Annual monitoring report on the cultivation of MON 810 in 2013

Czech Republic, Portugal, Romania, Slovakia, and Spain

Submitted by

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Data protection.

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

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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

® 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 August 28, 2014)

[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 August 28, 2014)

[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 August 28, 2014)

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 2013, MON 810 was planted in the EU on approximately 148 659 hectares across five countries: Czech Republic (2560 ha[5]), Portugal (8202 ha[6]), Romania (835 ha[7]), Slovakia (100 ha[8]) and Spain (136 962 ha[9]).

Results of Insect Resistance Management (IRM) are provided to the European Commission on an annual basis (*i.e.* this report) in line with our obligations under Commission Decision 98/294/EC of 22 April 1998. In addition, Monsanto has also always reported on a voluntary basis about its activities 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 (General Surveillance monitoring). In addition to any reporting obligation in terms of annual monitoring activities, in case an investigation establishes that MON 810 is the cause of an adverse effect, Monsanto will 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, will then 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, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013). Since 2010, our reports follow the format as laid out in Annex I to Commission Decision 2009/770/EC[10].

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[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 August 28, 2014)

[5] Ministry of Agriculture of the Czech Republic, 2013 - http://eagri.cz/public/web/mze/tiskovy-servis/tiskove-zpravy/x2013_geneticky-modifikovane-kukurice-se-letos.html (Accessed August 28, 2014)

[6] Ministry of Agriculture and Sea of Portugal, 2013 - http://www.dgv.min-agricultura.pt/xeov21/attachfileu.jsp?look_parentBoui=4260245&att_display=n&att_download=y (Accessed August 28, 2014)

[7] Ministry of Agriculture and Rural Development of Romania - http://www.madr.ro/docs/agricultura/suprafete-porumb-modificat-genetic-MON_810-2013.pdf (Accessed August 28, 2014)

[8] Ministry of Agriculture and rural development of the Slovak Republic, 2013 - http://www.mpsr.sk/index.php?navID=764&navID2=764&sID=40&id=7688 (Accessed August 28, 2014)

[9] Ministry of Agriculture, Food and Environment of Spain - http://www.magrama.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/Superficie_cultivada_Espa%C3%B1a_2013_tcm7-297620.pdf (Accessed August 28, 2014)

[10] 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 August 28, 2014)

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 2013 - July 2014

1.6 Other monitoring reports have been submitted in respect of:

- **Import and Processing** Yes, voluntary (September 2013)
- **Food/Feed** Not applicable

2. EXECUTIVE SUMMARY

In 2013, MON 810 was planted in the EU on approximately 148 659 hectares across five 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. The adherence to this stewardship measure in the context of the 2013 cultivation of MON 810 maize in Europe is detailed in this report.

The planting of MON 810 in the 2013 season was accompanied by a rigorous IRM plan involving four main elements: farmer education, refuge implementation, susceptibility monitoring and good stewardship practices. The initiatives developed to educate farmers about the importance of the implementation of IRM measures were continued in 2013 and the success of these initiatives was reflected in the high levels of compliance with requirements for refuge implementation observed in the 2013 season. A comprehensive IRM program demonstrated that there were no changes in susceptibility of neither *O. nubilalis* nor *S. nonagrioides* to the Cry1Ab protein in the major MON 810 growing regions in Europe in 2013.

To address General Surveillance (GS) for the current monitoring report, we have compiled all available EU cultivation monitoring reports for MON 810 rather than reporting specifically on our last year's GS efforts. The weight of evidence available to date confirms the initial conclusions of the safety assessment, namely that MON 810 is as safe as conventional maize with respect to human or animal health and the environment.

3. MONITORING RESULTS

3.1 General Surveillance

Current EU legislation requires applicants to include in their monitoring plan strategies to identify the occurrence of adverse effects of the GMO on human or animal health or the environment which were not anticipated in the environmental risk assessment. This type of monitoring, termed General Surveillance (GS), is not a condition of the current authorization for MON 810 issued in 1998. Nevertheless, Monsanto has been reporting on its activities for this non-hypothesis based monitoring on a voluntary basis since 2005. Over a number of years, several approaches to monitor unanticipated adverse effects were developed and their methodologies improved substantially. A number of the complementary approaches initially developed by Monsanto were taken up by EuropaBio in an effort to harmonize proportional monitoring approaches across the technology providers. Monsanto has traditionally reported on four complementary GS activities: (1) analysis of farmer questionnaires, (2) literature searches on the safety of MON 810 in peer reviewed journals, (3) Alerts on the product through stewardship programs, and (4) the use of existing environmental networks (EENs).

To address GS in the current monitoring report, all available EU cultivation monitoring reports for MON 810 were compiled rather than reporting specifically on Monsanto's last year's GS efforts since the weight of evidence available to date confirms the initial conclusions of the EU safety assessment in 1998, namely that MON 810 is as safe as conventional maize with respect to human or animal health and the environment. MON 810 has been safely grown in multiple countries around the world since 1997 as a single event, and later as part of several stacks. Following its approval in 1998 in the EU, MON 810 was first grown in European countries in 2003. From 2005 to date, Monsanto submitted ten post-market environmental monitoring (PMEM) reports covering eleven years of MON 810 cultivation in the EU and all confirming its safety. These reports describe the activities undertaken by Monsanto to identify and analyse anticipated and unanticipated effects related to MON 810 cultivation (Monsanto Europe S.A., 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013). The resulting weight of safety evidence is summarized below. Furthermore, irrespective of any annual monitoring reporting obligations, Monsanto will, in accordance with EU legislation, inform the European Commission and the appropriate national competent authorities of any confirmed adverse effect related to the MON 810 event should it occur.

