MONITORING REPORT

MON 810 cultivation

Czech Republic, France, Germany, Portugal, Slovakia and Spain

2006

Data protection.
This application contains scientific data and other information which are protected in accordance with Art. 31 of Regulation (EC) No 1829/2003.

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Introduction

Monsanto has developed an alternative to traditional insecticides for the control of lepidopteran insect pests, with reduced impact on the environment, by genetically modifying maize plants to produce the insecticidal protein Cry1Ab from the common soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*). These insect-protected maize plants, called MON 810, guard against foliage feeding and stalk tunneling from the European corn borer (ECB) (*Ostrinia nubilalis* (Hübner)) and the pink stem borer (*Sesamia nonagrioides*).

In April 1998, after a review of the risk assessment conducted for MON 810 in the notification (C/F/95/12/02, presented by Monsanto Europe S.A.) by France, acting as *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). According to this Decision, Monsanto S.A. committed to inform the Commission and the competent authorities of the Member States of the results of monitoring for insect resistance. On 4 May 2007, Monsanto addressed to the European Commission an application according to Article 20(1)(a) of Regulation (EC) No 1829/2003 on genetically modified food and feed for renewal of authorization of MON 810 maize products that were authorized under Directive 90/220/EEC[1]. In support of this renewal application, a monitoring plan (developed accordingly to Annex VII of Directive 2001/18/EC) and previous monitoring reports have been provided as part of the information required under Article 23(2) of Regulation (EC) No 1829/2003. This information confirms the conclusions of the original safety assessment. According to the legal framework these authorized products remain lawfully on the market until a decision on re-authorization is taken.

Decades of experience have taught entomologists that insect populations adapt, sometimes quickly, to insecticides if the use of those products is not managed appropriately. For this reason, as early as 1992 in the USA, Monsanto established an expert advisory panel composed of leading pest and resistance management researchers from academia, USDA-ARS, and university extension services to develop effective insect resistance management strategies for insect-protected maize.

Following this example, in the European Union, Monsanto has worked since 2001 to establish, with three other companies (Syngenta Seeds S.A.S., Pioneer Hi-Bred International, Inc., Dow AgroSciences), the "European Union Working Group on Insect Resistant Management" or EUWGIRM. This group developed an Insect Resistance Management (IRM) plan that enables strict implementation of the management strategy described in Appendix III of the notification C/F/95/12/02 (Monsanto Company, 1995). This IRM plan (Annex 1) is based on the empirical data acquired in world areas

[1] The other food and/or feed aspects were covered in separate renewal applications: Application for renewal of the authorisation for continued marketing of existing food additives, feed materials and feed additives produced from MON 810 maize that were notified according to Articles 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003 on genetically modified food and feed (Submitted to the European Commission on April 11, 2007) and Application for renewal of the authorisation for continued marketing of existing food and food ingredients produced from MON 810 maize that were notified according to Article 5 of Regulation (EC) No 258/97 and subsequently notified under Articles 8(1)(a) of Regulation (EC) No 1829/2003 on genetically modified food and feed (Submitted to the European Commission on April 18, 2007)

where MON 810 is grown, on results from research performed by scientists world-wide (including the EU) and on the scientific opinion regarding insect resistance published by the European Commission's Scientific Committee on Plants (SCP, 1999).

MON 810 was commercially planted for the first time in 2003 in Europe. The total acreage planted in 2006 with *Bt* maize expressing the Cry1Ab protein was approximately 65 000 ha, in seven EU countries (Czech Republic (1 290 ha), France (5 200 ha), Germany (950 ha), Poland[2] (30 ha), Portugal (1 250 ha), Slovakia (30 ha) and Spain (53 667 ha) (Brookes, 2007)). Spain began commercial cultivation of *Bt* maize in 1998. In 2006, Spain alone accounted for more than 50 000 ha of MON 810 and therefore is the only country where monitoring insects for resistance was relevant.

