

MONITORING REPORT

MON 810 cultivation

*Czech Republic, France, Germany, Portugal,
Slovakia, Poland, Romania and Spain*

2007

Data protection.

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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 (*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 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 has to inform the European Commission and the competent authorities of the E.U. Member States about 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/EEC¹. In support of this renewal application, a monitoring plan (developed according to Annex VII of Directive 2001/18/EC) and previously submitted monitoring reports have been provided as part of the information required under Article 23(2) of Regulation (EC) No 1829/2003. The information in these monitoring reports 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.

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)

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 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). The success of the IRM plan is ensured by the implementation of three key aspects:

- refuge;
- baseline studies and monitoring of the target pests;
- communication and education.

Consistent with the 2003-2004, 2005 and 2006 monitoring reports (Monsanto Europe S.A., 2005; Monsanto Europe S.A., 2006; Monsanto Europe S.A., 2007), the current monitoring report describes the components and results of the IRM plan for 2007.

In 2007, 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 2007 are described in this report 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 2007-2008, which relate 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.

The post market monitoring performed in 2007 addresses the total acreage planted in 2007 with *Bt* maize expressing the Cry1Ab protein (110 808 ha). Planting occurred in eight EU countries: Czech Republic (5 000 ha), France (22 135 ha), Germany (2 685 ha), Poland (327 ha), Portugal (4 263 ha), Romania (350 ha), Slovakia (900 ha) and Spain (75 148 ha) (James, 2007).

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 (Section 3) have been taken to explain to farmers the importance of implementing IRM measures. For cultural 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. The absence of direct sales between end-users and seed companies makes signed agreements very difficult to manage. As a consequence, the seed industry has put particular emphasis on the development of communication tools.

In Spain, farmer satisfaction and monitoring of use conditions (including IRM communication and effective refuge implementation) was assessed at the end of the 2007 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 maize²; 100 farmers planting *Bt* maize and 100 farmers planting conventional maize. The 100 farmers planting *Bt* maize collectively planted 2894.8 ha, of which 2461.4 ha were *Bt* maize. The conclusions from the answers delivered by the 100 farmers growing *Bt* maize are detailed below.

The survey addressed implementation of the IRM plan. Concerning dissemination of IRM information, 87% of the farmers planting *Bt* knew about the recommendation to plant a refuge. In this group, 63% considered themselves to be “well informed”, 17% “somehow informed”, 14% “little informed” and 6% “not informed”. Regarding the clarity of the recommendations about the implementation of refuges, 83% considered the recommendations “very clear/quite clear”, while only 10% considered them “little clear/unclear”. 63% of the interviewees considered that it is “very easy/quite easy” to follow the recommendations while 30% consider that is “little easy/not easy at all”. 7% of the farmers didn’t know or wouldn’t answer these questions.

This survey also revealed that 60% of the farmers planted both conventional and *Bt* maize on their farm, and most of them (92%) declared they did it on purpose to specifically implement a structured refuge in their fields. 40% of the farmers have

² If less than 5 ha are grown, there is no need to implement a refuge (Annex 1).

dedicated all available surface to grow exclusively *Bt* maize. The reasons given by the farmers were: (1) *Ostrinia nubilalis* causes significant economic losses, (2) the sowing is easier, (3) they want to try *Bt* maize on the whole surface they have for this crop, or (4) they consider their farms as small farms. Farms that cultivated relatively large areas of maize demonstrate better compliance with refuge implementation.

In addition, this survey analysed the satisfaction of the growers. The survey indicated that 97% of the farmers are very or quite satisfied, 3% a little satisfied, and 0% not satisfied at all. The main advantage/benefit, reported by 86% of the farmers, was the effective protection against corn borers, followed by the plant health (plants / ear of maize do not collapse (69%) and healthier plants (29%)), and good yield (41%).

Separate from the ANTAMA survey in Spain, in the context of Monsanto's 2007 general surveillance, 290 farmers across eight countries where MON 810 was commercially cultivated were surveyed for their implementation of a refuge (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. 92.4% of the farmers who answered the question indicated that they followed the technical guidelines regarding the implementation of a refuge (88.2% planted a refuge and 4.2% had less than 5 ha planted with MON 810 on their farm). In Spain, where 68% of the total EU 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 refuge. 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 compared to the other countries 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. Although these efforts were repeated in the 2007 season, both the ANTAMA survey and Monsanto's general surveillance (Annex 7) show that compliance to refuge implementation decreased in Spain from 2006 to 2007. This was a reason for the Asociación Nacional de Obtentores Vegetales (ANOVE or National Breeding Association) to organize an additional information session on the importance of the implementation of the refuge for all Monsanto licensees to prepare the 2008 growing season in Spain (Section 3).

