communities[8]. Densities are given in number of pairs per 100 hectares and clustered in six parts. To avoid subjective interpretation in regions with large Partridge communities, densities are given for the different hunting districts.

Partridge populations were evaluated in only two regions; Northwestern and mid-east Germany, regions of preferred habitat of the Partridge. In these two regions, Partridge densities did not change significantly over time since 2003, but do display some variation between the two regions (Figure 37, Grauer *et al*., 2008[9]). Highest pair densities were found in regions in Northwestern Germany where the climate is influenced by the Atlantic, while lower densities were observed in hilly areas of mid Eastern Germany. The range of German Partridge pair density is comparable with densities observed in the United Kingdom by the Game Conservancy Trust in 2005; ranging from levels of less than one to six pairs per 100 hectares (Kingdon, 2006).

Conclusion: Monitoring of Game Species

An analysis of information presented by the German Hunting Association in its WILD program was conducted. As can be seen from the available information, variation in population densities of representative species can be observed across regions in Germany. As mentioned in the report (Grauer *et al*., 2008), these observations do not appear to be unexpected given the differences across regions in Germany in terms of land use, habitat, predators or weather conditions (Bartel *et al*., 2005). Methods of data collection may have had some impact on the final numbers recorded, however crosschecks to other sources of available information did indicate some correlation between the WILD findings and other bird monitoring data (Sudfeldt *et al*., 2007).

None of the information analysed linked any differences in population distribution of game species across Germany with the cultivation of MON 810. Furthermore, differences in abundance of game species across Germany could not be explained by the cultivation of MON 810 in Germany.

[8] http://medienjagd.test.newsroom.de/projekthandbuch_wild0808.pdf (Last accessed 19 March, 2009)
[9] Grauer et al., 2008 - http://www.jagdnetz.de/wild?meta_id=1179 (Last accessed 19 March, 2009)

5.2.2 Monitoring of Common Birds: Dachverband Deutscher Avifaunisten e.V. (DDA) (Federation of German Avifaunists)

In order to facilitate statistically secure monitoring of sustainability in the area of nature protection, the Bundesamt für Naturschutz (BfN; Federal Agency for Nature Protection) commissioned the development of a sustainability indicator index. These nature protection indicators, embedded in the federal government's sustainability strategy, are essentially based on the nationwide trends in bird populations. The Dachverband Deutscher Avifaunisten (DDA; Federation of German Avifaunists) is involved in the coordination of a number of bird monitoring programmes throughout Germany and is comprised of all federal and regional ornithological associations and societies of Germany and represents some 8,000 – 9,000 field ornithologists and birdwatchers. The stated objective of the bird monitoring program is to identify trends in order to register serious and continuing population changes in order to initiate further studies or other measures before a species becomes so rare that help is possibly too late (DDA, 2009).

The monitoring uses a stratified, randomized sampling design of 1,000 sites (1 km^2 squares) encompassing different location types and land categories (Mitschke *et al*., 2005). Data on bird species showing breeding or territorial behavior are mapped using the line transect method along a 3 kilometre route, and covers all important habitats on the sampling site. Species specific mapping results can be drawn from an "aural corridor", which allows an area-related representative picture, as well as projections on the basis of habitat type.[10] Four monitoring walks are carried out by volunteers per season (early morning, no rain, less than 4 Bf of wind speed). All potential birds of the line-transect are consequently marked on maps (1 : 5,000) together with the landscape type. Results of the season's mapping are stated as number of breeding pairs. This method allows ecologically meaningful mapping.

Within the published data sets (Sudfelt *et al*., 2007; Sudfelt *et al*., 2008), several million data points were analysed by the authors. The authors present an overall summary of the information grouped into the categories of frequent breeding birds, endangered breeding birds, and birds as indicators. In Germany, 75 to 100 Million pairs of birds breed. The most frequent breeding bird species are the Finch, Sparrow and Blackbird. The Great Tit, Robin, Blue Tit, Common Chiffchaff, Blackcap and Sky Lark are also ranked as frequent breeding birds. Twenty percent of the frequent breeding birds are currently on the 'red list' (14 species are under a 'warning status'), however the overall number of species has increased to 305 due to recovery in some species and increased abundance of sporadically occurring species. The report indicates that the long term trend (50 to 150 years) for breeding birds has been negative. According to the authors, this is due to large changes within all landscapes (cultural landscapes, heath and sandy areas, river areas, wetlands and alpine areas). In the short term (25 years), the abundance of bird species has increased or remained stable. This is attributed to the change in agriculture during the 1970's. Currently, a positive change is evident, but every eighth domestic species is still endangered.