Farmers growing MON 810 are likely the first to observe any effects related to the GM event (adverse as well as beneficial) should they occur. Therefore, two of the four GS approaches are focused on the farmer, *i.e.*, the farmer questionnaire and Monsanto's product stewardship efforts. Since the first implementation of farmer interviews, more than 1800 farmers have been questioned about their experience with MON 810 in particular, about any observations or effects in the field that were different for MON 810 compared to conventional maize hybrids. None of the reports, for which the results were statistically analyzed, identified a statistically meaningful effect that was adverse to human or animal health, or the environment. Only beneficial effects were reported in those reports as being evaluated in MON 810 fields

compared to conventional maize fields. In addition, Monsanto's company-internal processes for issues and complaint handling could not identify any adverse effect caused by the MON 810 event. Furthermore, as a third GS approach activity, Monsanto reported on the peer reviewed articles that were published on the safety of MON 810. Across our regulatory submissions and monitoring reports, Monsanto has reported on more than 350 articles of which the vast majority is authored by independent academics and scientists. Allegations about the safety of our product were thoroughly reviewed, allowing Monsanto to confirm the validity of the initial conclusions on safety made in the food and feed risk assessment as well as the environmental risk assessment presented in our different applications for authorization of MON 810 in the EU. Finally, reports of EENs were used to confirm the safety of GM crops in general and MON 810 in particular, but were considered of less additional value than the other approaches. EuropaBio identified and characterized potential relevant EENs for PMEM of GM crop cultivation, but concluded that EENs are not well suited as a primary tool for GS in GM crop monitoring (Smets *et al.*, 2014[11]).

The aforementioned ten monitoring reports, covering eleven years of MON 810 cultivation in the EU, all support the original conclusion reached in the initial application of authorization, *i.e.*, MON 810 is as safe as conventional maize in terms of human and animal health or the environment. Global regulators reached the same conclusions as MON 810 is authorized for cultivation in Argentina, Brazil, Canada, Colombia, Honduras, Indonesia, Philippines, South Africa, Uruguay and the US. More specifically in the EU, independent scientific panels, such as the EFSA have reviewed our regulatory submissions (EFSA, 2009[4]; 2012[12]; 2012[13]), new scientific publications published from 2009 onwards (EFSA, 2012[14]), Monsanto's monitoring reports (EFSA, 2011[15]; 2012[16]; 2013[17]; 2014[18]) as well as challenges raised by various

[11] Smets *et al.*, 2014, The use of existing environmental networks for the post-market monitoring of GM crop cultivation in the EU, Environ. Sci.: Processes Impacts, 2014, 16 (7), 1754 - 1763 DOI: 10.1039/C4EM00093E http://pubs.rsc.org/en/content/articlelanding/2014/em/c4em00093e (Accessed August 28, 2014)

[12] EFSA, 2012 Scientific opinion on an application (EFSA-GMO-NL-2012-107) for the placing on the market of maize MON 810 pollen under Regulation (EC) No 1829/2003 from Monsanto - http://www.efsa.europa.eu/en/efsajournal/pub/3022.htm (Accessed August 28, 2014)

[13] EFSA, 2012 Scientific Opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations for the cultivation of the genetically modified insect resistant maize Bt11 and MON 810 - http://www.efsa.europa.eu/en/efsajournal/pub/3016.htm (Accessed August 28, 2014)

[14] EFSA, 2012 Scientific Opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize MON 810 - http://www.efsa.europa.eu/en/efsajournal/pub/3017.htm (Accessed August 28, 2014)

[15] EFSA, 2011 Scientific opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2009 - http://www.efsa.europa.eu/en/efsajournal/pub/2376.htm (Accessed August 28, 2014)

[16] EFSA, 2012 Scientific opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2010 - http://www.efsa.europa.eu/en/efsajournal/pub/2610.htm (Accessed August 28, 2014)

[17] EFSA, 2013 Scientific opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2011 - http://www.efsa.europa.eu/en/efsajournal/pub/3500.htm (Accessed August 28, 2014)

Member States related to human and animal health or the environment (EFSA, 2004[19]; 2005[20]; 2006[21]; 2008[22]; 2008[23]; 2008[24]; 2008[25]; 2012[26]; 2012[27]; 2013[28]; 2013[29]; 2014[30]). EFSA's first opinion based on regulatory data presented in our three complementary regulatory renewal submissions (in 2009) concluded that "*maize MON 810 is as safe as its conventional counterpart with respect to potential effects on human and animal health. The EFSA GMO Panel also concludes that maize MON 810 is unlikely to have any adverse effect on the environment in the context of its intended uses*". All subsequent EFSA opinions consistently concluded that there is no specific scientific evidence, in terms of risk to human

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[18] EFSA, 2014 Scientific opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2012 - http://www.efsa.europa.eu/en/efsajournal/pub/3704.htm (Accessed August 28, 2014)

[19] EFSA, 2004 Opinion of the Scientific Panel on genetically modified organisms [GMO] on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC - http://www.efsa.europa.eu/en/efsajournal/pub/78.htm (Accessed August 28, 2014)

[20] EFSA, 2005 Opinion of the Scientific Panel on genetically modified organisms [GMO] related to the safeguard clause invoked by Hungary according to Article 23 of Directive 2001/18/EC - http://www.efsa.europa.eu/en/efsajournal/pub/228.htm (Accessed August 28, 2014)

[21] EFSA, 2006 Opinion of the Scientific Panel on genetically modified organisms [GMO] related to the safeguard clause invoked by Greece according to Article 23 of Directive 2001/18/EC and to Article 18 of Directive 2002/53/EC - http://www.efsa.europa.eu/en/efsajournal/pub/411.htm (Accessed August 28, 2014)