Consistent with the 2003-2004 and 2005 monitoring reports (Monsanto Europe S.A., 2005; Monsanto Europe S.A., 2006), this monitoring report describes the components and results of the IRM plan for 2006.

In 2006, Monsanto has also continued the general surveillance monitoring program initiated in 2005 on a voluntary basis, anticipating the mandatory request 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 results of this general surveillance monitoring program performed in 2006 are reported and consist of four elements:

- a questionnaire to farmers that was designed to assess unusual observations in the areas where MON 810 has been cultivated;
- an assessment of the research work that led to peer reviewed publications in 2006-2007, that relates to MON 810 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 MON 810.

Implementation of the IRM plan

The success of the IRM plan is ensured by the implementation of three key aspects. These are 1) refuge, 2) baseline studies and monitoring of the target pests, and 3) communication and education. These different aspects are reviewed in the following sections:

1) Refuge

According to the "Harmonised insect resistance management (IRM) plan for cultivation of *Bt* maize in the EU" (Annex 1), farmers planting more than 5 ha of MON 810 must have a refuge area planted with maize that does not express Cry1Ab and that corresponds to at least 20% of the surface planted with MON 810.

Many initiatives (*see* Section 3 "Communication and education") have been taken to explain to farmers the importance of implementing IRM measures. For cultural

[2] No commercial crops planted to date – very small 'pre-commercial test' plantings in 2006

reasons, certain farming communities are reluctant to accept "signed agreements" imposing particular agricultural practices. Moreover, seeds are usually sold through distributors and farmer cooperatives, with at least one step in the commercial chain, consequently signed agreements are very difficult to manage without direct sales between end-users and seed companies. As a consequence, the seed industry has put particular emphasis on the development of communication tools (*see* below).

In Spain, farmer satisfaction and the monitoring of use conditions (including the diffusion of IRM communications and effective implementation of refuges on farms) was assessed at the end of the 2006 planting season, through a survey sponsored by ANTAMA (Spanish Foundation supporting the use of new technologies in agriculture). The survey was carried out in the Ebro Valley (Huesca, Lérida and Zaragoza), which is where most of the *Bt* maize is currently planted in Spain. The survey involved 200 farmers who each planted more than 5 ha of maize (Note: if below 5 ha, there is no need to implement a refuge (EU WG IRM plan, Annex 1)); 100 farmers planting *Bt* maize and 100 farmers planting conventional maize). The 100 farmers planting *Bt* maize collectively planted 2296.5 ha, of which 1849.7 ha were *Bt* maize. The conclusions from the answers delivered by the 100 farmers growing *Bt* maize are detailed below.

Primarily this survey analysed the satisfaction of the growers. The survey indicated that 94% of the farmers are very or quite satisfied, 6 % a little satisfied, and 0% not satisfied at all. The main advantage/benefit, reported by 91 % of the farmers, was the effective protection against corn borers, followed by the plant health (plants / ear of maize do not collapse (43%) and healthier plants (30%)), and peace of mind (40 %).

Secondly, the survey addressed implementation of the IRM plan. Concerning diffusion of IRM information, 99% of the farmers planting *Bt* knew the recommendation to plant a refuge. In this group, 69% considered themselves to be "well informed", 23% "somehow informed" and 8% "little informed". Regarding the clarity of the recommendations about the implementation of refuges, 90% considered themselves "very clear/quite clear", but 48% considered that it is "very easy/quite easy" to follow the recommendations while 52% consider that is "little easy/not easy at all". This survey also revealed that 64% of the farmers planted both conventional and *Bt* maize on their farm, and practically all of them declared they did it on purpose to specifically implement a structured refuge in their fields. 36% of the farmers have dedicated all available surface to grow exclusively *Bt* maize, because *Ostrinia nubilalis* causes significant economic losses, or because they consider their farms as small farms, or to try *Bt* maize on the whole surface they have for this crop, or because the sowing is easier. A relationship was observed between farms that cultivated relatively large areas of maize and an increase in compliance with refuge implementation.

