# Annual monitoring report on the cultivation of MON 810 in 2010

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

**Submitted by**

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## 1. GENERAL INFORMATION

Using modern biotechnology, Monsanto Company has developed insect-protected YieldGard® Corn Borer maize MON 810 (hereafter referred to as MON 810) that produces the naturally occurring *Bacillus thuringiensis (Bt)* protein, Cry1Ab. MON 810 is protected from foliage feeding and stalk tunneling damage by the European corn borer (*Ostrinia nubilalis*) and the pink stem borer (*Sesamia nonagrioides*).

In 1995, Monsanto submitted an application for import and use of MON 810 as any other maize (including cultivation) under Directive 90/220/EEC to France, the country acting as *rapporteur*. France subsequently forwarded the dossier to the European Commission with a favorable opinion. The other EU Member States raised objections. The European Commission sought the opinion of the Scientific Committee on Plants (SCP) that adopted a scientific opinion on 10 February 1998, concluding that "*there is no evidence that the seeds of insect-resistant maize (expressing the cry1Ab gene and protein) when grown, imported and processed in the manner indicated, are likely to cause adverse effects on human or animal health and the environment.*"[1] After receiving a qualified majority at the Regulatory Committee, composed of Member State experts, on 18 March 1998, MON 810 was approved for import and use (including cultivation)[2]. France, as *rapporteur*, ratified the Commission Decision on 3 August 1998. According to this Decision, Monsanto is required to inform the European Commission and the competent authorities of the European Union Member States about the results of monitoring for insect resistance.

On 4 May 2007, Monsanto submitted an application for renewal of authorisation of MON 810 maize products to the European Commission in accordance with Article 20(1)(a)[3] of Regulation (EC) No. 1829/2003 on genetically modified food and feed. 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. A positive scientific opinion from the European Food Safety Authority (EFSA), confirming the conclusions of the original safety assessment, was adopted on 15 June 2009 (and published as

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® YieldGard is a registered trademark of Monsanto Technology LLC.

[1] Opinion of the Scientific Committee on Plants Regarding the Genetically Modified, Insect Resistant Maize Lines Notified by the Monsanto Company - http://ec.europa.eu/food/fs/sc/scp/out02_en.html (Accessed June 17, 2011)

[2] 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 - http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998D0294:EN:NOT (Accessed June 17, 2011)

[3] For products previously authorised under Directive 90/220/EEC. Other food and/or feed aspects previously authorised under Regulation (EC) No. 258/97 or notified under Articles 8 and 20 of Regulation (EC) No. 1829/2003 were covered in separate renewal applications according to Articles 8(1)(a), 8(1)(b) and 20(1)(b) of Regulation (EC) No. 1829/2003 - http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1829:EN:NOT (Accessed June 17, 2011)

part of an EFSA overall opinion on 30 June 2009[4]). According to the legal framework, these authorised products remain lawfully on the market until a decision on re-authorisation is taken.

In 2010, MON 810 was planted in the EU on approximately 91 190 hectares across six countries: Czech Republic (4675 ha), Poland (ca. 3 000 ha), Portugal (4868.5 ha), Romania (822.6 ha), Slovakia (1248.7 ha) and Spain (76 574.75 ha) (see Appendix 1).

Results of Insect Resistance Management (IRM) are provided to the European Commission on an annual basis (*i.e.* this report) along with the results of the general surveillance monitoring. Monsanto also reports annually on general surveillance activities associated with the handling and use of viable MON 810 maize grain imported into the EU in a General Surveillance Import Monitoring Report. In both cases, if the investigation established 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.

MON 810 monitoring reports were submitted to the European Commission since 2005 (Monsanto Europe S.A., 2005; Monsanto Europe S.A., 2006; Monsanto Europe S.A., 2007; Monsanto Europe S.A., 2008; Monsanto Europe S.A., 2009; Monsanto Europe S.A., 2010).

The present report follows the format as laid out in Annex I to Commission Decision 2009/770/EC[5].

[4] EFSA scientific opinion on Applications (EFSA-GMO-RX-MON810) for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON 810; (2) feed consisting of and/or containing maize MON 810, including the use of seed for cultivation; and or (3) food and feed additives, and feed materials produced from maize MON 810, all under Regulation (EC) No. 1829/2003 from Monsanto - http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902628240.htm (Accessed June 17, 2011)

[5] Commission Decision of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (notified under document C(2009) 7680) - http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009D0770:EN:NOT (Accessed June 17, 2011)

**1.1 Crop/trait(s):** Maize/insect resistance

**1.2 Decision authorisation number pursuant to Directive 2001/18/EC, and number and date of consent pursuant to Directive 2001/18/EC:** Not available

**1.3 Decision authorisation number and date of authorisation pursuant to Regulation (EC) No. 1829/2003:** Not available

**1.4 Unique identifier:** MON-ØØ81Ø-6

**1.5 Reporting period:** July 2010 - July 2011

**1.6 Other monitoring reports have been submitted in respect of:**

- **Import and Processing** Yes (September 2010)
- **Food/Feed** No

## 2. EXECUTIVE SUMMARY

In 2010, MON 810 was planted in the EU on approximately 91 190 hectares across six countries. As part of stewardship of the technology, industry has implemented an Insect Resistance Management (IRM) plan to proactively avoid and/or delay the potential development of pest resistance to the Cry protein, as well as a voluntary general surveillance monitoring program. The adherence to these stewardship measures in the context of the 2010 cultivation of MON 810 maize in Europe is detailed in this report.

The planting of MON 810 in the 2010 season was accompanied by a rigorous IRM plan involving three main elements: refuge implementation, monitoring and farmer education. The initiatives developed to educate farmers about the importance of the implementation of IRM measures were continued in 2010 and the success of these initiatives was reflected in the high levels of compliance with requirements for refuge implementation observed in the 2010 season. A comprehensive IRM program demonstrated that there were no changes in resistance of *O. nubilalis* or *S. nonagrioides* to the Cry1Ab protein in the major MON 810 growing regions in Europe in 2010.