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[10] http://www.dda-web.de/index.php?cat=Monitoring&id=1&subid=1&ssc=0&lang=en (Last accessed 20 March, 2009)

Available reports were also analysed to determine if there were any negative trends in bird populations that inhabit specific areas such as agricultural landscapes (farmland birds), urban landscapes (urban birds), forest landscapes (forest birds) and mountainous landscapes (alpine birds) (Flade *et al*., 2008; Sudfelt *et al*., 2007, 2008), that could be attributed to the cultivation of MON 810. Bird populations in areas where MON 810 is unlikely to be cultivated, *i.e.* wetland birds, coastal and sea birds and migrating seabirds, were not considered.

Negative trends were observed in farmland bird and urban bird populations over the period of the study (Flade *et al*., 2008; Sudfelt *et al.,* 2007, 2008). Forest birds also displayed a negative trend in some species (*e.g.* red kite, European honey buzzard, lesser spotted eagle, European turtle dove, European pied flycatcher, tree pipit, wood warbler), while an increase in numbers were recorded for others species (*e.g.* stock dove, black woodpecker, great spotted woodpecker, Eurasian nuthatch) (Sudfelt *et al*., 2007, 2008). Alpine bird populations generally remained stagnant.

Negative trends in bird populations in agricultural landscapes were attributed to farming conditions, irrigation, predatory mammals, climate change and over-fertilisation. An increased demand for land to produce 'bio-fuels', loss of grassland, and the spread of agricultural monocultures were also given as possible causes of bird population decline in these areas. The expansion and redevelopment of urban areas, were listed as possible reasons for declines in populations of urban birds, and negative trends in some forest bird species were connected to a reduction in food supply (Flade *et al*., 2008). Cultivation of biotech crops were not listed as possible reasons for decreased numbers of farmland or alpine birds.

Conclusion: Monitoring of Common Bird Species

An overall assessment of the evaluation of the publicly available information indicates that a broad range of influencing factors, mainly associated with land use and disturbance, contribute to variations in population dynamics of breeding birds. The network did not report any adverse effect that, according to the network, could be related to the cultivation of MON 810. Furthermore, an in depth analysis of the data and information available from this network allows the conclusion that the cultivation of MON 810 does not appear to have an effect on the bird population in Germany.

Bird monitoring data will be incorporated into the national program of sustainable indicators, also known as 'Kernindikatorenprogramm', looking into 59 bird species across the different landscapes (see also ***Section 4.3.1***). The species serve as indicator species for the quality of their habitats, and could be seen as representative for the development of the landscape in general[11]. In future, data will be entered into the EU-wide bird monitoring program.

[11] http://www.umweltdaten.de/publikationen/fpdf-l/3436.pdf (Last accessed 20 March, 2009)

5.2.3 Monitoring of Butterfly population dynamics in Germany: Tagfalter-Monitoring Deutschland

In 2005, a nationwide butterfly monitoring scheme commenced in Germany. The project is coordinated by the Helmholtz Centre for Environmental Research (UFZ: Helmholtz-Zentrum für Umweltforschung), and is supported by the Federal Institute for Nature Protection (BfN), several non-governmental organisations, and Butterfly Conservation Europe. Key objectives of the monitoring program are to look at the population dynamics of butterflies and their role as suitable biodiversity indicators, and to develop a database that will allow the analysis of biodiversity. According to the authors, the data available[12] is of a quality to perform a suitable scientific evaluation of butterfly abundance and flight behaviour, and in the future, long term assessment of trends will be possible (Kühn *et al*., 2008). The BVL cited the key goal of butterfly monitoring as … *to demonstrate long term population developments for single species and to prove that for a number of species monitored so far, there is no quantifiable decline. The butterflies serve as an indicator function, the collected data could recognise the impact of changes within the landscape on communities*" (Gathmann, 2008).

Available information on transect mapping, information on species and their distribution, and (regional) results of collections can be accessed by the public[13,14]. The transect method is used to map butterflies qualitatively and quantitatively, and collection is performed once a week from April to September, depending on climatic conditions, *e.g.* temperature, wind speed, rainfall. A transect is defined as a 500 metre to 1.5 kilometre line in the countryside, separated in 50 metre sections[15]. State of the habitats (*e.g.* grass harvested, bushes cut) within the transect must also be noted by the collector. It is important to note that the accessibility of locations and numbers of volunteers participating in data collection are proportional to the amount of data that can be collected, and therefore has an influence on the final results. A report summarising the information from 2007 (Tagfalter-Monitoring Deutschland, 2008), and news and progress from 2008[16] can be obtained on request from the project coordinators; and is according to them widely distributed. Apart from species related distribution maps, regional data and seasonal timing of butterfly flights can also be found on the website[13, 14, 17].