In the context of the 2006 general surveillance, 252 farmers were surveyed across six countries where MON 810 was commercially cultivated (see report in Annex 7). This general surveillance took place in representative environments, reflecting the range and distribution of farming practices and environments exposed to MON 810 plants and their cultivation. 92.8 % of the farmers indicated that they followed the technical guidelines regarding the implementation of a refuge (80% planted a refuge and 12.8% had less than 5 ha planted with MON 810 on their farm). In Spain, where

86% of the total MON 810 acreage was planted, among the farmers who had to plant a refuge (*i.e.* farm growing more than 5 ha of maize), 77 % declared that they implemented the IRM plan. In other countries, where the technology has been introduced more recently and monitored very closely, a high degree of compliance was reported Lower compliance to the use of a refuge, in Spain, may be linked to the history of *Bt* maize introduction, when the area planted with *Bt* maize was limited and remained below 6% of the total maize market. Farmers planting *Bt* maize also tend to rely on their neighbours' conventional maize fields as refuge. The efforts put into place after the 2005 growing season showed an improvement in refuge implementation in 2006 in Spain. These efforts will be reconducted in the 2007 growing season.

It is important to continue educating the farmers on the necessity to implement refugia. It has been reiterated, for example in Spain, by different actions which have been put in place by the seed industry for the 2007 cultivation year (*see* Section "Communication and education"). In addition, the strict monitoring of the farmers in other countries where the technology has been introduced more recently will be maintained.

2) Baseline and monitoring studies

a) Baseline studies

Baseline studies with Cry1Ab were performed in Spain with populations collected in the three major regions where insect pressure would justify the use of MON 810 (Ebro Valley, centre of Spain and Extremadura-Andalusia) prior to the introduction of *Bt* maize in Spain (Gonzalez-Nunez *et al.*, 2000).

Upon request of Monsanto, additional baseline studies have been conducted within Europe during 2005-2006. In 2005, the baseline susceptibility to Cry1Ab was established for the French and Portuguese field populations of *S. nonagrioides* and *O. nubilalis* in the Insect-Plant Interaction lab, led by Dr. [redacted] and Dr. [redacted] (Department of Plant Biology, CIB-CSIC). *S. nonagrioides* was collected from the Midi-Pyrénées (France) and Bajo-Alentejo (Portugal) areas while *O. nubilalis* was sampled from the Bajo-Alentejo area (Ortego, 2006a; Ortego, 2006b). These results have been reported previously in the 2005 monitoring report. In 2006, the same laboratory established the baseline susceptibility to Cry1Ab within the French field population of *S. nonagrioides* collected from Poitou-Charentes (France) area (Annex 2.1).

The susceptibility to Cry1Ab of these species lies within the range obtained in baseline studies and subsequent monitoring performed after Bt 176 maize cultivation (Farinos *et al.*, 2004), prior to MON 810 introduction. No resistance to Cry1Ab has been observed in any of the analyzed populations.

Furthermore, in 2005-2006, BTL Bio-Test Labor GmbH (Sagerheide, Germany) also established the baseline susceptibility to Cry1Ab in 16 subpopulations of *O. nubilalis*. The study covers five major European maize growing regions: South West and West France, Rhine valley/Southern Germany, Northern Germany/South West Poland, Moravia/Czech Republic and the Panonian region (Western Slovakia and North West Hungary) (Annex 2.2) .

Differences between the most susceptible and most tolerant field collected subpopulations were 5.8-fold. A dose response was not found for ECB collected in France (Miradoux dans le Gers, Lezat sur Leze en Ariege and Pamproux). The high mortality observed in insects sampled from Miradoux dans le Gers and Pamproux even at low concentrations indicate increased susceptibility to a stress factor like *Bt* caused by infection with an entomopathogenic microsporidium, *e.g. Nosema*. It is unknown why the mortality of instars from Lezat sur Leze en Ariege show higher variability. To clarify this, the test will be repeated in 2007 with larger number of individuals per dosage from a new sample collected from this location.