In 2010, Monsanto continued its general surveillance monitoring program, aimed at identifying the occurrence of adverse effects of the GMO or its use on human or animal health or the environment, which were not anticipated in the environmental risk assessment. The analysis of 271 questionnaires from a survey of farmers cultivating MON 810 in six European countries in 2010 did not reveal any unexpected adverse effects that could be associated with the genetic modification in MON 810. Furthermore, a detailed analysis of more than 40 publications related to MON 810 and/or Cry1Ab did not reveal any new scientific evidence that would invalidate the conclusions of the risk assessment concluding that MON 810 is as safe to human and animal health as its conventional counterpart, and 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. Also, company stewardship activities and issue alerts did not reveal any adverse effects related to MON 810 cultivation in 2010. Taken together, these results demonstrate that there are no adverse effects attributed to the cultivation of MON 810 in Europe in 2010.

# 3. MONITORING RESULTS

## 3.1 General surveillance

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[2]).

### 3.1.1 Description of general surveillance

In 2010, Monsanto continued the general surveillance monitoring program initiated in 2005 on a voluntary basis.

The objective of general surveillance is to identify the occurrence of adverse effects of the GMO or its use on human or animal health or the environment which were not anticipated in the environmental 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 agriculture, 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[6].

General surveillance is focused on the geographical regions within the EU where the GM crop is grown, therefore takes 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.

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[6] Opinion of the Scientific Panel on Genetically Modified Organisms on the Post Market Environmental Monitoring (PMEM) of genetically modified plants, The EFSA Journal (2006) 319, 1-27 – http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769727.htm (Accessed June 17, 2011)

The general surveillance monitoring program performed by Monsanto in 2010 consisted of four elements:

- a farmer questionnaire designed to assess unusual observations in the areas where MON 810 has been cultivated;
- data collected from scientific publications or reports relating to MON 810 and its comparative safety (to conventional counterparts) with respect to human, and animal health and the environment;
- 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.

### 3.1.2 Details of surveillance networks used to monitor environmental effects during general surveillance and description of other methodologies

#### *3.1.2.1 Farmer questionnaire*

Farmers are the closest observers of the cultivation of 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 farmers cultivating GM crops 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[6]. 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. The current version of the questionnaire has been used since 2006 (see Appendix 2). As appropriate, in each season adjustments were made to improve the statistical relevance of the collected data. Questions were designed to be easily understood and not to be too burdensome. Also, it had to be sufficiently pragmatic to take into account real commercial situations.

Farmers are 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 2010 (Czech Republic, Poland, Portugal, Romania, Slovakia and Spain) and thus was 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).

In 2010, 39 farmers in the Czech Republic, 10 farmers in Poland, 43 farmers in Portugal, 25 farmers in Romania, 4 farmers in Slovakia, and 150 farmers in Spain were asked to complete the questionnaire (271 in total). The farmers/fields were randomly selected between the countries depending on the market maturity and the size of the sample was considered large enough to give sufficient power to the test (*i.e.* the probability to reject the null hypothesis while the value of the probability of the answer is small) (see Appendix 1 for details on methodology). The interviews have been completed between November 2010 and March 2011. In Spain, which represented the largest market, the survey was performed by Markin[7] while in Portugal, it was performed by Agro.Ges[8]. In Romania, the survey covered all farmers that cultivated MON 810 in 2010 and was performed by MIA[9]. From the 25 farmers interviewed, 22 cultivated MON 810 for commercial purposes whereas 3 farmers planted MON 810 for demonstration purposes[10]. In the Czech Republic and Slovakia, the surveys were performed by the Czech Agriculture University[11]. In Poland, the farmers were interviewed by NAP[12].

The questionnaire was designed to collect data in four specific areas:

*Part 1: Maize grown area*

Responses to this section will enable records of 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). It includes questions on 'fixed factors', *e.g.* soil characteristics, and 'random factors', *e.g.* diseases, pests and weeds.

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[7] Instituto Markin, Spain.

[8] Agro.Ges - Sociedade de Estudos e Projectos, Portugal.

[9] MIA Marketing Institute Ltd., Romania.

[10] In the demonstration trials, plots planted with MON 810 were part of biotechnology demonstration platforms where the performance of several biotechnology-enhanced crops were shown to farmers. All genetically modified crops grown on these plots, including MON 810, were destroyed and were therefore not considered to be commercial plantings.

[11] Czech Agricultural University, Prague, Czech Republic.

[12] Niezalezna Agencja Prasowa, Poland.

*Part 2: Typical agronomic practices to grow maize on the farm*

Questions in this section aim to establish the agricultural practices to cultivate conventional maize. The data collected in this section constitutes a baseline against which insect protected maize cultivation can be compared. It includes questions on 'adjustable factors', *e.g.* irrigation, soil tillage, planting technique, weed and pest control practices, fertiliser, etc.

*Part 3: Observations of the insect protected maize event*

Questions in this section collect information to assess the specific insect protected maize practices, observations and performance. It includes questions on 'monitoring parameters' for comparison with conventional maize, *e.g.* germination, time to emergence, etc.

*Part 4: Implementation of insect protected maize event specific measures*

Questions in this section are intended to survey the implementation of the recommendations for insect protected maize cultivation.

#### *3.1.2.2 Company stewardship activities*

Monsanto is committed to the management of its products in a responsible and ethical way throughout their entire life cycle, from the stages of discovery to their ultimate use. It includes *1)* assessment of the safety and sustainability of the products, *2)* absolute respect of all the regulations in place, and *3)* support to the products by explaining and promoting the proper and responsible use of those products and technologies.

As part of product stewardship and responsible use, Monsanto urges user/licensees to notify of any unexpected potential adverse effects observed that might be linked to the use of its products. This can be done through the phone, fax or mail contact information given in the Technology User Guides (TUGs), (see Appendix 3.1 to Appendix 3.6). Alternatively, EuropaBio[13] and Monsanto[14] websites offer a contact point.