[22] EFSA, 2008 Request from the European Commission related to the safeguard clause invoked by Hungary on maize MON810 according to Article 23 of Directive 2001/18/EC - Scientific opinion of the Panel on Genetically Modified Organisms - http://www.efsa.europa.eu/en/efsajournal/pub/756.htm (Accessed August 28, 2014)

[23] EFSA, 2008 Request from the European Commission related to the safeguard clause invoked by Greece on maize MON810 according to Article 23 of Directive 2001/18/EC - Scientific opinion of the Panel on Genetically Modified Organisms - http://www.efsa.europa.eu/en/efsajournal/pub/757.htm (Accessed August 28, 2014)

[24] EFSA, 2008 Request from the European Commission related to the safeguard clause invoked by France on maize MON810 according to Article 23 of Directive 2001/18/EC and the emergency measure according to Article 34 of Regulation(EC) No 1829/2003 - Scientific opinion of the Panel on Genetically Modified Organisms - http://www.efsa.europa.eu/en/efsajournal/pub/850.htm (Accessed August 28, 2014)

[25] EFSA, 2008 Request from the European Commission related to the safeguard clause invoked by Austria on maize MON810 and T25 according to Article 23 of Directive 2001/18/EC - http://www.efsa.europa.eu/en/efsajournal/pub/891.htm (Accessed August 28, 2014)

[26] EFSA, 2012 Scientific Opinion on a request from the European Commission related to the emergency measure notified by France on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003 - http://www.efsa.europa.eu/en/efsajournal/pub/2705.htm (Accessed August 28, 2014)

[27] EFSA, 2012 Scientific Opinion on a request from the European Commission related to the safeguard clause notified by Greece on genetically modified maize MON 810 according to Article 23 of Directive 2001/18/EC - http://www.efsa.europa.eu/en/efsajournal/pub/2877.htm (Accessed August 28, 2014)

[28] EFSA, 2013 Scientific Opinion on a request from the European Commission related to the emergency measure notified by Italy on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003 - http://www.efsa.europa.eu/en/efsajournal/pub/3371.htm (Accessed August 28, 2014)

[29] EFSA, 2013 Scientific Opinion on a request from the European Commission related to the emergency measure notified by Luxembourg on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003 - http://www.efsa.europa.eu/en/efsajournal/pub/3372.htm (Accessed August 28, 2014)

[30] EFSA, 2014 Statement on a request from the European Commission related to the emergency measure notified by Greece on genetically modified maize MON 810 according to Article 18 of Directive 2002/53/EC - http://www.efsa.europa.eu/en/efsajournal/pub/3732.htm (Accessed August 28, 2014)

and animal health or the environment that would invalidate the previous EFSA GMO Panel risk assessments of maize MON 810.

In conclusion, the available weight-of-evidence continuing to support the safety of MON 810 and the absence of unanticipated adverse effects consists of:

- regulatory safety studies presented in the different EU applications,
- more than a dozen EFSA opinions concluding on the safety of MON 810,
- cultivation approvals for MON 810 in multiple countries around the world based on the same scientific risk assessment data and local safety opinions,
- hundreds of peer reviewed publications relevant to the safety assessment of MON 810 and the expressed Cry1Ab protein,
- more than ten years of experience with MON 810 cultivation in the EU
- more than 17 years of experience worldwide on millions of hectares,
- multiple PMEM reports for the EU reporting on the commercial experience confirming the initial safety conclusions (and endorsed by EFSA),
- absence (in the EU and on a global scale) of demonstrated field resistance for the target pests,
- absence of any confirmed adverse effect related to the event.

3.1.1 Description of General Surveillance

General Surveillance (GS) is not a condition of the current authorization for MON 810 issued in 1998 (Commission Decision 98/294/EC). Moreover, the weight of evidence as described in Section 3.1 continues to support the safety conclusions for MON 810.

3.1.2 Details of surveillance networks used to monitor environmental effects during General Surveillance and description of other methodologies

General Surveillance (GS) is not a condition of the current authorization for MON 810 issued in 1998 (Commission Decision 98/294/EC). Moreover, the weight of evidence as described in Section 3.1 continues to support the safety conclusions for MON 810.

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

General Surveillance (GS) is not a condition of the current authorization for MON 810 issued in 1998 (Commission Decision 98/294/EC). Moreover, the weight of evidence as described in Section 3.1 continues to support the safety conclusions for MON 810.

3.1.4 Results of General Surveillance

General Surveillance (GS) is not a condition of the current authorization for MON 810 issued in 1998 (Commission Decision 98/294/EC). Moreover, the weight of evidence as described in Section 3.1 continues to support the safety conclusions for MON 810.

3.1.5 Review of peer-reviewed publications

General Surveillance (GS) is not a condition of the current authorization for MON 810 issued in 1998 (Commission Decision 98/294/EC). Moreover, the weight of evidence as described in Section 3.1 continues to support the safety conclusions for MON 810. Therefore, the literature that appeared during the last year relevant to the safety of MON 810 will not be summarized.

We noted, however, that in its most recent opinion on the annual post-market environmental monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2012[18], EFSA identified a publication by Albajes *et al.* (2012) which it did not assess previously. The authors published a two year study with the objective to test the effects of MON 810 cultivation on non-target predatory fauna. Abundance of plant-dwelling and soil-dwelling predators in *Bt* maize *vs* non-*Bt* near-isogenic varieties was compared in plots from two Spanish locations (north (NS) and central Spain (CS)). The abundance of plant-dwelling predators was examined by visual inspection, whereas the soil-dwelling predators were inspected by use of pitfall traps. No significant differences in predator densities on plants were found between *Bt* and non-*Bt* varieties. In the pitfall traps, significant differences (~30%) between the two types of maize were found only in Staphylinidae (only rove beetles), in which trap catches in non-*Bt* maize were higher than in *Bt* maize in one of the two locations (central Spain). The EFSA GMO Panel recommended, in the light of the outcome of this two-year study by Albajes *et al.* (2012), the applicant to follow up possible adverse effects of maize MON 810 on rove beetles.