Results for subpopulations were pooled according to geographic and climatic conditions. These pooled populations correspond to homogeneous regions based on available knowledge of insect biology and geography. This approach follows the IRM industry working group guidelines (see Annex 1).

Although variation in susceptibility to Cry1Ab was found within subpopulations and among regions, the magnitude of the variation was small (*i.e.* less that sixfold). Variability in susceptibility to Cry1Ab was related to differing geographic and climatic conditions, but to a lesser extent (less than fourfold). These results suggest that the observed susceptibility differences reflect natural variation in Cry1Ab susceptibility among *O. nubilalis* populations rather than variation caused by native/natural resistance. Therefore, *O. nubilalis* apparently are susceptible to Cry1Ab across Europe without unexpected variation and without a specific genetic structure linked to geographical and biological factors.

The future continuous monitoring program, will also help to develop an understanding of the *Ostrinia* population structure with regard to its susceptibility towards Cry1Ab. In 2007 baseline studies will be performed in east Romania and will in the future be further extended to cover all commercial areas in the E.U.

b) Monitoring for insect resistance

As mentioned previously, monitoring for *O. nubilalis* and *S. nonagrioides* resistance to Cry1Ab across the Ebro Valley, central Spain and Extremadura-Andalusia since 1999 was in place after the commercialization of varieties including *Bt* 176 from Syngenta, that also express a Cry1Ab protein (Farinos *et al*., 2004).

Over the last three growing seasons (2004 - 2006) the same laboratory performed monitoring for *O. nubilalis* and *S. nonagrioides* resistance to Cry1Ab expressed in MON 810 (Annex 3, Crespo, 2007; Ortego, 2005; Ortego, 2006c). Samples were collected from the MON 810 growing areas in Spain, that is Ebro Valley, Albacete, and the Extremadura-Andalusia regions

The monitoring studies performed with *O. nubilalis* and *S. nonagrioides* collected during the 2006 season did not reveal any resistance to Cry1Ab among the regions. The susceptibility to the Cry1Ab of the *O. nubilalis* and *S. nonagrioides* populations lies within the range obtained with populations of these species collected from the same geographical areas during the 1999-2002 period (Farinos

et al., 2004) and during the 2003-2005 period (Monsanto Europe S.A., 2005; Monsanto Europe S.A., 2006).

In parallel with the resistance monitoring on corn borers populations through field collection and lab bioassays, seed companies are addressing complaints by farmers about lack of efficacy, which could indicate resistance development. So far, no complaint related to lack of efficacy of a MON 810 field has been reported and results from the ANTAMA survey (*see* point 1) showed 94% of the farmers who planted *Bt* maize in 2006, were very or quite satisfied with the overall results.

3) Communication and education

An extensive grower education program is essential for the successful implementation of the IRM plan.

As mentioned in last year's report, each purchaser of *Bt* maize receives a technical user guide that contains the latest information on the growers' IRM obligations. The user guide requires farmers to implement IRM measures, including refuge planting. Examples of these documents can be found in Annex 4.

The grower education programme has been communicated within all seed companies that sell maize expressing Cry1Ab protein.

The survey sponsored by ANTAMA, and referred to in point 1, showed an excellent diffusion of IRM measures as 99% of the farmers acknowledge they were made aware of the fact that they are required to plant a refuge, and this result is being consistently recorded in previous surveys, with 100% of answers in 2005 and 97% in 2006.

The initiatives taken to emphasize the importance of refuge implementation during 2006 field season have probably contributed to the increase in the percentage of farmers declaring that they had specifically implemented refuge from 49% in 2005 up to 64% in 2006.