In the butterfly monitoring report, 155 946 individuals were counted from 340 transects. 73% of all butterfly species known to occur in Germany were detected (*i.e.* 110 out of 150 butterfly species). Species not found are either extremely rare or only occurring sporadically. The most frequent species and highest numbers of individuals detected were *Pieris rapae/napi, Maniola jurtina, Coenonympha pamphilus, Inachis io, Pieris brassicae,*

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[12] http://www.science4you.org/platform/lex/falterfunde/atlas/phenoplate/index.do (Last accessed 23 March, 2009)
[13] http://www.tagfalter-monitoring.de (Last accessed 23 March, 2009)
[14] http://www.science4you.org/platform/tmd/tmd-top/index.do (Last accessed 23 March, 2009)
[15] http://www.tagfalter-monitoring.ufz.de/index.php?de=5356 (Last accessed 23 March, 2009)
[16] As of 13 November 2008, 223 transects were reported showing 87 584 individuals; however at that time, not all entries had been delivered to the network or entered into the database.
[17] http://www.science4you.org/platform/lex/falterfunde/atlas/index.do (Last accessed 23 March, 2009)

Polyomatus icarus, Melanargia galathea, Aphantopus hyperanthus, Gonepteryx rhamni, and *Nymphalis urticae*. A comparison of the number of entries (occurrence of a species within a transect section) versus the number of individual butterflies, showed almost identical results (except *M. Galathea* and *V. Atalanta*) (Tagfalter-Monitoring Deutschland, 2008). This allows a comparison of the spatial distribution of selected species across Germany over time, based on the information in the publicly available database[18]. This was conducted for three subsequent years from 2006 to 2008. Around 20 generalist species were mapped; these were classified by van Swaay *et al.* (2006) as being relevant with respect to timing of butterfly flights during the year[19], and of showing a stable abundance across Germany. Between 2006 and 2008, the distribution of butterflies found within the transects (individuals), showed spatial variance over time for the most frequent species, irrespective of the German regions (**Figure 2**). Comparing these patterns of distribution with the areas listed in the public register where planting of biotech crops (*i.e.* MON 810) occur, no link between these areas and the abundance of butterflies in Germany can be observed.