As a general remark, it is surprising that EFSA recommends Monsanto to conduct case-specific monitoring on rove beetles (be it in terms of a literature assessment) based on one publication, whereas the weight of evidence shows that rove beetles neither are a target of the Cry1Ab protein nor are affected by MON 810 as a whole. This weight of evidence is described in more detail below. Furthermore, despite the single significant difference for rove beetles in one of the two locations, the authors themselves acknowledge that Staphylinid populations are known to be heterogeneous and conclude that, in general, no significant differences in non-target arthropod (NTA) abundance were found between MON 810 and the non-*Bt* maize. Finally, we note that the study design used by the authors is not in line with the minimum requirements for the experimental design for the safety evaluation of GMOs (EFSA, 2010[31]); it is therefore unclear why EFSA recommends Monsanto to conduct case-specific monitoring on rove beetles based on this one publication.

Notwithstanding these general observations, from a technical perspective the significant difference in Staphylinid abundance attributed to MON 810 in Albajes *et al.* (2012) is unexpected as the Cry1Ab protein expressed in MON 810 is generally active on Lepidoptera (*e.g.*, butterflies) and not Coleoptera (beetles). The specificity of Cry proteins is dependent

[31] EFSA, 2010 Scientific Opinion on statistical considerations for the safety evaluation of GMOs - http://www.efsa.europa.eu/en/efsajournal/pub/1250.htm (Accessed August 28, 2014)

upon binding to specific receptors present in the insect mid-gut (OECD, 2007[32]) (Pigott and Ellar, 2007) and the insecticidal activity of Cry1 class proteins has been shown to be specific for lepidopteran insects (Crickmore *et al.*, 1998; de Maagd *et al.*, 2001; Romeis *et al.*, 2006).

Laboratory studies with rove beetles (Garcia *et al.*, 2010; Porcar *et al.*, 2010) have confirmed no adverse effects of the Cry1Ab protein at concentrations equal to or exceeding field exposure concentrations. Porcar *et al.* (2010) continuously exposed the rove beetle *Atheta coriaria* in diet bioassays to solubilized Cry1Ab and trypsin-activated Cry1Ab proteins in for 15 days at a concentration 5-fold greater than the expression of Cry1Ab in MON 810 maize. Due to the lack of toxicity in laboratory feeding studies with both solubilized and trypsin-activated Cry1Ab proteins, Porcar *et al.* (2010) concluded that *A. coriaria* adults were not sensitive to the tested proteins and therefore would not be adversely impacted by Cry1Ab crops. García *et al*. (2010) assessed potential effects of Cry1Ab protein expressed in maize MON 810 on the larvae and adults of *A. coriaria* in prey-mediated tritrophic feeding studies. Newly hatched larvae of *A. coriaria* were fed *ad libitum* on *Tetranychus urticae* (Acari: Tetranychidae) that were fed *ad libitum* on leafs of maize MON 810 (*Bt* maize) or leafs of non-*Bt* maize and evaluated for the development time and mortality of immature stages, emergence of adults, sex ratio, and the survivorship, fecundity and egg fertility on the adults that emerged from each treatment. Adult feeding studies were also preformed to assess egg fertility and characterize the proteolytic enzyme activities in the adults exposed to prey fed *Bt*- versus non-*Bt* maize. García *et al*. (2010) reported that the bioassays with larvae or adult *A. coriaria* to determine the *Bt* fed-prey-mediated effects, indicated that the Cry1Ab protein has no negative effects on the biological parameters measured.

Additionally, a recent field study confirmed the lack of adverse effects attributable to MON 810 on rove beetle assemblages as compared to conventional maize fields (Twardowski *et al.*, 2014). In total, over 35,000 rove beetles were documented in weekly pitfall traps collections from two field sites in southern Poland for over a 3 year (growing season) period. Though variability of rove beetle numbers were recorded within this study between cultivars, Twardowski *et al.* (2014) concluded that none of the observed differences were attributable to MON 810 but rather environmental factors such as crop type and/or crop rotation.

Therefore, it is more likely that the observed differences in Staphylinid abundance between MON 810 and conventional maize fields reported in Albajes *et al.* (2012) are related to other factors such as study design and detection capabilities rather than any potential toxicity of the Cry1Ab protein. An international scientific workshop on the topic of non-target organisms (NTOs) and genetically modified crops was organized by the EFSA on 29 and 30 November 2012 (EFSA, 2012[33]). More specifically, this workshop addressed the effects of *Bt* proteins on

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[32] OECD, 2007 Consensus document on safety information on transgenic plants expressing *Bacillus thuringiensis*-derived insect control proteins - http://www.epa.gov/oppbppd1/biopesticides/pips/reg-biotech.pdf (Accessed August 28, 2014)