#### *3.1.2.3 Alerts on environmental issues*

*Internal procedure on alerts on environmental issues*

Since the commercial introduction of MON 810, attention to potential environmental issues has been raised through a number of sources. An issue management process has been put in place by Monsanto to deal with these 'issue alerts'. The process involves:

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[13] EuropaBio info for operators webpage - http://www.europabio.org/InfoOperators/NationalContactPoints.pdf (Accessed June 23, 2011).

[14] Monsanto product stewardship webpage - http://www.monsanto.com/ourcommitments/Pages/product-stewardship.aspx (Accessed June 23, 2011).

- Identification of potential issues (by anticipation of potential or emerging issues through external relationships with regulators and academics or publication in media and scientific journals (see Section 3.1.6));
- Analysis of the potential issue and its relevance to the safety assessment of the product;
- Sharing of expert commentary with regulators and other stakeholders (if warranted);
- Communication of conclusions to internal and external stakeholders (if warranted)[15].

*Alerts on environmental issues by existing networks*

An initial effort to categorize, evaluate and select Existing Environmental Surveillance (EES) networks was presented by BioMath GmbH (contracted by Monsanto) in frame of Post Market Environmental Monitoring (PMEM) for MON 810 in Germany[16]; it illustrated a structured and systematic approach, focused on Germany. An example of the German EES monitoring report, entitled *2008 German Network Monitoring*, can be found in the monitoring report submitted in 2010 (Note that such report was not developed this year as MON 810 was not planted in Germany in 2010).

In anticipation of 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 for the MON 810 consent), based on the MON 810 example in Germany, the EuropaBio Working Group on monitoring is currently coordinating a more general effort to map EES networks in Europe and to set up a unique reporting system. Harmonisation of effort allows improving the quality of the data collection and reporting, bringing consistency across criteria for the selection of networks, methodology in the assessment of data and translations of surveillance reports and having a single interface with networks. In what follows, a general approach is described on how these EES networks could be selected and used in PMEM of GM crops.

EuropaBio will identify a list of EES networks operating in the field of environmental monitoring as part of the harmonized EU approach for the General Surveillance of cultivated GM crops. These networks will be selected from a pool of national or EU-wide obligatory monitoring activities (according to EU directives 92/43/EEC and 2004/35/EC) and other existing national or EU-wide environmental monitoring programs. This approach was also

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[15] Channels of communication to external stakeholders include the Monsanto website - http://www.monsanto.com/newsviews/Pages/Issues-and-Answers.aspx (Accessed July 7, 2011).

[16] On 27 April 2007, the German Competent Authority (CA), the Federal Office of Consumer Protection and Food Safety, temporarily suspended the authorisation to distribute MON 810 maize seeds for commercial planting in Germany until Monsanto submitted an 'appropriate' monitoring plan for MON 810 cultivation in Germany. An agreement on this monitoring plan, which included both Farmer Questionnaires and the use of available information from defined existing networks as key components of general surveillance, was the basis for the lifting of the German suspension. An analysis of these networks was carried out and reported to the German CA for the 2008 cultivation season.

proposed by Bartsch *et al.* (2008). Once agreed upon by the different stakeholders, an annual report will be provided based on the review of the publications from those networks.

*Identification of the EES networks*

Firstly, the initial list of available EES networks will be classified according to the protection goals they are addressing and to their geographical coverage. No specific protection goals are defined in Directive 2001/18/EC or other GMO legislation. Directive 2002/811/EC only states that 'the monitoring plan should […] incorporate general surveillance for unanticipated or unforeseen adverse effects'. Therefore, protection goals for GM monitoring have to be sought in other EU and national legislation as already mentioned above, such as Directives 92/43/EEC and 2004/35/EC. Examples of these protection goals could be biodiversity, human health, animal health, plant health, soil function, water quality, and sustainable agriculture. These will form the basis for categories of EES networks identified.

*Inclusion of the EES networks for the PMEM plan*

In a second step, the EES networks will be analyzed for their relevance and usability for GM cultivation monitoring. To that end, an EES network datasheet can be developed and used to find relevant information about the applicability of the network in accordance with set criteria, *i.e.* frequency of data collection, quality of data, availability of report, willingness to collaborate, *etc*. On the basis of information collected by these EES network datasheets, networks can be analyzed, scored and ranked. Based on this analysis, EES networks will be included in the final list of EES networks.

*Analysis of the reports from the included EES networks*

On an annual basis, the reports of selected EES networks will be analysed by a third party for EuropaBio. However, it should be noted that the "non-hypothesis" driven observation of the networks can only provide insights on important unanticipated adverse effects (or lack thereof) and cannot deliver final conclusions.

### 3.1.3 Details of information and/or training provided to operators and users, etc.

Each purchaser of MON 810 receives a Technical User Guide (TUG) that provides a concise source of technical information about the product and sets forth use requirements and guidelines. Examples of the documents distributed in the 2010 season can be found in Appendix 3. Additional details on growers education in the context of refuge implementation is given in section 3.2.1.3.

In the context of the farmer questionnaire initiative (see Sections 3.1.2.1 and 3.1.4.1), all interviewers have been trained to understand the background of the questions. Here also experience gained during surveys of the previous years (uncertainties, misinterpretation of questions) could be shared. While questions have been carefully phrased to obtain accurate observations from farmers, previous experience with the questionnaire may increase awareness and thus result in slightly inconsistent observations from one year to the next. To

assist the interviewers in filling in the questionnaires with the farmers, a 'user manual' was developed (see Appendix 4).

### 3.1.4 Results of general surveillance

#### *3.1.4.1 Farmer questionnaires*

The methodology is described in section 3.1.2.1. The analysis of 271 questionnaires from the survey of farmers cultivating MON 810 in six European countries during the 2010 growing season did not reveal any unexpected adverse effects that could be associated with the genetic modification in MON 810. The full report is presented in Appendix 1.

The farmer questionnaires are distributed, completed and collated each year. Reports are also prepared on an annual basis. If the findings of the surveys indicate any adverse effects directly associated with MON 810 cultivation that require risk mitigation, these will be reported immediately.