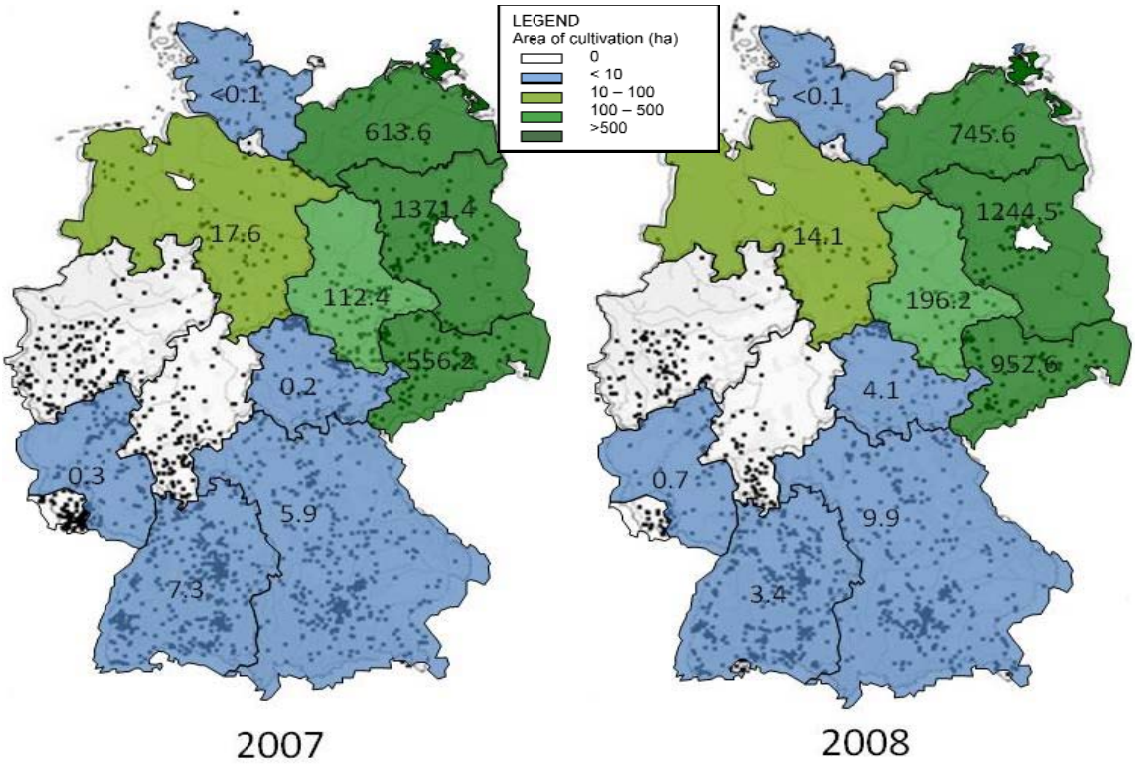

Figure 2: Example of 2008 MON 810 cultivation in Germany acc. to the federal register and spatial distribution of Peacock butterfly (Inachis io) in 2008
(data source: BVL(coloured), *http://194.95.226.237/stareg_visual_web/localeSwitch.do?language=en&page=/data.do* ***and*** *http://www.science4you.org/platform/tmd/tmd-top/species/maps/map.do;jsessionid=6E5954C97D5DA630BCDCB1D447652D8B?ptnameId=109769)*.

[18] http://www.science4you.org/platform/lex/falterfunde/atlas/phenoplate/index.do (Last accessed 23 March, 2009)
[19] http://www.tagfalter-monitoring.ufz.de/index.php?de=6246 (Last accessed 23 March, 2009)

The European Climatic Risk Atlas for European Butterflies (Settele *et al*., 2008) states that butterfly populations experience considerable fluctuations due to environmental variations, such as weather. Moreover, the impact of climate change on the population dynamics of butterflies was modelled in this analysis taking into account different scenarios associated with the impact of global warming. Species favouring colder environments will disappear, while species adapted to warmer environments will move further north. Furthermore, secondary effects are expected due to land use and habitat quality which will also have an impact on the dynamics of butterfly populations.

Conclusion: Monitoring of Butterfly Population Dynamics

An overall evaluation of the publicly available information indicated that the population dynamics of butterflies, and their spatial distribution vary from year to year. The network did not report any adverse effects associated with MON 810 cultivation. While the variation observed may be attributed to environmental factors such as weather or impacts associated with land use, the difficulty in collecting data representative of butterfly population dynamics cannot be ruled out as one of the major factors contributing to variation in data. Despite this, an analysis of the available information did reveal that there was no apparent link between any variation observed and the cultivation of MON 810 in Germany.

5.2.4 Monitoring of Bees Germany: Deutsches Bienenmonitoring (German Honey Bee Monitoring Network)

The German honey bee monitoring network was founded in 2004 to track honey bee mortality, collapse and weakening in bee hives; bee poisoning was also taken into account. Members of the program are beekeeping and farmer organisations, agricultural institutes, the Ministry of Agriculture, and chemical companies.

All data for the project are collected locally by beekeepers, distributed over all regions and climates in Germany. The results of monitoring are published annually. Overall, approximately 120 beekeepers with 1,200 colonies covering the entire country participate in the project, *Deutsches Bienenmonitoring* (DEBIMO)[20]. This guarantees a practical approach and for the first time in research history, allows a representative investigation of the study area, by beekeepers and bee scientists of the causes of bee population decline.

The beekeepers examine the bee colonies throughout the year and report regulatory on various aspects such as:

- **Data on the location:** climatic region, altitude, primary stresses.
- **Data on beekeeping:** system of hives, migration, bee keeping measures against Varroa
- **Data on colonies:** winter losses, population strength, offspring, honey production, swarm tendency
- **Residue data:** Study of insecticide and seed treatment residues in honey and honeycomb
- **Disease investigations:** Varroa, Nosema, mites, bee viruses associated with Varroa, amoeba

All results are entered into the database and subsequently analysed for total beehive losses, honey yield, bee diseases (varroa mites, viruses, nosema parasites, amoeba), and long term assessment of pesticide residues in honeycomb. Numerous animal and plant samples are collected for subsequent analysis. Through these well-informed and structured investigations, there is a scientifically validated analysis, not only of the number of bees dying and an explanation of the causes, but also the beekeepers specific instructions and/or recommendations for the management of bee colonies.