The message on the importance of refuge implementation will be repeated in all countries growing MON 810 in the 2008 growing season. It is important to continue educating the farmers on the necessity to implement refuges. It has been reiterated, for example in Spain, by different actions which have been put in place by the seed industry for the 2008 cultivation year (Section 3). 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 *S. nonagrioides* and *O. nubilalis* 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). These results were reported in the 2003-2004 Monitoring Report (Monsanto Europe S.A., 2005).

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 for the Portuguese populations of *O. nubilalis* in the Insect-Plant Interaction lab, led by Dr. [REDACTED] and Dr. [REDACTED] (Department of Plant Biology, CIB-CSIC). *S. nonag* s 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 (Monsanto Europe S.A., 2006). 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, reported in the 2006 Monitoring Report (Monsanto Europe S.A., 2006; Monsanto Europe S.A., 2007).

Overall, the susceptibility to Cry1Ab of the species studied in 2005-2006 was within the range obtained in baseline studies and subsequent monitoring performed after Bt 176 maize cultivation (Farinós *et al.*, 2004; Gonzalez-Nunez *et al.*, 2000), prior to MON 810 introduction. No resistance to Cry1Ab has been observed in any of the analyzed populations.

Furthermore, in addition to the above described baseline results on *S. nonagrioides* in France, Portugal and Spain, and on *O. nubilalis* in Portugal and Spain, BTL Bio-Test Labor GmbH (Sagerheide, Germany), led by Dr. [REDACTED] established the baseline susceptibility to Cry1Ab in 16 subpopulations of *O. nubilalis* in 2005-2006. This lab continued this baseline study in 2007 and analyzed the susceptibility of one laboratory colony and 25 populations of *O. nubilalis* collected in maize fields. The study covers six major European maize growing regions: South West and West France, Rhine valley/Southern Germany, Northern Germany/South West Poland, East Poland, Moravia/Czech Republic and the Panonian region (Western Slovakia and North West Hungary) (Annex 2 – Thieme (2008)).

Differences between the most susceptible and most tolerant field-collected subpopulations were 5.8-fold. A concentration response was not found for some *O. nubilalis* collections from France (Miradoux dans le Gers, Lezat sur Leze en Ariège and Pamproux) apparently because of bacterial infections in the collections from Miradoux dans le Gers and Pamproux, and for unknown reasons for the collection from Lezat sur Leze en Ariège. Subsequent collections from the same regions exhibited normal levels of susceptibility to Cry1Ab.

Results for populations 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 (Annex 1).

Although variation in susceptibility to Cry1Ab was found among populations and among regions, the magnitude of the variation was small (*i.e.* less than 4-fold, 9-fold and 2-fold for *O. nubilalis* collected in 2005, 2006 and 2007, respectively). The results of the populations pooled according to geographic and climatic conditions differed less than 4-fold and 2-fold for *O. nubilalis* collected in 2005-2006 and 2007, respectively. A similar degree of variability was reported for *O. nubilalis* susceptibility to Cry1Ab for populations from three broad geographic areas in the USA, chosen on market penetration for *Bt* maize. Similar levels of variability were also observed in a study that included populations of different voltine ecotypes and pheromone strains (Annex 2).

These results indicate that the observed population variation in susceptibility reflects natural variation in *Bt* susceptibility among *O. nubilalis* populations. Therefore, European populations of *O. nubilalis* are uniformly susceptible to Cry1Ab without any obvious genetic difference linked to geographic or other factors. In the future, other regional sources may be added to ensure that the monitoring program continues to represent the Cry1Ab maize market in Europe.

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 (Farinós *et al.*, 2004).

During 2004 – 2006, the laboratory of Dr. [REDACTED] performed monitoring for *O. nubilalis* and *S. nonagrioides* resistance to Cry1Ab expressed in MON 810 (Ortego, 2005; Ortego, 2006c). In 2007, this monitoring was continued and samples were collected from the MON 810 growing areas in Spain (Ebro Valley, Albacete, and the Extremadura-Andalusia regions, *see* Annex 3.1 - (Hernández-Crespo, 2008a)) and France (Midi-Pyrenées, *see* Annex 3.2 - (Hernández-Crespo, 2008b)).

The monitoring studies performed with *O. nubilalis* and *S. nonagrioides* collected during the 2007 season did not reveal any resistance to Cry1Ab among the regions. The susceptibility to the Cry1Ab of the *O. nubilalis* and *S. nonagrioides* field populations lies within the range obtained for laboratory populations in 2004 and 2007 and also within the range for field populations of these species collected from the same geographical areas during the 1999-2002 growing seasons (Farinós *et al.*, 2004) and during the 2003-2006 growing seasons (Monsanto Europe S.A., 2005; Monsanto Europe S.A., 2006; Monsanto Europe S.A., 2007).