#### *3.1.4.2 Company stewardship activities*

The methodology is described in section 3.1.2.2. To date, no unexpected potential adverse effects related to MON 810 have been reported or confirmed.

#### *3.1.4.3 Alerts on environmental issues*

The methodology is described in section 3.1.2.3. No potential adverse effects related to MON 810 were reported in 2010.

### 3.1.5 Additional information

Not applicable as no adverse effects were observed.

### 3.1.6 Review of peer-reviewed publications

*Peer reviewed publications on the safety of MON 810 and/or the Cry1Ab protein published in 2010 – 2011*

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. During the period between the search conducted for the last MON 810 cultivation monitoring report, *i.e.* June 2010, and beginning of June 2011, more than 40 publications related to MON 810 and/or Cry1Ab were published in high quality journals. In order to be able to cite scientific work with the highest credibility, Monsanto uses to the extent possible publications from journals that are included in the Web of Science[SM] database[17], accessible through the Web of Knowledge[SM] platform[18], a product of

[17] http://apps.webofknowledge.com/WOS_GeneralSearch_input.do?SID=R2COEh8dkg4AFJkLed8&product=WOS&search_mode=GeneralSearch&preferencesSaved= (Note that access to the database requires a subscription) (Accessed July 26, 2011).

[18] http://isiwebofknowledge.com (Accessed July 26, 2011).

Thomson Reuters. The web-based interface allows for a customized search using key words in a certain combination. The key words used for this search and the operators to combine them are provided in Table 1. All publications that resulted from the search as described in set #10 in Table 1 were screened, and relevant publications to the risk assessment were subsequently assessed. The detailed analysis of these peer reviewed publications is presented in Appendix 5. Publications were classified into the categories of food/feed (Molecular characterization, Protein expression, Animal feeding study, Toxicology/Allergenicity, and Protein/DNA fate in digestive tract - see Appendix 5.1) and environment (Non-target organisms, Protein/DNA fate in soil; Protein/DNA fate in stream water, and Insect resistance management - see Appendix 5.2).

**Table 1. List of key words and operators used to obtain relevant publications related to MON 810 in Thomson Reuters Web of Science℠**

| Set | Search criteria |
|---|---|
| **#10** | #7 NOT #9<br>*DocType=All document types; Language=All languages;* |
| **#9** | #8 NOT (#4 OR #5 OR #6)<br>*DocType=All document types; Language=All languages;* |
| **#8** | TS= (BT176 OR BT11 OR BT-176 OR BT-11 OR CRY1A.105 OR CRY1A105 OR CRYIA105 OR CRYIA 105 OR CRYIA.105 OR CRY2AB2 OR CRYIIAB2 OR CRY2-AB2 OR CRYII-AB2 or Cry1F or Cry1Ac OR Cry3Bb1 OR Cry11* OR Cry4* OR Roundup-ready OR ((Yieldg* OR Yield-g*) SAME (rootworm OR VT OR PLUS OR PRO OR RR OR roundup)) OR (bt SAME (cotton OR soy* OR rape OR potato OR brinjal OR rice)) OR herculex OR MON-89034 OR MON89034 OR TC1507 OR 59122 OR MON88017 OR MON-88017 OR MON-863 OR MON863 OR MIR604 OR DBT418 OR 15985)<br>*DocType=All document types; Language=All languages;* |
| **#7** | #6 OR #5 OR #4 OR #3<br>*DocType=All document types; Language=All languages;* |
| **#6** | TS= (Bt-Maize OR Bt-corn OR Yieldg* OR Yield-gard OR Yield-guard)<br>*DocType=All document types; Language=All languages;* |
| **#5** | TS=(MON810 OR MON-810)<br>*DocType=All document types; Language=All languages;* |
| **#4** | TS=(Cry1Ab OR CryIab OR Cry-1Ab OR CryI-Ab OR Cry1A-B OR CryIA-B)<br>*DocType=All document types; Language=All languages;* |
| **#3** | #2 AND #1<br>*DocType=All document types; Language=All languages;* |
| **#2** | TS=(((TOLERAN* OR RESISTAN* OR PROTEC*) SAME (LEPIDOPTERA* OR CORN-BORER* OR Ostrinia* OR nubilalis*)) AND (Genetically-modified OR modified-genetically OR transgenic* OR GM OR GMO OR MONSANTO))<br>*DocType=All document types; Language=All languages;* |
| **#1** | TS=(MAIZE OR CORN OR ZEA-MAYS)<br>*DocType=All document types; Language=All languages;* |

Twelve original research publications were evaluated in terms of food/feed safety (Adel-Patient *et al.*, 2011; Barros *et al.*, 2009; Delgado and Wolt, 2010; Folcher *et al.*, 2010; Guertler *et al.*, 2010; Kamath *et al.*, 2010; La Paz *et al.*, 2010; Paul *et al.*, 2010; Randhawa *et al.*, 2011; Steinke *et al.*, 2010; Swiatkiewicz *et al.*, 2011; Swiatkiewicz *et al.*, 2010). Molecular stability of the DNA insert and the surrounding locus in multiple generations of MON 810 maize was determined in La Paz *et al.* (2010) and found to be no lower than that of endogenous maize genes. A commentary article which reviewed two publications related to MON 810 genetic stability was also identified in the literature search (Brants *et al.*, 2010). These authors also stated that there is no scientific evidence for MON 810 instability. Kamath *et al.* (2010) measured Cry1Ab levels in leaf and tissues of several MON 810 hybrid varieties,