Data sets published annually for the years 2004/05, 2005/06, 2006/07 and 2004-2008 summarise the most significant problems[21]. Losses in all years were on average, lower compared to the 'catastrophic' year of 2002 / 2003, but differ significantly on a regional basis from year to year. Less than a third of the beekeepers did not loose any bee hives over the

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[20] http://www.gesundebienen.de/89/Krankheiten/Bienenmonitoring/Deutsches_Bienenmonitoring.htm (Last accessed 24 March, 2009)

[21] http://www.ag-bienenforschung.de/ (Last accessed 24 March, 2009)

years whereas more than 80% of the beekeepers lost up to 20% of their bees (2004-2008). Variations observed within that time frame could be attributed to seasonal climatic conditions (*e.g.* long winter in 2005/06 versus a warm, short winter in 2006/07). Bee diseases varied from year to year, and were dependent on:

a) Infestation level and success of treatment before winter (varroa)
b) Coincidence with varoa infestation and occurrence of viruses
c) Training and treatment success

Honey production was analysed across regions and showed good to very good yield [2004-2008]. In 2007/08, a significant variation was observed between regions ranging from more than 50 kg honey per bee hive (Brandenburg) to 16 kg honey per bee hive (Northrhine-Westphalia).

While there were some variations and loss of bee colonies observed over the years and between seasons, these impacts were generally linked to diseases prevalent in bee colonies. 4.8 to 6% of the bee hives were affected by varroa mite infestations over the years, while other viruses (*e.g.* acute bee paralysis virus, sacbrood virus and deformed wing virus) affecting bee colonies also varied over the regions but are seen to also be linked to varroa mite infestations. Effects on bee colonies from nosema parasites also displayed many fluctuations between years and seasons, however no regional trend could be found. Additional tests demonstrated that the disease is now linked to a new variant of nosema. Amoebes were found only in the south of Germany, but the values were low over the years.

A significant amount of available information linked variation in bee colonies to the impacts of pesticide residues; however no mention of genetically modified crops was made. From 2005 – 2007, honeycomb samples were analysed for 258 different compounds. Apart from a few single values showing relatively high concentrations, the overall level of residues present in honeycomb were below 10 µg/kg honeycomb. No clothianidin and only one positive finding of imidacloprid were found in the 215 samples, and therefore no direct adverse effect on honeybees is expected. Sub-lethal effects are the subject of further trial developments within the project council.

Conclusion: Monitoring of Bees in Germany

The DEBIMO project represents an effective, science based approach to answer questions in relation to bee health. An analysis of the available information indicated that impacts on bees and bee colonies observed in Germany were mainly due to disease in bee populations and effects of pesticides on bee colonies. The network did not report any adverse effect that, according to the network, would be related to MON 810. The analysis of the available information also did not reveal any impacts on bees or bee colonies that might have occurred as a result of cultivation of MON 810.

On an EU level, a recommendation of a recent publication by the European Food Safety Authority, "*Bee Mortality and Bee Surveillance in Europe"* (EFSA, 2008), was to combine member state surveillance data on issues affecting bee populations. This type of information

could potentially be used in the future to analyse any impacts of biotech crops on bee populations.

5.2.5 Monitoring of soil in Germany: Boden-Dauerbeobachtung

Soil monitoring has a long history in Germany. In 1986, the first long term soil monitoring sites (Boden-Dauerbeobachtungsflächen (BDF)) were established in former West Germany. After reunification, the soil monitoring network was able to extend data collection to all German federal states (Länder). The German Soil Protection Act (Bundes-Bodenschutzgesetz or BBodSchG) sets out a system to deal with information on the soil itself (*e.g.* maps, soil analytical databases), other geo-relevant data, data relevant for soil protection such as that from monitoring sites, data on soil background values, as well as data on contaminated sites (BBodSchv, 1999). Under the Act, the Federal Environmental Agency (UBA) coordinates the efforts of the German soil monitoring.

Creating a uniform starting point for soil monitoring allowed a nation wide evaluation of existing German country data to define a baseline. Key objectives going forward were to analyse trends in information about soil condition, influences on soil and adverse changes in soils, to check measures of environmental protection, to create data harmonisation across Länder, to allow reporting on the environment looking at long term changes in soil, and to predict future developments.