From the 2008 growing season onwards, Monsanto will continue its collaboration with the laboratories of Dr. [REDACTED] (Spain) and Dr. [REDACTED] (Germany). However, to facilitate the comparison of results across all regions where MON 810 is being

cultivated, the laboratory of Dr. Ortego will focus on *Sesamia nonagrioides*, while the one of Dr. Thieme will focus on *Ostrinia nubilalis*. This will allow a consistent testing for each of the pests and therefore simplify the interpretation of the results. In parallel with the resistance monitoring on corn borer 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 confirmed complaint related to lack of efficacy of a MON 810 field has been reported and results from the ANTAMA survey in Spain (Section 1) showed 97% of the farmers who planted *Bt* maize in 2007, 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 the Cry1Ab protein.

The initiatives taken ahead of and during the 2006 and 2007 growing seasons to emphasize the importance of refuge implementation have probably contributed to the maintenance of a high level of compliance (>90%) for refuge implementation (Monsanto Europe S.A., 2006; Monsanto Europe S.A., 2007); Annex 7).

In the 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 to each MON 810 bag (leaflet common to all companies in Spain);
 - Technical Guide on MON 810 "Guía Técnica YieldGard®";
 - Using a bag tag which displays the IRM refuge requirement;
- 2) Talking directly to farmers (presentation used by the sales team and distributors);
 - 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) Reinforcing IRM implementation during the Sales Team meeting;
 - 6) Advertising the IRM plan on the main National Ag fair;
 - 7) Publishing Monsanto's recommendations for refuge compliance in a key Ag Magazine;

- 8) Sending a letter on behalf of ANOVE (each company to their farmers data base in *Bt* maize areas);
- 9) Sending a letter to Monsanto distributors encouraging them to promote refuge compliance.

The survey in Spain, sponsored by ANTAMA and referred to in Section 1, showed a good communication of IRM measures as 87% of the farmers acknowledged they were made aware of the fact that they are required to plant a refuge. This result, however, is somewhat lower than the recordings in previous surveys. Because of the trend of decreasing IRM plan awareness and the slight decline in compliance during the 2007 growing season, additional actions were undertaken ahead of the 2008 growing season. The seed companies associated in ANOVE (the National Breeder Association in Spain) developed an action plan which involved more efforts to educate own personnel (train the trainers), dealers, cooperatives and individual farmers (Annex 5):

- 1) Train the trainers: an IRM session was organized and a presentation on IRM was jointly created and followed by all the companies operating in the market to ensure common messages;
- 2) Communication to dealers: posters and stickers to be used with invoices and letters were sent by each company;
- 3) Communication plan for cooperatives, small points of sales and farmers: trained ANOVE inspectors completed 41 visits to inform them, distribute material and ensure that farmers are well informed on refuge implementation upon buying *Bt* maize seeds;
- 4) Communication to farmers: a letter stressing the importance of implementing the IRM plan was sent on behalf of ANOVE to individual farmers.

A further action to consolidate the awareness and compliance for refuge implementation is an audit by ANOVE of several farmers *in situ* during the 2008 planting season. The farmers who don't comply will be strictly monitored during the following seasons.

General surveillance

In 2007, 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 2007 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 2007-2008, that relate 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. This new version of the questionnaire was used in 2006 and 2007 (Annex 6). Questions were designed to be easily understood by farmers and not to be too burdensome. Also, it had to be sufficiently pragmatic to take into account real commercial situations.

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 2007 (Czech Republic, France, Germany, Poland, Portugal, Romania, 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).

45 farmers in the Czech Republic, 79 farmers in France, 36 farmers in Germany, 12 farmers in Portugal, 10 farmers in Slovakia, 3 farmers in Poland, 5 farmers in Romania 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 (Datagri³ in France and Markin⁴ in Spain). In Czech Republic and Slovakia the surveys were performed by the Czech Agriculture University⁵. In the other countries, Monsanto and Monsanto's licensees' field representatives interviewed the farmers. To assist the interviewers with the questionnaire, also a manual was 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:

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

⁵ Czech Agricultural University, Kamýcká 129, Praha 6 – Suchbát, 165 21 – CZECH REPUBLIC

- Part 1: Maize grown area
- Part 2: Typical agronomic practices to grow maize on the 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 290 questionnaires being surveyed in 2007 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 need risk mitigation, this will be reported immediately.

2). Peer reviewed publications on the safety of MON 810 and/or Cry1Ab published in 2007 - 2008

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 2007 and 2008. Those references were obtained by running a search using the search engine ISI Web of Knowledge™ (search terms: ((lepidoptera* resistan*) or (lepidoptera* tolerant) or (insect resist*) or (insect toleran*)) and (maize or corn); ((genetically modified or genetically transformed) and (corn or maize)); (GM maize or GM corn or transgenic maize or transgenic corn or Bt maize or Bt corn); Cry1Ab; (MON 810 or MON810 or Bt176 or Bt11)).