In 2007 planting season, in Spain, the importance of refuge implementation was reiterated by:

1) Continuing communications about IRM implementation in all sales tools (leaflets, brochures, catalogues, hybrid guides on packaging):

   Examples:

   - Good agricultural practices leaflet attached in each MON 810 bag (leaflet common to all companies in Spain);
   - Technical Guide on MON 810 "Guía Técnica YieldGard®";
   - Hybrid variety Guides (attached DKc 6575 hybrid but one per registered hybrid has been created, delivered in the bag or through distributors)

2) Talking directly to farmers (presentation used by our sales team/distributors in all farmers talks)

3) Displaying "ad hoc" posters during field days

4) Emphasizing the presence of "real refuges" in our demo trials in order to educate and train farmers planting Bt maize

5) Using a bag tag which displays the IRM refuge requirement

6) Reinforcing IRM implementation during the Sales Team meeting

7) Advertising IRM in magazines and trade fairs

8) Publishing in a key Ag Magazine an article on Monsanto recommendations for refuge compliance

9) Sending a letter on behalf of ANOVE (each company to their farmers data base in Bt maize areas)

10) Sending a letter to Monsanto distributors encouraging them to promote refuge compliance

Illustration of some of these actions is presented in Annex 5.

General surveillance

In 2006, Monsanto continued the general surveillance monitoring program initiated in 2005 on a voluntary basis, anticipating the mandatory request for post market environmental monitoring in all applications or renewal 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 the general surveillance is to identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment. It is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects might have been caused by the placing on the market of a genetically modified crop in its receiving agricultural or non-agricultural environment.

General surveillance is focused on the geographical regions within the EU where the GM crop is grown, and is taking place in representative environments, reflecting the range and distribution of farming practices and environments exposed to GM plants and their cultivation.

Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect), linked to the genetic modification, then further evaluation of the consequence of that effect should be science-based and compared with baseline information. Relevant baseline information will reflect prevalent agricultural practice and the associated impact of these practices on the environment. In many cases it may not be possible to establish a causal link between a potential adverse effect and use of a particular GM crop.

The general surveillance performed in 2006 consisted of four elements, firstly the questionnaire to farmers that was designed to assess unusual observations in the areas where MON 810 has been cultivated, secondly an assessment of the research work that led to peer reviewed publications in 2006-2007, that relates to MON 810 and its environmental safety, thirdly company stewardship activities designed to ensure and maintain the value of the product and finally, the alerts on environmental issues by

authorities, existing networks and the press on potential adverse effects associated with MON 810.

1) Questionnaire

Farmers are the closest observers of the cultivation of the GM crops and routinely collect information on the cultivation and management of their crops at the farm level. Therefore they can give details on GM plant-based parameters (referring to species/ecosystem biodiversity, soil functionality, sustainable agriculture, or plant health) and on background and baseline environmental data (*e.g.* soil parameters, climatic conditions and general crop management data such as fertilisers, crop protection, crop rotations and previous crop history). Additionally farmers may give empirical assessments which can be useful within general surveillance to reveal unexpected deviations from what is common for the crop and cultivation area in question, based on their historical knowledge and experience.

A questionnaire addressed to the GMO cultivating farmers is a monitoring tool that is specifically focused on the farm level. EFSA explicitly considers questionnaires a useful method to collect first hand data on the performance and impact of a GM plant and to compare the GM plant with conventional plants (EFSA, 2006). The questionnaire approach has also proven its applicability with other industries, *e.g.* the pharmaceutical industry.

A farmer questionnaire has been developed as the key tool for monitoring of MON 810. It was inspired by the experimental questionnaire developed by the German Federal Biological Research Centre for Agriculture and Forestry (BBA), maize breeders and statisticians in Germany (Wilhelm *et al.*, 2004). It was first applied in 2005 and adapted based on experience to create a new version for 2006 (*see* Annex 6). Questions were refined to be easily understood by farmers and not to be too burdensome. The most important change was a switch from binary (Yes/No) to categorical answers with three levels (*e.g.* less, as usual and more). This allowed the farmers to specify the observed effects in two different ways and to refine the analyses.