[33] EFSA, 2012 International scientific Workshop "*Non-Target Organisms and Genetically Modified Crops: Assessing the effects of Bt proteins*" (29-30 November 2012, Amsterdam, the Netherlands) - http://www.efsa.europa.eu/en/supporting/pub/484e.htm (Accessed August 28, 2014)

non-target organisms and therefore the lead author of Albajes *et al.* (2012) was invited to present the results of the paper. During this presentation, dr. Albajes stated that "*the design and analysis of field trials should be reviewed to improve detection capacities*" (EFSA, 2012[33]). Furthermore, dr. Albajes presented the results of 14 years of field trials in Spain, including the results from the publication discussed here, and concluded that "*in general no negative effects of Bt crops (Bt176 or MON810) on NTOs were observed*" and "*Cry1Ab maize has no adverse effects on NTOs and no further NTO tests have to be conducted on Cry1Ab maize"*. In that same workshop, dr. Rauschen reported that predatory rove beetles may occur inconsistently at a given site or in only very low densities in maize fields (Rauschen *et al.*, 2010) as was also indicated by Albajes *et al.* (2013). For example, sampling of saprophagous Staphylinids requires special techniques (*e.g.*, soil emergence traps, soil bait cylinders, pitfall arenas) because of their obscure lifestyle. Therefore, reliable assessments with many beetle families in the field have significant challenges and an assessment of toxicity can be assessed in the laboratory with higher certainty (Rauschen *et al.*, 2010).

More recently, Albajes *et al.* (2013) also discussed that identifying the most appropriate NTAs (with a high capacity to detect potential adverse effects of GM maize on biological control functions), is a key concern in field study design. In an analysis of 14 field trials over a 10 year period in Spain, they determined that not all NTAs that are present and representative of ecological functions (*e.g.*, predators) could be reliably used as indicators to detect small changes in abundance. Based on this analysis, the authors concluded that Staphylinids, though often recorded in maize fields, are highly variable between years and plots and therefore should not be used as representative NTAs in field studies (Albajes *et al.*, 2013). Further, a recent meta-analysis was conducted to confirm the no adverse effects conclusions on NTAs from individual field trials for single and stacked *Bt* traits (Comas *et al.*, 2014). The global analysis was conducted to provide a higher detection capability of adverse effects than is possible with single trial analysis. Thirteen independent field trials across Spain were analyzed, and the conclusion of the meta-analysis supported the previous determination of no adverse effects on NTAs from *Bt* maize cultivation (Comas *et al.*, 2014).

In conclusion, based upon 1) the widely known specificity of the Cry1Ab protein to the Order Lepidoptera; 2) the lack of corroborating evidence of adverse effects from Cry1Ab or MON 810 to Staphylinids from both laboratory and more recent field studies; and 3) the high variability within Staphylinid populations in maize fields and consequently their unsuitability as a representative NTA in field studies, it is unlikely that the observed significant difference in Staphylinid numbers in MON 810 fields reported by Albajes *et al.* (2012) are attributable to the Cry1Ab protein, but are rather an artefact of study design and the natural biological variability of this taxa. Based on this weight of evidence no further monitoring for adverse effects of MON 810 maize on rove beetles is considered necessary.

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. 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 efficient Insect Resistance Management (IRM) strategies for insect-protected maize.

Following this example, Monsanto along with three other companies[34] established the European Union Working Group on Insect Resistance Management and developed together a harmonized IRM plan specific for the EU which was implemented until the 2011 growing season (reported on in 2012, see Monsanto Europe S.A. (2012)). This plan enabled the implementation of the management strategy described in Appendix II of the notification submitted to the French Commission du Génie Biomoléculaire (Monsanto Company, 1995), and has been based on published research, current EU legislation, the European Commission's Scientific Committee on Plants (SCP) opinion on IRM[35] and practical experience gained during the implementation of IRM plans in other parts of the world.

Meanwhile, EFSA published an updated guidance document on post-market environmental monitoring of GM crops as well as four specific opinions on the monitoring conducted by Monsanto on MON 810 in the 2009, 2010, 2011 and 2012 growing seasons (EFSA, 2011[36]; 2011[15]; 2012[16], 2013[17], 2014[18]). One of the elements described in the original plan was to maintain it updated in view of the findings and new scientific information. Taking into account the opinions from EFSA on the matter, the large amount of data generated in the past growing seasons, data in the scientific literature, and the experience gained from IRM plans established in other regions, the EuropaBio Monitoring working group has updated the IRM plan in September 2012 to anticipate approvals for the cultivation in the EU of different *Bt* maize products (see Appendix 1). 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(s) expressed in *Bt* maize. This harmonized IRM plan contains guidance on the following key elements:

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

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

[35] 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 August 28, 2014)

[36] EFSA, 2011 Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants - http://www.efsa.europa.eu/en/efsajournal/pub/2316.htm (Accessed August 28, 2014)

3.2.1.1 Refuge

According to the *Harmonised insect resistance management (IRM) plan for cultivation of Bt maize (single insecticidal traits) in the EU* (see Appendix 1), farmers planting more than five 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 a survey organized by Monsanto following the 2013 growing season, 256 farmers across four countries where MON 810 was commercially cultivated (Czech Republic, Romania, Portugal and Spain) were interrogated about the seed companies' compliance with GMO seed bag labelling requirements, their awareness of the communication efforts undertaken by seed companies, and their compliance with refuge implementation requirements (see Appendix 2). This survey took place in representative environments, reflecting the range and distribution of farming practices and environments exposed to MON 810 plants and their cultivation.

Firstly, all farmers confirmed that the seed bags were correctly labelled indicating that the product is genetically modified maize. Next, 98.4% of the farmers reported to have been informed about the good agricultural practices applicable to MON 810, and 95.6% of them considered the training useful, indicating that the great majority of the farmers have been exposed to a valuable training concerning MON 810.