To achieve these goals, BDFs of at least 1,000 m^2 were established across Germany in sites representative of the landscape, soil use, load and long term site availability (Umweltbundesamt, 2004). Around 800 representative soil sites have been established in Germany. The spatial distribution of the sampling / monitoring sites can be found at:

http://www.unweltbundesamt.de/boden-und-altlasten/boden/bilder/700schutz_bdf_Typen.pdf

Properties of soil at the selected sampling sites, such as soil physics (fraction, density, soil pore distribution, water capacity), soil chemistry (pH, C_{total}, C_{org}, P, N, cation exchange capacity, and heavy metals), organic soil chemistry (*e.g.* poly-aromatic hydrocarbons) and soil biology (*e.g.* biomass) were determined (Barth *et al.*, 2001). Results from 802 BDF sites were entered into a database, 326 of the sites were rated as agricultural areas, 209 were linked to forestry, 214 to grassland, and the rest to fallow land, parks, speciality crops and non used areas (~53 sites) (Umweltbundesamt, 2004). Due to its legal importance with respect to precautionary values as outlined in the BBodSchV, a significant amount of information was dedicated to the status of heavy metals in soil. An in-depth statistical analysis of the BDF data sets was conducted; however no adverse effects related to the cultivation of MON 810 were described within the report. In 2007, the 'soil protection' working group of the German government and federal states (Bund/Länder-Arbeitsgemeinschaft Bodenschutz) has decided to set up a sub-team to further harmonise and report the methods and results of the BFD-monitoring project. The first outcome was expected by mid-2008 (http://www.labo-deutschland.de/pdf/Jahresbericht-LABO_2007.pdf), but no information is publicly available at the time of writing this report.

Soil monitoring was also used to determine the fate and the soil microbiology of Bt-corn in Bavaria (Lange *et al.*, 2005). Over four years, on a number of sites at Bavarian agricultural research stations, Bt-corn (Bt176 and MON 810), were tested versus the conventional near

isogenic lines. Species spectrum, biomass, and total number of earthworms in Bt and non-Bt maize samples were examined according to international standardised methods, and statistical analysis was performed. The results of these long term research station field trials showed that no effects of the Cry proteins produced by Bt-maize were found on species composition or numbers of individuals. These results confirm the findings of Dubelman *et al*. (2005), who demonstrated that the Cry1Ab protein does not accumulate or persist in the environment after three years of continuous use.

Conclusion: Monitoring of soil in Germany

The soil monitoring network did not report any adverse effects that could be linked to the cultivation of MON 810. Conclusions that can be made from an analysis of the data and reports available from this network are that there are no indications of any adverse effects on soil with respect to MON 810. This is further supported by research performed with respect to the fate of *Bt* proteins and material in soil, and supports the conclusions made by authorities that cultivation of MON 810 does not pose any risk for soil microbial communities or biota (ZKBS, 2008).

It is anticipated that the collection and analysis of data will be a long term project (10 – 15 years). Discussions will take place with the coordinators of the network regarding the data that is currently being analysed and, in line with Monsanto's commitment, if any adverse effects are raised, action will be taken where it is scientifically justified.

5.3 Results of Analysis of Selected Networks: Category 2

5.3.1 Monitoring for indicators of biodiversity in agriculture: Daten zur Umwelt

The Federal Environmental Agency (UBA) has set up an environmental indicator programme to provide up-to-date information to a broader audience with respect to environmental progress for sustainable development in Germany. Environmental indicators describe the state of the environment, positive and negative trends, and illustrate developments on the path to achieve environmental protection goals defined by the Federal Government. The Environmental Indicators for Germany (Umweltindikatoren Deutschland) are part of a networked system of key environmental information in four priority areas, *1)* climate change, *2)* biodiversity and the landscape, *3)* environment, health and quality of life, and *4)* natural resource management. If possible, trends will be compared with quantifiable environmental targets and assessed.

For the purposes of network monitoring in relation to General Surveillance, the programme's data on biodiversity and the landscape was analysed to determine if any impacts on the environmental indicators of this area could be determined that may have been influenced by the cultivation of MON 810. The programme looks into the following indicators:

1. *Diversity of species (e.g., red lists, threatened or endangered species)*[22]
   This category looks at 'sub-indicators' for the main types of habitats and landscape in Germany: agricultural land, forests, settlements, inland waters, coasts / seas and alpine areas. Trends in population sizes of 59 selected species of birds within the six different habitats and landscapes listed above are used as the Sustainability Indicator Species for diversity. Given that the major part of land in Germany is for agricultural use, bird populations in agricultural land account for 50% of the Sustainability Indicator Species for diversity, while forests, settlements, inland waters, coasts/seas and alpine areas account for 27%, 11%, 6%, 3% and 3%, respectively.