Farmers have been asked for their observations and assessment in and around MON 810 cultivated fields in comparison to a baseline, this being their own historical local knowledge and experience. This general surveillance for MON 810 focused on the geographical regions within the EU where MON 810 was grown in 2006 (Czech Republic, France, Germany, Portugal, Slovakia and Spain). It was also performed in areas reflecting the range and distribution of farming practices and environments exposed to MON 810 plants and their cultivation. This allows for cross-checking of information indicative of an unanticipated effect, and the possibility to establish correlations either by comparing questionnaires between regions, or associating answers to observations made by existing networks, such as meteorological services (weather conditions) or extension services (pest pressure).

38 farmers in the Czech Republic, 58 farmers in France, 37 farmers in Germany, 16 farmers in Portugal, 3 farmers in Slovakia and 100 farmers in Spain were asked to complete the questionnaire. In France and Spain, where the largest acreages were planted, the survey was performed through a contractor specialized in agricultural

surveys (Datagri[3] in France and Markin[4] in Spain). In the other countries, the field representatives distributed the questionnaires to the farmers. To assist the farmers with the questionnaire, a manual was also developed and supplied. This manual clarifies the objectives of each question. Additional training was performed by the statisticians who developed the questionnaire.

The questionnaire was organised around collecting data in four specific areas:

Part 1: Maize grown area
Part 2: Typical agronomic practices to grow maize on your farm
Part 3: Observations of YieldGard® CornBorer (MON 810)
Part 4: Implementation of *Bt* maize specific measures

Part 1 allows to record general, basic data on maize cultivation, cultivation area and local pest and disease pressure (independent from GM or non-GM cultivation – background and possible influencing factors). Part 2 refers to the non *Bt* area. The goal was to find out what are the normal practices in place to cultivate conventional maize, to enable later their comparison to those in *Bt* areas (baseline data). Part 3 collects information to assess the specific MON 810 practices and observations. In addition, Monsanto took advantage of this questionnaire to check if farmers are in compliance with the MON 810 cultivation recommendations. For that purpose, the answers and free remarks in Part 4 were evaluated.

The analysis of the 252 questionnaires being surveyed in 2006 on the cultivation of MON 810 maize did not indicate any potential adverse effect. The full report is presented in Annex 7. This set of data is entered in a database which will be updated on an annual basis.

The farm questionnaires will be distributed, completed and collated each year. Reports will also be prepared on an annual basis. In addition, in case of adverse findings that needs immediate risk mitigation, this will be reported as soon as available.

2) Peer reviewed publications on the safety of MON 810 and/or Cry1Ab published in 2006 - 2007

An important source of information on MON 810 is the extensive independent research that is performed by scientists with a wide range of expertise such as insect and microbial ecology, animal toxicology, molecular biology or chemistry. More than 60 publications related to MON 810/Cry1Ab were published in peer reviewed journals in 2006 and 2007. Those references related to MON 810 or pure Cry1Ab were obtained by running a search using the search engine ISI Web of Knowledge™ (search terms: MON 810 or MON810; *Bt* maize or corn; insect resistant maize or corn; maize or corn expressing Cry1Ab; maize or corn containing Cry1Ab).

The publications identified by this literature search reinforce our knowledge of MON 810 and its safety. The peer-reviewed literature convincingly confirms that there is negligible impact from the cultivation of MON 810 on biodiversity, abundance, or survival of non-target species, and the environmental risk of

[3] Datagri SARL, 12 Avenue Georges Dimitrov, BP 115, 69512 Vaulx-en-Velin Cedex - FRANCE
[4] Instituto Markin, SL; c/ Caleruega, 60 4º D - 28033 Madrid - SPAIN

MON 810 is considered to be negligible compared to conventional maize. The list of those peer reviewed publications can be found in Annex 8.