When they were asked about their compliance with the label recommendations on seed bags, 91.4% of the farmers reported that they followed the technical guidelines regarding the implementation of a refuge (85.5% planted a refuge and 5.9% had less than 5 ha planted with MON 810 on their farm[37]). Overall, countries reported a high level of compliance with refuge requirements. The farmers in the Czech Republic, Romania and Portugal were in full compliance with refuge requirements. Responses of the Spanish farmers show that 87.4% of them were compliant with refuge planting while 22 farmers out of 175 (*i.e.*, 12.5%) indicated they did not plant a refuge. The farmers gave two main reasons for not being compliant with the refuge requirements: (1) lack or not enough information about the technical guidelines (4/22, 18.2%) and (2) the refuge implementation complicates the sowing and other agronomic practices (18/24, 81.8%).

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

In Portugal, an independent Monitoring Report on the planting of MON 810 varieties (including IRM communication and refuge implementation) during the 2013 growing season was prepared by the Portuguese authorities[38]. In addition to the farmers trained in previous seasons, and in compliance with the Portuguese law, 82[39] new farmers were trained in 2013 on national and EU legislations that regulate the cultivation of GM varieties and to learn about the main characteristics of MON 810 maize. Furthermore, 113 inspections were performed of farmers planting MON 810 maize (out of the total 232 notifications received in 2013). These inspections showed good compliance in general terms, with minor changes compared to the declared information, and no sanctions were needed. Full compliance with refuge and labelling requirements was found. In addition, 63 farmer questionnaires were completed by farmers growing MON 810 maize in Portugal. None of them declared that an adverse effect related to the GM crop was observed. All the interviewed farmers stated that the technical information on the seed bags was sufficient and clear.

In conclusion, the results from the presented surveys (Monsanto and Portuguese authorities) during the 2013 season are consistent and do show high level of compliance, probably due to the high effectiveness of the grower education and the presence of long term experienced technology users. The message on the importance of refuge implementation were repeated in countries growing MON 810 in the 2014 growing season. It is important to continue educating the farmers on the necessity to implement refuges and align them with a responsible use of the technology.

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, 2007). Overall, the susceptibility to Cry1Ab of these species 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.

In addition to the above, the baseline susceptibility of *O. nubilalis* to Cry1Ab was explored from 2005 to 2007 in other major European maize growing regions based on the potential

[38] Direção General de Agricultura e Desenvolvimento Rural - http://www.dgadr.mamaot.pt/ (Accessed August 28, 2014)

[39] So far, 1611 farmers have been trained on national and EU legislations since 2005.

MON 810 adoption. During this period, levels of susceptibility to Cry1Ab have been determined for one laboratory colony and several field collected *O. nubilalis* species in maize fields in the Czech Republic, France, Germany, Italy, Hungary, Slovakia, Poland, Portugal and Romania (Monsanto Europe S.A., 2006, 2007, 2008).

Monitoring of the target pests

Monitoring for changes in susceptibility to Cry1Ab in *O. nubilalis* and *S. nonagrioides* across the Ebro Valley, central Spain and Extremadura-Andalusia since 1999 was in place after the commercialisation of varieties including *Bt*176 maize from Syngenta, that also expressed the Cry1Ab protein (Farinós *et al.*, 2004).

During 2004-2011, monitoring for *O. nubilalis* and *S. nonagroides* susceptibility to Cry1Ab expressed in MON 810 was performed following the IRM plan developed by the European Union Working Group on Insect Resistance Management. Different geographical areas with considerable commercial plantings of MON 810 varieties were selected. The monitoring studies performed with *O. nubilalis* and *S. nonagrioides* showed that the susceptibility of the collected insect samples to Cry1Ab were within what is considered a normal range, demonstrating no change in susceptibility.

Since the 2012 growing season, Monsanto revised its IRM plan in view of the opinions from EFSA on the matter, the large amount of data generated in the past growing seasons, data in the scientific literature, and the experience gained from IRM plans established in other world areas. The elements that changed for the 2012 growing season compared to previous seasons are all reflected in the updated IRM plan from the EuropaBio Monitoring working group of September 2012 (Appendix 1). A significant change in the sampling approach was introduced in order to address EFSA's guidelines; the approach as defined in Table 4 of the EuropaBio harmonized IRM plan was implemented to be able to connect sampling frequency to the MON 810 adoption rate and the ecology of the target pests (*i.e.*, multivoltine versus univoltine life cycles). MON 810 adoption in the areas covering the Czech Republic, Romania and Slovakia was well below 20%. The three areas identified in the entire EU where adoption of MON 810 in 2013 was expected to be greater than 20% are the Ebro valley (defined in earlier reports as Northeast Iberia), Central Iberia (particularly the province of Albacete) and the Southwest Iberia area (Southwest of Spain and south Portugal). Since adoption in those areas is below 80% Monsanto samples them every two years. Therefore, monitoring activities in 2013 were concentrated in Spain and Portugal, more in particular in Northeast Iberia for *Sesamia* and *Ostrinia*, and Central Iberia for *Ostrinia*. Central Iberia was not sampled for *Sesamia* and Southwest Iberia was neither sampled for *Sesamia* nor *Ostrinia* since those collections and analyses were conducted during the 2012 growing season, and reported in previous year's monitoring report (Monsanto Europe S.A., 2013).

1. *Sesamia nonagrioides*

   In 2013, susceptibility of *S. nonagrioides* to the Cry1Ab toxin has been assessed from collections in Northeast Iberia (see Appendix 3). Values of moulting inhibition

concentration (MIC) have been used to assess the susceptibility of this species to Cry1Ab. In addition, a diagnostic dose (DD) was used as an alternative approach to test the dose-mortality for monitoring the susceptibility of *S. nonagrioides* to Cry1Ab.