2. *Threat to biotopes*[23]
   This indicator is an index of loss of area and is categorised based on the level of endangerment (*i.e.* regional endangerment, complete destruction, threat of complete destruction, strongly endangered, early warning, *etc*).

3. *Invasive species*[24]
   This indicator is defined as potential threats to the environment of invasive plants and invasive animals, *i.e.* interaction with predators, competition with local species *etc*.

[22] http://www.env-it.de/umweltdaten/public/theme.do?nodeIdent=2855 (Last accessed 23 March, 2009)
[23] http://www.env-it.de/umweltdaten/public/theme.do?nodeIdent=2856 (Last accessed 23 March, 2009)
[24] http://www.env-it.de/umweltdaten/public/theme.do?nodeIdent=2857 (Last accessed 23 March, 2009)

4. *Areas of low traffic intensity*[25]
   According to set criteria, these areas, a) are of a minimum size of 100 km^2, b) are not intersected by any roads with an average traffic density exceeding 1000 vehicles / 24 hours, c) are not intersected by any railway lines, d) do not contain any areas of water occupying more than half the total area. This indicator promotes undisturbed areas and establishes proper land use.

The program also looks at the following three areas influencing or impacting land use:

1. *Ecological land management*[26]
   A political target was defined to increase the share of ecological farming up to 20% by supporting such initiatives as farmer programmes. This is seen to have a positive impact on environmental protection and biotopes.

2. *Agricultural subsidy programs*[27]
   Using statistical indicators, the use of subsidies will be linked to environmental questions defined by European, nationwide or federal states. A cross reference will be made to species protection.

3. *Genetically modified crops*[28]
   The indicator programme specifically mentioned GM crop cultivation as one potential indicator or influencing factor, but information in relation to genetically modified crops is still being compiled.

A summary of the report states that indicators in farmland, forest and coastal/sea areas have remained more or less stable over a period of time, while there has been a slight downward trend in settlement and alpine areas. The negative impacts on settlement and alpine areas were attributed to building activities, increased settlement activity, intensified agriculture and abandonment of traditional farming methods (Federal Environment Agency, 2007). There was no information reported that could be attributed to any adverse effects associated with the cultivation of MON 810.

[25] http://www.env-it.de/umweltdaten/public/theme.do?nodeIdent=2858 (Last accessed 23 March, 2009)
[26] http://www.env-it.de/umweltdaten/public/theme.do?nodeIdent=2864 (Last accessed 23 March, 2009)
[27] http://www.env-it.de/umweltdaten/public/theme.do?nodeIdent=2866 (Last accessed 23 March, 2009)
[28] http://www.env-it.de/umweltdaten/public/theme.do?nodeIdent=2867 (Last accessed 23 March, 2009)

5.3.2 Plant protection services: Informationssystem Integrierte Pflanzenproduktion (ISIP)

The Information System for Integrated Plant Protection (ISIP) is organised by the German Federal Extension Services (www.isip.de). Key agricultural problems with respect to plant health and agricultural production are discussed, and decision making tools can be downloaded or simulated online by the farmer. Monitoring is also laid down in ISIP and comments of the local extension officer, automatically working prognosis models, monitoring for special diseases on specific monitoring sites and the site-specific possibility for recommendations are also available (von Kröcher and Röhrig, 2007).

Web based information sources were looked at in regions where MON 810 was planted via general access through the internet, or more specifically, through an online sign-in account. The only common reference with respect to MON 810 was the pest corn borer (*Ostrinia nubilalis*), which is controlled by MON 810. For example, observations issued in June by the Brandenburg extension office, indicated that corn borer infestation had been observed in the districts of Neutrebbin and Heinersdorf. A decision making tool and recommendation for the use of insecticides[29] was given by the extension officer.

It is important to note that, because of the local contact with the extension service, any effect of MON 810 cultivation versus conventional maize would be directly reported to the Monsanto technical / sales team. In particular, performance aspects such as efficacy, plant health and yield are looked at and comparison with untreated maize, maize treated with insecticide, and MON 810 maize has been published[30]. Additionally, commercial recommendations are available for farmers at Das Informationszentrum für die Landwirtschaft[31] where general information on the pest can be found[32], as well as advice on infestation mitigation after the season[33].