For completeness, the scientific opinions made publicly available by European authorities have also been collected and assessed with the peer reviewed publications. This includes the opinion upon which the French authorities justified the ban of MON 810 cultivation on the French territory and a specific assessment of this document by Monsanto.

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 MON 810 is considered to be negligible compared to conventional maize. This assessment concurs with the assessment of the available scientific opinions. The list of peer reviewed publications and opinions 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 effects but more to product performance or guidance for cultivation.

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 effects related to MON 810 were confirmed through this process in 2007. An example of an E.U. MON 810 related safety issue raised in 2007-2008 is illustrated as follows:

A study published by Rosi-Marshall and colleagues examined the input of *Bt* maize by-products in agricultural streams and its potential effects on caddisflies (2007). Regarding the safety of *Bt* plants to caddisflies, the authors analyzed the growth rate and mortality of two species of caddisflies, exposed to an unspecified *Bt* maize variety and one non-*Bt* maize variety (not the near-isoline). They found an increased mortality and reduced growth of the caddiflies.

Monsanto conducted a technical review of this study and concluded that this study, while innovative and ambitious, has too many design and methods problems, which make it impossible to draw any useful conclusions from the data as presented. Furthermore, the omission of results previously presented by the authors in the same year at the North American Benthological Society is troublesome. Inclusion of these findings likely would have changed the experimental design and interpretation of the results, and potentially may have impacted the overall conclusions of the PNAS paper.

This paper has also been reviewed by EFSA (EFSA, 2007a; EFSA, 2007b) which concluded “In summary, the conclusions of the paper Rosi-Marshall *et al.* (2007) are not supported by the data presented in this paper. The GMO Panel is of the opinion that based on the available information such a low level of exposure to *Trichoptera* in aquatic ecosystems is unlikely to cause a toxic effect”. Other scientists have also provided comments to this paper (Beachy, 2008; Parrott, 2008).

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. Monsanto and the seed companies marketing maize expressing the Cry1Ab protein have been operating together to establish and implement 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.

For the 2007 planting season, no issues related to Insect Resistance Management were experienced. Following the reinforcement of the education and communication process in countries where MON 810 was grown in previous years, and the good establishment of communication strategies to farmers in countries where MON 810 was planted for the first time, the percentage of farmers implementing refuges in their fields is very high.

Regarding general surveillance, the results of the analysis of the 2007 set of questionnaires did not identify any potential adverse effects that might be related to MON 810 plants and their cultivation. 2007 and 2008 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.

References

- Beachy, R. (2008) The burden of proof: A response to Rosi-Marshall *et al.*, 2008, Letter, <http://www.pnas.org/cgi/reprint/0711431105v1>.
- Commission Decision. (1998) Commission Decision 98/294/EC 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 L* **131/32**
- 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.
- EFSA. (2007a) Minutes of the 37th plenary meeting of the scientific panel on genetically modified organisms held on 22-23 November 2007 in Brussels, Belgium (adopted on 18 December 2007), *EFSA/GMO/380*
- EFSA. (2007b) Minutes of the 38th plenary meeting of the scientific panel on genetically modified organisms held on 18-19 December 2007 in Parma, Italy (adopted on 30 January 2008), *EFSA/GMO/385*
- Farinós, 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.
- Hernández-Crespo, P. (2008a) Monitoring of resistance development to Cry1Ab protein within the Spanish populations of corn borers (*Ostrinia nubilalis* and *Sesamia nonagrioides*) Final Report - Season 2007, *Ministerio de Educacion y Ciencia*
- Hernández-Crespo, P. (2008b) Monitoring of resistance development to Cry1Ab toxin within the French populations of the mediterranean corn borer - 2007 Report, *Ministerio de Educacion y Ciencia*
- James, C. (2007) Global status of commercialized biotech/GM crops: 2007, *ISAAA, Brief 37*
- 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 Management 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*

- Monsanto Europe S.A. (2007) Monitoring report - MON 810 cultivation - Czech Republic, France, Germany, Portugal, Slovakia and Spain - 2006, *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.
- Parrott, W. (2008) Study of *Bt* impact on caddisflies overstates its conclusions: Response to Rosi-Marshall *et al.*, 2008, Letter, <http://www.pnas.org/cgi/reprint/0711284105v1>.
- Rosi-Marshall, E. J., Tank, J. L., Royer, T. V., Whiles, M. R., Evans-White, M., Chambers, C., Griffiths, N. A., Pokelsek, J. and Stephen, M. L. (2007) Toxins in transgenic crop byproducts may affect headwater stream ecosystems, *Proceedings of the National Academy of Sciences*, **104**, 16204-16208.
- 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*
- Thieme, T. (2008) Baseline study of Cry1Ab susceptibility in populations of *Ostrinia nubilalis* (ECB) - results for 2005-2007, *Report*, 1-19.
- 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.