The results of MIC_{50} (19 ng Cry1Ab/cm²) and MIC_{90} (163 ng Cry1Ab/cm²) for Northeast Iberia are in the range of those obtained in previous years. Bioassays of susceptibility performed in the laboratory with the progenies of the field populations of *S. nonagrioides* since 2004 have yielded low variability in MIC_{50} and MIC_{90} values. MIC_{50}s ranged between 7 ng Cry1Ab/cm² (Central Iberia in 2006) and 29 ng Cry1Ab/cm² (Southwest Iberia in 2012). These results evidenced a magnitude variation of 4.1-fold. Likewise, values of MIC_{50} of laboratory strains were also very uniform, ranging between 5 and 19 ng Cry1Ab/cm², which means a magnitude variation of 3.8-fold. In the light of these results, MIC_{50} values obtained during this campaign for the field collected populations and for the laboratory strain are within the range of values obtained in the past years. These measured differences and oscillations in susceptibility values to the Cry1Ab toxin reflect the common natural variations in *S. nonagrioides* previously reported (Farinós *et al.*, 2004).

Another approach to test the dose-mortality for monitoring the susceptibility to Cry1Ab is the diagnostic dose (DD), which facilitates the monitoring execution (Halliday and Burnham, 1990; Roush and Miller, 1986). The DD is here defined to cause 99% of moulting inhibition to first instar larvae (MIC_{99}) and was determined to be 726 ng Cry1Ab/cm², based on data obtained from larvae collected in different locations of Southwest, Central and Northeast Iberia between 2008 and 2012 (Monsanto Europe S.A., 2013). This protein concentration was applied to the population of *S. nonagrioides* collected in Northeast Iberia in 2013. A moult inhibition of 97 (± 2)% was observed on neonates exposed to this concentration.

2. Ostrinia nubilalis

In 2013, susceptibility to the Cry1Ab toxin of *O. nubilalis* has been assessed from collections in Northeast and Central Iberia (see Appendix 4). It must be noted that in Central Iberia collection of larvae was only possible in two fields instead of the aimed three, since no sufficient numbers could be found in other inspected fields. Furthermore, the two sites for collection were separated by less than 50 km due to the fact that maize planting is very concentrated in a relatively small area in Central Iberia. Nonetheless, sufficient larvae for the study could be collected from the two fields in this region. To determine the susceptibility to Cry1Ab, larval moult inhibition data at the different concentrations of Cry1Ab tested were analyzed, together with the dose-mortality by use of a DD. The results of MIC_{50} for *O. nubilalis* collected in Northeast and Central Iberia were 2.48 and 2.40 ng Cry1Ab/cm², respectively. The MIC_{90} values for *O. nubilalis* collected in Northeast and Central Iberia were 5.41 and 6.38 ng Cry1Ab/cm², respectively. Variation in Cry1Ab susceptibility (MIC_{50} and MIC_{90}) of *O. nubilalis* collected in the field during the 2013 growing season was 0.97-fold and 1.2-fold, respectively. Variation in Cry1Ab susceptibility (MIC_{50} and MIC_{90}) of *O. nubilalis*

collected in the field during the 2013 growing season in comparison with the lab strain was 1.26-fold and 0.97-fold, respectively. The observed variation in susceptibility reflects natural variation in Cry1Ab susceptibility among *O. nubilalis* collections. Any evidence for a decrease of Cry1Ab susceptibility of *O. nubilalis* during the monitoring duration from 2005–2013 could not be detected.

Like for *S. nonagrioides*, a DD was applied to *O. nubilalis*. The same definition was used and the DD was determined to be 28.22 ng Cry1Ab/cm². This value was based on MIC_{99} values obtained from larvae collected in 2005-2012 in fields from Czech Republic, France, Germany, Italy, Panonia, Poland, Portugal, Romania and Spain (Monsanto Europe S.A., 2013). Not a single larva tested in 2014 survived this dose.

In conclusion, differences found in the susceptibility to the toxin are within the range of variability expected for field collections of these corn borers. Further, the analyses of historical series of susceptibility data of *S. nonagrioides* or *O. nubilalis* to Cry1Ab did not reveal signs of changed susceptibility to this toxin by field collections from the sampling the areas considered.

3.2.1.3 Communication and education

An extensive grower education program is essential for the successful implementation of the IRM plan. Each purchaser of MON 810 receives a Technical User Guide (see Appendix 5). 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 and as in previous seasons, for the 2013 planting season in Spain, a number of initiatives were taken to emphasise the importance of refuge implementation. A comprehensive program to raise awareness of refuge requirements and educate personnel, distributors, cooperatives and individual farmers was implemented. Activities included:

1) Ensuring continuous communication about IRM implementation in all sales tools (leaflets, brochures, catalogues, *etc.*). Also, in addition to the TUG (Appendix 5), which is included in seed bags and has been extensively distributed, other communication materials previously printed like the Guía Técnica YieldGard® (YieldGard Technical Guide) (see Appendix 6.1) will continue to be available.
2) Stewardship requirements and IRM compliance for MON 810 cultivation are reviewed with licensee companies and Monsanto sales teams every season in different training sessions. After this annual review, a presentation on IRM was provided by ANOVE (the National Breeder Association in Spain) and by individual companies ensuring common messages across the market. In 2013, the following actions were taken:
    a. Advertisement about refuge compliance, articles and references to the TUG published in key agricultural magazines (see Appendix 6.2)

b. Sending a postcard (on behalf of ANOVE) from each company to farmers in their database located in MON 810 growing areas reinforcing the key messages of refuge implementation (see Appendix 6.3)

c. Presentation by sales and marketing teams of IRM requirements in farmer meetings/farmer talks to reinforce the need for refuge compliance (see Appendix 6.4)

d. Posters reminding the obligation to plant a refuge distributed among seed distributors and point of sales (see Appendix 6.5)

e. Communication plan for cooperatives, small points of sales and farmers: trained ANOVE inspectors completed 71 visits in MON 810 growing areas (Andalucía, Aragón, Castilla la Mancha and Extremadura) to inform, distribute material and ensure that farmers are well informed on refuge implementation when buying MON 810 seeds.