confirming expected efficiency against pests such as *Chilo partellus* and *Sesamia inferens*. Recent animal feeding studies in cows (Guertler *et al.*, 2010; Paul *et al.*, 2010; Steinke *et al.*, 2010), hogs (Swiatkiewicz *et al.*, 2011) and broiler (Swiatkiewicz *et al.*, 2010) continue to support the nutritional equivalence of MON 810 maize compared to isogenic lines or conventional controls. In these trials, Cry1Ab DNA and protein were digested in the gastro-intestinal tract and were not detectable in animal tissues. From a toxicology point of view, bioinformatics screening by Randhawa *et al.* (2011) confirmed the lack of significant alignment or amino acid sequence similarity between Cry1Ab protein and known allergens, indicating no potential for allergenic cross-reactivity. Testing in mice showed immunogenicity of purified Cry1Ab protein, but no evidence of allergenic potential (Adel-Patient *et al.*, 2011). Finally, two papers reported on fungal contamination and mycotoxin concentrations in MON 810 maize grain in France (Folcher *et al.*, 2010) and Argentina (Barros *et al.*, 2009). Zearalenone levels were slightly increased compared to near-isogenic controls in France, however this has not been observed in trials with *Bt* maize in other countries[19]. Delgado and Wolt (2010) conducted deterministic and stochastic modelling for comparative analyses of long-term exposure to Fumonisin $B_1$ ($FB_1$) toxin for nursery swine. Based on these estimates, swine populations in nursery facilities may frequently exhibit incipient effects (*i.e.*, LOC1) of $FB_1$ toxicity under blended maize source feeding conditions. However, the authors concluded that impacts on production efficiency remain uncertain.

Twenty-five original research publications were reviewed in terms of environmental safety of MON 810 (Alcantara *et al.*, 2011; Álvarez-Alfageme *et al.*, 2010; Andow *et al.*, 2010; Balog *et al.*, 2010; Crespo *et al.*, 2010; Desneux *et al.*, 2010; Emmerling *et al.*, 2011; Engels *et al.*, 2010; Feng *et al.*, 2010; Garcia *et al.*, 2010; Ghimire *et al.*, 2011; Knecht and Nentwig, 2010; Lehman *et al.*, 2010; Lopez *et al.*, 2010; Lumbierres *et al.*, 2011; O'Rourke *et al.*, 2010; Porcar *et al.*, 2010; Rauschen *et al.*, 2010; Sander *et al.*, 2010; Tank *et al.*, 2010; Wolt and Peterson, 2010; Yanni *et al.*, 2011a; Yanni *et al.*, 2011b; Yanni *et al.*, 2011c; Zeilinger *et al.*, 2010). Studies related to non-target organisms confirmed that there are no harmful effects of Cry1Ab protein on soil-dwelling dipterans (Knecht and Nentwig, 2010), various species of coleopterans (Álvarez-Alfageme *et al.*, 2010; Balog *et al.*, 2010; Garcia *et al.*, 2010; Porcar *et al.*, 2010; Rauschen *et al.*, 2010), aphid parasitism and aphid-parasitoid complexes (Lumbierres *et al.*, 2011 ), aquatic arthropods (Wolt and Peterson, 2010) and earthworms (Zeilinger *et al.*, 2010). Desneux *et al*. (2010) reported that females of the moth parasitoid *Cotesia marginiventris* responded positively to host-associated and host-induced odors derived from both conventional and *Bt* maize seedlings when searching for *Spodoptera frugiperda* hosts. The results of this study show that when complete plant–host systems representing realistic field conditions were tested, no significant differences were found in the frequency of parasitoid female attraction or in the time spent in the odor fields of the MON 810 and conventional maize. In Feng *et al.* (2010), some differences between MON 810 maize and the conventional control in systemic response of plant defense gene expression to feeding

[19] Ostry *et al.* (2010). A review on comparative data concerning *Fusarium* mycotoxins in *Bt* maize and non-*Bt* isogenic maize. Mycotox. Res. 26:141–145.

damage of *Ostrinia furnacalis* are described. The feeding damage between MON 810 and the conventional control maize would not be expected to be equivalent, and is not controlled for in this experiment. There were numerous papers dealing with insect resistance management. Engels *et al.* (2010) investigated *Bt* resistance alleles in European corn borer (ECB) populations using F2 screens and concluded that Cry1Ab resistance is rare enough for a successful deployment of the high dose/refuge strategy in Europe. According to O'Rourke *et al.* (2010), attention should be paid to differences in E and Z races of ECB when determining appropriate *Bt* maize refuge requirements, especially where the E race is predominant; however this is not applicable to the EU since in the EU MON 810 is grown following a structured refuge strategy. Ghimire *et al.* (2011) discussed the risk of resistance development in *Diatraea saccharalis* using single gene *Bt* maize technologies and presented alternatives. Lopez *et al.* (2010) found that *Nosema pyrausta* infection may slow down the evolution of *Ostrinia nubilalis* resistance to *Bt* maize and this third trophic level interaction should be accounted for in modeling resistance evolution. Work by Crespo *et al.* (2010) showed that field-derived Cry1Ab-resistant homozygote populations display considerable fitness costs. Andow *et al.* (2010) studied in-field refuge, or refuge in the bag (RIB) planting patterns of MON 810 maize in Minnesota and found higher risk in fields with less than the required number of contiguous non *Bt* rows and less than 20% overall in-field refuge. However, RIB is not an approved strategy for refuge implementation in the EU. Finally, Alcantara *et al.* (2011) reported that Philippine *Ostrinia furnacalis* populations remain susceptible to Cry1Ab *Bt* maize hybrids.

There were also a number of studies looking into the degradation of MON 810 plant material and Cry1Ab protein in the environment. Several trials concluded that *Bt* and non *Bt* maize do not differ in terms of decomposition and should have no effects on soil carbon dynamics in maize agroecosystems (Lehman *et al.*, 2010; Yanni *et al.*, 2011a). In contrast, Yanni *et al.* (2011b) determined that the residues of selected *Bt* maize analysed in one study decomposed faster than non-*Bt* maize residues; however, no lasting adverse effects were noted on soil decomposers, and the authors state that the impact of *Bt* maize production on the soil ecosystem is minimal. Yanni *et al.* (2011c) investigated the effect of ECB injury on maize tissue chemistry and found that the *cry1Ab* gene had subtle effects on the chemical composition of maize tissue; however, those differences did not alter the short-term decomposition of maize residues from stems and leaves. Emmerling *et al.* (2011) showed how degradation of Cry1Ab protein in *Bt* maize litter was accelerated by the presence of earthworms. Cry1Ab protein binding to soil and remaining toxicological activity was analysed by Sander *et al*. (2010). Tank *et al*. (2010) discuss how maize detritus can be dispersed within stream networks associated with maize farming regions and Cry1Ab proteins are distributed beyond field boundaries and persist after initial crop harvest. However, protein concentrations are below levels of concern for non-target aquatic organisms.