It can be concluded that apart from a broad range of information linked to corn, pests in corn (*e.g. Ostrinia*), levels of infestation, control strategies, performance of products *etc*, the analysed information did not reveal any information that could be attributed to adverse effects from the cultivation of MON 810. Based on experience and established relationships at local level, it could be assumed that if abnormalities with respect to MON 810 cultivation were observed, Monsanto would be informed immediately by local extension officers.

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[29] http://www.wetter-bw.de/schaderreger/maiszuensler/index_vergleich.php#oben (Last accessed 23 March, 2009)
[30] http://www.lfl.bayern.de (Last accessed 23 March, 2009)
[31] http://www.proplanta.de (Last accessed 23 March, 2009)
[32] http://www.proplanta.de/Mais/themen.php?Fu1GrI=1142935937&MOF1=1200149696&__utmb=77131348.3.10.1237209221&__utmc=77131348&MOID=1&MUID=5&MHID=6&MLID=1200331219&MLF1=1140269517&MRID=1201714677&&T=1237209390&&Fu1=1141635115&Fu1Ba=11402695171140446618&ALPHA=&Fu1GrI=1142935937 (Last accessed 23 March, 2009)
[33] http://www.proplanta.de/Agrar-Nachrichten/agrar_news_themen.php?SITEID=1140008702&WEITER=99&MEHR=99&Fu1=1222503450&Fu1Ba=1140008702 (Last accessed 23 March, 2009)

5.3.3 Register for cultivation of GM crops: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

The 'public register', which is coordinated by the Federal Institute of Consumer Protection and Food Safety (BVL), can be used to get an (historical) overview of genetically modified crop planting in Germany[34]. The public register is designed to inform farming community about GM crop cultivation with respect to coexistence, demonstrate transparency with the public and to serve monitoring and general surveillance purposes *i.e.* informing scientists, regulators and other stakeholders (*e.g.* farmers) about GM crops in specific environments (Vaasen *et al*., 2008a; 2008b).

If any adverse information is reported to Monsanto, the public register could be used to map the location of the adverse effect in relation to the area of cultivation of genetically modified crops in order to assess the probability of cause. To date, no indications of adverse effects associated with the cultivation of MON 810 have been notified to Monsanto, and therefore the public register as a tool for general surveillance has not been needed.

[34] http://194.95.226.237/stareg_visual_web/localeSwitch.do?language=en&page=/data.do (Last accessed 23 March, 2009)

6. OVERALL CONCLUSIONS OF THE GERMAN NETWORK MONITORING

This report presents Monsanto's analysis of German monitoring networks as one component of the contribution to general surveillance of MON 810 in Germany, in keeping with Monsanto's commitment to the BVL of 5 December 2007. Two categories of networks were monitored, the first providing information on relevant monitoring characters, while the second category looked at relevant influencing characters which play a critical role in determining the context in which the crop was cultivated.

Under the first category (relevant monitoring characters), five networks were assessed; game species, birds, butterfly population dynamics, bees and soil. None of the five networks specifically mentioned MON 810 as an influencing factor in any observed variation in data. Furthermore, an analysis of the available information to determine if the data indicated any effects that may have been caused by the cultivation of MON 810 was conducted. While some fluctuations and variations in populations of game species, birds, butterflies, and honeybees were reported in the data; in no instances could any differences be explained as an effect of the planting of MON 810. In most instances, differences were attributed to the impacts of weather, land use, predators, land disturbance, expansion of agriculture and urbanisation into pristine areas, disease or pesticides. It must also be acknowledged that in some instances, methods of data collection may have had an impact on observed fluctuations from region to region and year to year.

The network measuring indicators of biodiversity in agriculture and the Plant Protection Service were also assessed to determine if they reported any adverse effects attributed to the cultivation of MON 810 in Germany. There was no information reported in either of these networks that indicated any adverse effects in relation to planting of MON 810 in Germany. The register for cultivation of GM crops was not used as a confirmatory tool for general surveillance given that no adverse effects from the cultivation of MON 810 were observed from any of the other networks.

This information confirms the validity of the assumptions and conclusions laid down in the environmental risk assessment, that the product is as safe as conventional corn when cultivated in an agricultural environment.

The analysis of the networks will be an ongoing process and therefore, the suitability of the networks may also be evaluated over the course of general surveillance to ensure that methodology and reporting of the findings of the existing networks remain meaningful in respect of GM crop plantings. Nevertheless, improvement and adjustment needs the active contribution of those networks in the future, and a more direct involvement from the competent authority may be desirable.

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