3) IRM information has been exhibited at different national and regional agricultural fairs.

Both Monsanto's survey as well as the independent survey in Portugal by the local authorities further demonstrate the effectiveness of the education program to raise awareness on refuge implementation (Section 3.2.1.1 of this report). Users have received information through the TUG attached to the seed bags and went through training sessions. It demonstrates a high level of commitment with these requirements from both seed companies and farmers.

3.2.1.4 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 any unexpected observations that might be linked to the use of its products, especially in relation to complaints about product performance, difficulties with product management, and compliance implementation. This can be done through the phone, fax or mail contact information given in the Technical User Guides (TUGs), (see Appendix 5). Alternatively, EuropaBio[40] and Monsanto[41] websites offer a contact point.

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[40] EuropaBio info for operators webpage - http://www.europabio.org/information-operators-contact-point (Accessed August 28, 2014)

[41] Monsanto product stewardship webpage http://www.monsanto.com/products/pages/product-stewardship.aspx (Accessed August 28, 2014)

Farmer complaints are a key indicator to quickly identify potential issues related to an agricultural product. To date, Monsanto is not aware of any farmer complaints in EU Member States where MON 810 is grown that would question the product performance. This confirms that the susceptibility to the Cry1Ab protein of neither *S. nonagrioides* nor *O. nubilalis* changed over the years.

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

Not applicable.

3.3 Concluding remarks

The results of the insect resistance monitoring program for the 2013 season demonstrate that there were no changes in susceptibility of neither *Ostrinia nubilalis* nor *Sesamia nonagrioides* to the Cry1Ab protein in the MON 810 growing areas in Europe. This supports the results of the previous growing seasons and is in line with the observation that also on a global level no Cry1Ab resistance has been reported for neither *O. nubilalis* nor *S. nonagrioides*. Furthermore, the weight of evidence available on the safety of MON 810 demonstrates that there are no unanticipated adverse effects impacting human or animal health, or the environment.

4. SUMMARY OF RESULTS AND CONCLUSIONS

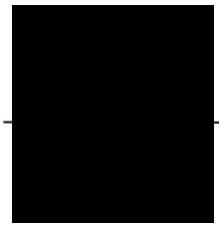
Monsanto and the seed companies marketing maize expressing the Cry1Ab protein have been operating together to establish and implement an IRM programme that is adapted to the EU agricultural landscape, and will continue to work closely together to assess its implementation and subsequently build on this learning. The commercial planting of MON 810 in Europe has been accompanied by a rigorous proactive Insect Resistance Management (IRM) plan, involving these key elements: refuge implementation, susceptibility monitoring, farmer education and company stewardship activities.

Following the establishment and reinforcement of an effective education and communication program in countries where MON 810 was grown in 2013, the percentage of farmers implementing refuges in their fields was very high. As a result, a comprehensive insect resistance monitoring program and stewardship activities demonstrated that there were no changes in susceptibility of either *O. nubilalis* or *S. nonagrioides* to the Cry1Ab protein in the MON 810 growing regions in Europe in 2013. This is in line with the observation that also on a global level no resistance is found for *O. nubilalis* and *S. nonagrioides* (Tabashnik *et al.*, 2013), which confirms the appropriateness of the implemented IRM plan.

The weight of evidence available to date confirms the initial conclusions of the EU safety assessment in 1998, namely that MON 810 is as safe as conventional maize with respect to human or animal health and the environment. Indeed, MON 810 has been safely grown in multiple countries around the world since 1997. Following its approval in 1998 in the EU, MON 810 was first grown in European countries in 2003. From 2005 to date, Monsanto submitted ten post-market environmental monitoring (PMEM) reports covering eleven years of MON 810 cultivation in the EU and all confirming its safety. These reports describe the activities undertaken by Monsanto to identify and analyse anticipated and unanticipated effects related to MON 810 cultivation. In summary, the weight of evidence continuing to support the safety conclusions consists of regulatory safety studies presented in the different EU applications, more than a dozen EFSA opinions concluding on the safety of MON 810, cultivation approvals for MON 810 in multiple countries around the world based on the same scientific risk assessment data and local safety opinions, hundreds of peer reviewed publications relevant to the safety assessment of MON 810 and the expressed Cry1Ab protein, more than ten years of experience with MON 810 cultivation in the EU, more than 17 years of experience worldwide on millions of hectares, multiple PMEM reports for the EU reporting on the commercial experience confirming the initial safety conclusions (and endorsed by EFSA), and absence of any confirmed adverse effect related to the event. All together, these results demonstrate that there are no adverse effects attributed to the cultivation of MON 810 in Europe. The result of the 2013 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 validity of the methodology for the different aspects to environmental monitoring are continuously evaluated. The improvements that were implemented over the years are the result of experience gained while conducting environmental monitoring of MON 810 cultivation for now about ten years, and discussions with different stakeholders such as the European Commission, Member States, independent experts and other biotech industries. Furthermore, in anticipation of the approval of other *Bt* maize events conferring protection against Lepidoptera, Monsanto has collaborated with the other applicants towards a harmonized approach for environmental monitoring of these GM maize varieties. This PMEM plan includes a proposal for a harmonized approach towards case-specific monitoring (IRM), which is currently a condition of the MON 810 authorization in the EU.

Signed: 

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