Finally, three review papers on *Bt*-maize were identified in the search output (de Vendomois *et al.*, 2010; Romeis and Meissle, 2011; Yanni *et al.*, 2010). de Vendomois *et al*. (2010) deals with previous studies by these authors on the statistical reevaluation of data from rat feeding studies conducted with several varieties of genetically modified (GM) maize. The authors

conclude that their alternate statistical analysis uncovers evidence that the GM maize causes hepatorenal toxicity when fed to rats. However, peer review by expert toxicologists and statisticians in academia and government have previously concluded that there is no evidence to indicate these crops are unsafe to consume as food or feed[20]. Romeis and Meissle (2011) analysed studies involving aphid feeding on different *Bt* crops and concluded that no significant amount of Cry protein was found in aphids. Yanni *et al*. (2010) reviewed studies on *Bt* and non *Bt* maize and concluded that their impact on the soil agro-ecosystems is minimal.

The publications identified by this literature search confirm the conclusions of the risk assessment. The peer-reviewed literature demonstrates that MON 810 is as safe to human and animal health as its conventional counterpart and 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 recent scientific opinion from EFSA on MON 810.

## 3.2 Case specific monitoring

### 3.2.1 Description and results of case-specific monitoring (if applicable)

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 US, 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 (IRM) strategies for insect-protected maize.

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[20] French High Counsel on Biotechnology review of the study: http://www.ogm.gouv.fr/article.php3?id_article=115 (Accessed July 29, 2011).

The Food Standards Australia New Zealand review of the study. http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets2009/fsanzresponsetoseral4647.cfm (Accessed July 29, 2011).

AFSSA, 2007. De l'Agence Française de Sécurité Sanitaire des Aliments relatif à la récente étude publiée sur le maïs génétiquement modifié MON 863. Agence Française de Sécurité Sanitaire des Aliments. La Directrice Générale. AFFSA Dossier No. 2007-SA-0109, 26 April 2007. http://www.anses.fr/ (Accessed July 29, 2011).

Doull, J., Gaylor, D., Greim, H.A., Lovell, D.P., Lynch, B. and Munro, I.C. (2007). Report of an Expert Panel on the reanalysis by Seralini *et al*. (2007) of a 90-day study conducted by Monsanto in support of the safety of a genetically modified corn variety (MON 863). Food and Chemical Toxicology 45:2073–2085.

European Food Safety Authority (EFSA) (2007). Statement of the Scientific Panel on Genetically Modified Organisms on the analysis of data from a 90-day rat feeding study with MON 863 maize. Adopted 25 June 2007. http://www.efsa.europa.eu/cs/BlobServer/Statement/GMO_statement_MON863.pdf?ssbinary=true (Accessed, July 29, 2011).

Following this example, Monsanto along with three other companies[21] have established the European Union Working Group on Insect Resistance Management (EUWGIRM). This group, formed in 2001, has developed a harmonised IRM plan specific for the EU (see Appendix 6), that enables the implementation of the management strategy described in Appendix II of the notification submitted to the French Commission du Génie Biomoléculaire (Monsanto Company, 1995). The harmonised IRM plan is based on published research, current EU legislation, the European Commission's Scientific Committee on Plants (SCP) opinion on IRM[22] and practical experience gained during the implementation of IRM plans in other parts of the world. The purpose of the IRM plan is to proactively avoid where possible, and in all cases delay the potential development of pest resistance to the Cry protein expressed in *Bt* maize. This harmonised IRM plan contains guidance on the following key elements:

- Refuge;
- Baseline studies and monitoring of the target pests;
- Communication and education.

#### *3.2.1.1 Refuge*

According to the *Harmonised insect resistance management (IRM) plan for cultivation of Bt maize in the EU* (see Appendix 6), farmers planting more than 5 hectares 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 have been taken to educate the farmers on the importance of implementing IRM measures (see Section 3.2.1.3). For cultural reasons, certain farming communities are reluctant to accept 'signed agreements' requiring them to adhere to particular agricultural practices. Moreover, seeds are usually sold through distributors and farmer cooperatives, which adds another '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 2010 planting season, through a survey sponsored by ANTAMA (Spanish Foundation supporting the use of new technologies in agriculture[23]). The survey, as in previous years, was carried out in the Ebro Valley (Huesca, Lérida and Zaragoza), which is where most of MON 810 is currently planted in Spain. The survey involved 200 farmers and half of them had planted MON 810 maize. The

[21] Syngenta Seeds, Pioneer Hi-Bred International Incorporated and Dow AgroSciences.

[22] 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* - http://ec.europa.eu/food/fs/sc/scp/out35_en.print.html (Accessed June 23, 2011)

[23] ANTAMA - http://fundacion-antama.org/ (Accessed July 26, 2011).

100 farmers planting MON 810 maize collectively planted 3 532 hectares. The conclusions from the answers delivered by the 100 farmers growing MON 810 maize are detailed below.

Farmer responses demonstrated the effectiveness of communication regarding IRM requirements. 100% of the farmers planting MON 810 knew about the recommendation to plant a refuge. In this group, 80% considered themselves to be "well informed", 15% "somehow informed", and 5% "little informed". The farmers responses regarding the clarity of the recommendations about the implementation of refuges were as follows: 100% considered the recommendations "very clear/quite clear", 75% of the interviewees considered that it is "very easy/quite easy" to follow the recommendations while 25% considered that it is "little easy/not easy".

The survey also revealed a high level of compliance with refuge requirements indicating that 88 of the 100 farmers that were included in the final survey planted a conventional maize refuge on their farm. The remaining farmers surveyed (*i.e.* 12%) did not plant a refuge. Reasons given by the farmers for not planting a refuge were: *(1)* corn borers (*Ostrinia nubilalis*) cause significant economic losses (5%), *(2)* the sowing is easier (7%), or *(3)* they consider their farms as small farms (*i.e.* less than 5 hectares and therefore no refuge required) (7%).