3) Company stewardship activities

Monsanto is committed to the management of its products in a responsible and ethical way through-out their whole life cycle, from discovery to ultimate use stages. It includes:

- Assessment of the safety and sustainability of the products
- Absolute respect of all the regulations in place
- Support to the products by explaining and promoting the proper and responsible use of those products and technologies.

As part of product stewardship, and the "responsible use", as referred above, Monsanto urges users/licensees to notify any unexpected potential adverse effects observed that might be linked to the use of its products. Until now, reports or questions collected do not relate to potential adverse effect but more to product performance or guidance for cultivation. For example, a distributor in Spain reported a severe infestation by corn borers on young MON 810 plants. Although caterpillars could not be identified because the farmer sprayed the field, once the second generation became active, MON 810 was protected as expected, so the leaf attacks were probably due to some other pests. In 2006, in Czech Republic and Slovakia, before and during the planting season, Monsanto handled calls/questions on various subjects such as IRM, isolation distances and traceability. In almost all the cases satisfying answers could be handled by phone. In very few cases, a specific visit was organised with the farmer. In addition, in those specific countries, at early stage of market introduction, Monsanto customers have been visited regularly, for example Slovakian farmers growing MON 810 have been consulted on average 3 to 4 times in 2006.

Across countries growing MON 810, Monsanto has several contact points to capture product information (hotlines, representatives in each country, websites, product leaflets with a contact phone number and/or internet site). Illustrations of those can be found in Annex 1.

To date no unexpected potential adverse effects related to MON 810 have been reported and confirmed.

4) Alerts on environmental issues

Since the commercial introduction of MON 810, various sources are raising attention to potential environmental issues.

An issue management process has been put in place to deal with these issue alerts. The process involves:

- identification of potential issues (by anticipation of potential or emerging issues through external relationship with regulators and academics or publication in media and scientific journals);
- analysis of the potential issue and its relevance to the safety assessment of the product;

- sharing of expert commentary with regulators and other stakeholders;
- communication of conclusions to internal and external stakeholders.

No potential adverse effect related to MON 810 were confirmed through this process in 2006.

An example of E.U. MON 810 related safety issue raised in 2006-2007 is illustrated as follow:

A study conducted by Greenpeace called for commercial cultivation of MON 810 maize to be stopped until their questions regarding *Bt* Cry1Ab expression variability, monitoring, and risk assessment are answered (May 2007). Following this report and upon request from the French Competent Authority, the French "Commission du Génie Biomoléculaire" issued on June 14, 2007 an opinion[5] concluding that the scientific data provided by Greenpeace (Lorch and Then, 2007) do not bring new elements that could change the environmental evaluation of MON 810 cultivation.

Conclusions

The commercial planting of MON 810 in Europe has been accompanied by a rigorous Insect Resistance Management (IRM) plan, centred on three major elements: refuge implementation, monitoring, and farmer education.

No issues related to Insect Resistance Management were experienced in 2006. Following the reinforcement of the education/communication process, the percentage of farmers implementing refuges in their fields is slightly increasing compared to previous years.

Monsanto and the seed companies marketing maize expressing the Cry1Ab protein have been operating together to establish an IRM programme that is adapted to the EU agricultural landscape, and will continue to work closely together to assess its implementation and subsequently build on those learnings.

Regarding general surveillance, the results of the analysis of the 2006 set of questionnaires did not identify any potential adverse effects that might be related to MON 810 plants and their cultivation. 2006 questionnaire has been improved based on the experience acquired with 2005 questionnaire. 2006 and 2007 peer reviewed publications confirmed the negligible potential of MON 810 and/or Cry1Ab to cause adverse effects. Furthermore, company stewardship activities and issue alerts did not reveal any adverse effect related to MON 810 cultivation.