In addition, this survey analysed the satisfaction of the growers. The survey indicated that 79% of the farmers are very satisfied and 21% quite satisfied. The main advantage/benefit, reported by 98% of the farmers, was the effective protection against corn borers, followed by the plant health (plants/ear of maize do not collapse) (48%), peace of mind (44%), healthier plants (41%), and good yield (41%).

In the context of Monsanto's 2010 general surveillance, 271 farmers across six countries where MON 810 was commercially cultivated were surveyed for their implementation of a refuge (see Appendix 1). 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.

94.8% of the farmers who answered the question indicated that they followed the technical guidelines regarding the implementation of a refuge (90.8% planted a refuge and 4.1% had less than 5 ha planted with MON 810 on their farm[24]). Most countries reported a very high level of compliance with refuge requirements. The results of this survey are discussed in further detail in Section 3.1.4.1. In general, the farmers in the Czech Republic, Slovakia, Romania and Poland, were in full compliance with refuge requirements. Responses of the Monsanto 2010 Farmer Questionnaire Survey show that in Portugal one farmer (*i.e.*, 1 of 43) indicated he did not plant a refuge. This farmer explained that his "transgenic maize plots were totally alienated from others plots". Finally, compliance in Spain as reported through the

[24] The IRM plan states that no refuge is required if there is less than 5 ha of MON 810 planted on the farm.

Monsanto 2010 Farmer Questionnaire Survey (*i.e.* 137 of 150 farmers, 91%) was similar as surveyed by ANTAMA.

The message on the importance of refuge implementation will be repeated in all countries growing MON 810 in the 2011 growing season. It is important to continue educating the farmers on the necessity to implement refuges.

#### *3.2.1.2 Baseline studies and monitoring of the target pests*

*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).

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 2005 and again for the French samples of *S. nonagrioides* in 2006 (Monsanto Europe S.A., 2006; Monsanto Europe S.A., 2007). Overall, the susceptibility to Cry1Ab of theses species was within the range obtained in baseline studies and subsequent monitoring performed after Bt176 maize cultivation (Farinós *et al.*, 2004; Gonzalez-Nunez *et al.*, 2000), prior to MON 810 introduction.

In addition to the above, a German lab (BTL Bio-Test Labor GmbH) explored the baseline susceptibility of *O. nubilalis* to Cry1Ab from 2005 to 2007 in other major European maize growing regions based on the MON 810 adoption. During this period, levels of susceptibility to Cry1Ab have been determined for one laboratory colony and several populations collected in maize fields in the Czech Republic, France, Germany, Italy, Hungary, Slovakia, Poland, Portugal and Romania (Monsanto Europe S.A., 2006; Monsanto Europe S.A., 2007; Monsanto Europe S.A., 2008).

*Monitoring of the target pests*

Monitoring for resistance to Cry1Ab in *O. nubilalis* and *S. nonagrioides* populations across the Ebro Valley, central Spain and Extremadura-Andalusia since 1999 was in place after the commercialisation of varieties including Bt176 maize from Syngenta, that also expresses a Cry1Ab protein (Farinós *et al.*, 2004).

During 2004-2009, monitoring for *O. nubilalis* and *S. nonagroides* resistance to Cry1Ab expressed in MON 810 was performed. Different geographical areas with considerable commercial growing of MON 810 varieties were selected. The monitoring studies performed with *O. nubilalis* and *S. nonagrioides* showed that the susceptibility of the population samples to Cry1Ab were within what is considered a normal range, demonstrating no development of resistance.

In 2010, susceptibility to the Cry1Ab toxin of the *S. nonagrioides* populations from Southwest and Central Iberia has been assessed for the fourth time since 2004, but it has been the first time that larvae collected from Southwest Spain and Portugal have been analyzed together representing a single population. For both populations (Southwest Spain/Portugal and Central Iberia), differences found in the susceptibility to the toxin are within the range of variability expected for field populations of this corn borer. Further, the analyses of historical series of susceptibility data of *S. nonagrioides* to Cry1Ab did not reveal signs of development of resistance to this toxin by field populations from the sampling areas considered. (see Appendix 7).

The susceptibility of the *O. nubilalis* laboratory strain to the Cry1Ab toxin was comparable with values of susceptibility obtained for laboratory strains in previous years. Both Lethal Concentrations (LC) and Molting Inhibition Concentrations (MIC) values evidenced consistency through time, showing around 5-fold variation in both $LC_{50}$ and $MIC_{50}$ values (see Appendix 7).

In addition to the baseline results described above, BTL Bio-Test Labor GmbH determined the susceptibility of *O. nubilalis* to Cry1Ab from 2005 to 2010 in major European maize growing regions. The susceptibility of 15 populations with 104 samples (including replicates and assays without concentration response relationship) of *O. nubilalis* were analysed. Thus far, susceptibility to Cry1Ab have been assessed for one laboratory colony and populations collected in maize fields in Czech Republic, France, Germany, Italy, Hungary, Slovakia, Poland, Portugal, Romania, and Spain. *O. nubilalis* larvae were exposed to artificial diet treated with increasing Cry1Ab concentrations, and mortality and growth inhibition were evaluated after 7 days (see Appendix 8).

Results for *O. nubilalis* populations were pooled according to geographic and climatic conditions. These pooled populations correspond to homogenous regions based on available knowledge of insect biology and geography. This approach follows the IRM industry working group guidelines (see Appendix 6). The results of the *O. nubilalis* populations pooled according to geographic and climatic conditions were similar and differed 1.8-fold, 6.6-fold, 2.6-fold, 4.2-fold and 3.2-fold and 2.04-fold for *O. nubilalis* collected in 2005, 2006, 2007, 2008, 2009 and 2010 respectively. A similar degree of variability was reported for *O. nubilalis* susceptibility to Cry1Ab for populations from three broad geographic areas in the US, chosen based 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 (Marçon *et al.*, 1999). For the current study, the pheromone races were not distinguished.