[5] http://www.ogm.gouv.fr/experimentations/evaluation_scientifique/cgb/autres_avis/MON_810.pdf

References

Brookes, G. (2007) The benefits of adopting genetically modified, insect resistant (Bt) maize in the European Union (EU): first results from 1998-2006 plantings. *www.pgeconomics.co.uk*, 1-39.

Commission Decision. (1998) Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC. *Official Journal*

Crespo, P.H. (2007) Seguimiento de la resistencia de las poblaciones espanolas de taladro del maiz a la proteina Cry1Ab.

EFSA. (2006) New chapter 11.4: general surveillance of unanticipated adverse effects of the GM plant. *In the EFSA Guidance document of the Scientific Panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed*, 1-11.

Farinos, G.P., de la Poza, M., Hernandez-Crespo, P., Ortego, F. and Castanera, P. (2004) Resistance monitoring of field populations of the corn borers *Sesamia nonagrioides* and *Ostrinia nubilalis* after 5 years of Bt maize cultivation in Spain. *Entomologia Experimentalis et Applicata*, 110, 23-30.

Gonzalez-Nunez, M., Ortego, F. and Castanera, P. (2000) Susceptibility of Spanish populations of the corn borers *Sesamia nonagrioides* (Lepidoptera: Noctuidae) and *Ostrinia nubilalis* (Lepidoptera: Crambidae) to a *Bacillus thuringiensis* endotoxin. *J. Economic Entomology*, 93, 459-463.

Lorch, A. and Then, C. (2007) How much Bt toxin do genetically engineered MON 810 maize plants actually produce ? Bt concentration in field plants from Germany and Spain.
h*ttp://www.greenpeace.de/fileadmin/gpd/user_upload/themen/gentechnik/greenpeace_bt_maize_engl.pdf*

Monsanto Company. (1995) Submission to the French Commission du Génie Biomoléculaire. Application to place on the market genetically modified higher plants: insect-protected maize (MON810). *Monsanto report*

Monsanto Europe S.A. (2005) Report on the implementation of the Insect Resistant Managment plan for MON 810 in the European Union - MON 810 cultivation in Spain in 2003 and 2004. *Monsanto Report*

Monsanto Europe S.A. (2006) Monitoring report - MON 810 cultivation - Czech Republic, France, Germany, Portugal and Spain - 2005. *Monsanto Report*

Ortego, F.A. (2005) Study on the monitoring of development of resistance to Bt protein within the Spanish populations of European corn borer. *Centro de Investigaciones Biologicas - Consejo Superior de Investigaciones Cientificas*, 1-13.

Ortego, F.A. (2006a) Monitoring of resistance development to Cry1Ab toxin within the French populations of the Mediterranean corn borer. *Centro de Investigaciones Biologicas - Consejo Superior de Investigaciones Cientificas*, 1-9.

Ortego, F.A. (2006b) Monitoring of resistance development to Cry1Ab toxin within the Portuguese populations of corn borers. *Centro de Investigaciones Biologicas - Consejo Superior de Investigaciones Cientificas*, 1-11.

Ortego, F.A. (2006c) Study on the monitoring of development of resistance to Cry1Ab toxin within the Spanish populations of European corn borer - Final report - Season 2005. *Centro de Investigaciones Biologicas - Consejo Superior de Investigaciones Cientificas*, 1-15.

SCP. (1999) Opinion of the Scientific Committee on Plants on Bt resistance monitoring (Opinion expressed on March 04, 1999. *Document SCP/GMO/094-Rev.5*

Wilhelm, R., Beissner, L., Schmidt, K., Schmidtke, J. and Schiemann, J. (2004) Monitoring des Anbaus gentechnisch veränderter Pflanzen - Fragebögen zur Datenerhebung bei Landwirten. *Nachrichtenbl. Deut. Pflanzenschutzd.*, 56, 184-188.