These results indicate that the observed population variation in susceptibility reflects natural variation in *Bt* susceptibility among *O. nubilalis* populations. Any evidence for a decrease of Cry1Ab susceptibility of populations during the monitoring duration from 2005–2010 could not be detected. In the future, other regional sources may be added to ensure that the monitoring program continues to represent the Cry1Ab maize market in Europe.

In conclusion, data collected on *S. nonagrioides* and *O. nubilalis* indicate that the IRM plan proposed by the industry is still valid since no change in susceptibility to Cry1Ab was observed.

These results are aligned with the conclusions of independent studies conducted in Spain and recently summarized in the review published by the Spanish Ministry of Environment, Rural and Marine Affairs (MARM). It is concluded that monitoring results from 12 years of *Bt* maize cultivation in Spain (including MON 810 since 2003) indicate no evidence of increased susceptibility of target pests to the Cry1Ab protein[25].

#### *3.2.1.3 Communication and education*

An extensive grower education program is essential for the successful implementation of the IRM plan. As stated in section 3.1.3, each purchaser of MON 810 receives a Technical User Guide (see Appendix 3). It contains the latest information on the growers' IRM obligations. The user guide requires farmers to implement IRM measures, including refuge planting. In addition to the widespread dissemination of information pertaining to refuge requirements to users of the technology, a grower education programme is also conducted with sales and agronomic advisory teams to ensure that farmer awareness of refuge compliance is reinforced.

In addition to the above, other initiatives on communication are taken. In the 2010 planting season in Spain, a number of initiatives were taken, as in previous seasons, to emphasise the importance of refuge implementation. A comprehensive program to raise awareness of refuge requirements and educate personnel, dealers, cooperatives and individual farmers was implemented. Activities included:

1) Ensuring continuous communication about IRM implementation in all sales tools (leaflets, brochures, catalogues, hybrid guides on packaging). Some examples include the good agricultural practices (GAP) leaflet (see Appendix 9.1) and Guía Técnica YieldGard® (YieldGard Technical Guide) (see Appendix 3.6) that are attached to each MON 810 bag sold in Spain.
2) Presentation by sales and marketing teams of IRM requirements in farmer meetings/farmer talks to reinforce the need for refuge compliance.
3) IRM information exhibited at different national and regional agricultural fairs.
4) Advertisement about refuge compliance published in key agricultural magazines (Vida Rural and Phytoma) (see Appendix 9.2).
5) Sending a letter (on behalf of ANOVE: the National Breeder Association in Spain) from each company to their farmer's database in MON 810 areas reinforcing the key messages of refuge implementation (see Appendix 9.3).

[25] http://www.marm.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/notificaciones-y-autorizaciones/comercializacion.aspx (Accessed July 28, 2011).

6) Train the trainers: an IRM session was organised and a presentation on IRM was jointly created and followed by all companies operating in the market to ensure common messages (see Appendix 9.4).

7) Posters and stickers distributed among seed distributors and point of sales to be used with invoices and letters (see Appendix 9.5 and Appendix 9.6).

8) Communication plan for cooperatives, small points of sales outlets and farmers: trained ANOVE inspectors completed several visits in MON 810 growing areas to inform, distribute material and ensure that farmers are well informed on refuge implementation when buying MON 810 seeds.

9) Interview with farmers implementing refuge published in Spanish agricultural journal as Vida Rural (see Appendix 9.7).

The ANTAMA survey conducted in Spain, and referred to in Section 3.2.1.1, demonstrates the effectiveness of the education program to raise awareness of refuge implementation. 100% of the farmers surveyed acknowledged they were made aware of the fact that they are required to plant a refuge.

### 3.2.2 Monitoring and reporting of adverse effects resulting from accidental spillage (if applicable)

Not applicable.

## 3.3 Concluding remarks

Monitoring results obtained via questionnaires (see Section 3.1.4.1 and Appendix 1), the scientific literature (see Section 3.1.6 and Appendix 5.1 and Appendix 5.2), company stewardship activities (see Section 3.1.4.2) and alerts on environmental issues (see Section 3.1.4.3) demonstrated that there are no adverse effects attributed to the cultivation of MON 810 in Europe.

## 4. SUMMARY OF RESULTS AND CONCLUSIONS

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

Following the establishment and reinforcement of an effective education and communication program in countries where MON 810 was grown in 2010, the percentage of farmers implementing refuges in their fields was very high.

The results of the analysis of 2010 farmer questionnaires did not identify any potential adverse effects that might be related to MON 810 plants and their cultivation. Company stewardship activities and issue alerts did not reveal any adverse effect related to MON 810 cultivation. A review of high quality publications confirmed the negligible potential of MON 810 and/or the Cry1Ab protein to cause adverse effects. Also, no issues related to Insect Resistance were experienced for the 2010 planting season.

A comprehensive insect resistance monitoring program demonstrated that there were no changes in resistance of *O. nubilalis* or *S. nonagrioides* to the Cry1Ab protein in the major MON 810 growing regions in Europe in 2010.

All together, these results demonstrate that there are no adverse effects attributed to the cultivation of MON 810 in Europe. The result of the 2010 monitoring concurs with the results observed since monitoring was started in 2003.

## 5. ADAPTATIONS OF THE MONITORING PLAN AND ASSOCIATED METHODOLOGY FOR FUTURE YEARS

The current monitoring plan and associated methodologies were considered to be adapted to the purpose of monitoring for adverse effects. As indicated in the monitoring plan submitted as part of the renewal application EFSA-GMO-RX-MON810 (20.1a), the Farmer Questionnaire can be improved based on experience from year to year. Also, in anticipation of the mandatory request in all applications or renewals for deliberate release submitted under Directive 2001/18/EC and Regulation (EC) No. 1829/2003, the monitoring of existing environmental networks on an EU scale is in development phase (see Section 3.1.2.3).

**Signed:** _____

**Date:** 29/7/11

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