Annual monitoring report on the cultivation of MON 810 in 2017

Portugal 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 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[1] 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"*[2]. 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) (Commission Decision, 1998). 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) (Commission Regulation, 2003)[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 risk assessment, was adopted on 15 June 2009 (and published as part of an EFSA overall opinion on 30 June 2009 (EFSA, 2009)). According to the legal framework, these authorised products remain lawfully on the market until a decision on re-authorisation is taken. Due to continuing discussions at political level on nationalization of GMO cultivation to provide freedom to the Member States to decide on the

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® YieldGard is a registered trademark of Monsanto Technology LLC.

1 **Disclaimer**: Note that Monsanto has become the member of the Bayer group as of 21 August 2018. However, as the monitoring tasks for this season were conducted before the specified date, the name 'Monsanto' is kept throughout the document. The owner of this report is Bayer Agriculture BVBA.

2 Opinion of the Scientific Committee on Plants Regarding the Genetically Modified, Insect Resistant Maize Lines Notified by the Monsanto Company - http://ec.europa.eu/ (Accessed 27 September 2017)

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.

cultivation of genetically modified crop, the renewal applications failed to progress since the positive EFSA opinion was published in 2009. Therefore, in order to provide certainty on the international trade of MON 810 for food and feed uses, Monsanto requested the European Commission on 9 March 2016 to progress separately two complementary decisions for the renewal applications EFSA-GMO-RX-MON 810 (8-1a, 20-1a and 8-1b/20-1b), *i.e.*, the renewal of authorization for (1) existing food and food ingredients produced from MON 810; feed consisting and/or containing MON 810 and food and feed additives, and feed materials produced from MON 810; and (2) the use of seed for cultivation. Following Directive (EU) 2015/412 of 11 March 2015, the geographical scope of the authorization for cultivation of MON 810 was adapted on 3 March 2016 (European Commission, 2016). On 8 July 2016, the European Commission presented the Draft Commission Implementing Decision authorizing the renewal of existing food and food ingredients produced from MON 810; feed consisting and/or containing MON 810 and food and feed additives, and feed materials produced from MON 810 to the Standing Committee on Plants, Animals, Food and Feed (PAFF) for a vote, where no qualified majority was reached. On 4 July 2017, the European Commission adopted the renewal of the authorisation for the placing on the market of MON 810 for all uses, with the exception of pollen and cultivation (European Commission, 2017).

In 2017, MON 810 was planted in the EU on approximately 131 553 hectares in two countries: Portugal (7 308 ha[4]) and Spain (124 227 ha[5]).

Results of Insect Resistance Management (IRM) are provided to the European Commission on an annual basis (*i.e.* this report) in line with the 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 MON 810 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 the competent authorities of relevant member states, 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, 2015, 2016, 2017). Since 2010, the reports follow the format as laid out in Annex I to Commission Decision 2009/770/EC (Commission Decision, 2009).

[4] Anpromis: http://www.anpromis.pt/dados-estatisticos/ (Accessed on 27 August 2018)

[5] Ministry of agriculture, food and environment of Spain: https://www.mapama.gob.es/es/ (Accessed on 27 August 2018)

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 2017 - July 2018

1.6 Other monitoring reports have been submitted in respect of:

- **Import and Processing** Yes voluntary (October 2018)
- **Food/Feed** Not applicable

2. EXECUTIVE SUMMARY

In 2017, MON 810 was planted in the EU on approximately 131 553 hectares in two countries. As part of stewardship of the technology, industry has implemented an Insect Resistance Management (IRM) plan to proactively delay the potential development of pest resistance to the Cry1Ab protein. The adherence to this stewardship measure in the context of the 2017 cultivation of MON 810 maize in Europe is detailed in this report.

The planting of MON 810 in the 2017 season was accompanied by a rigorous IRM plan involving five main elements: a farmer complaint system, 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 2017 and the success of these initiatives was reflected in the high levels of compliance with requirements for refuge implementation observed again in the 2017 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 2017. No complaint allegedly caused by reduced target pest susceptibility to MON 810 was received from farmers in 2017.

The weight of evidence available to date confirms the initial conclusions of the risk assessment, namely that MON 810 is as safe as conventional maize with respect to human or animal health and the environment (*see* Section 3.1).

In 2017, Monsanto continued its General Surveillance monitoring program, implemented on a voluntary basis and 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 250 questionnaires from a survey of farmers cultivating MON 810 in two European countries in 2017 did not reveal any adverse effects associated with the genetic modification in MON 810. Furthermore, a detailed analysis of 25 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 did not reveal any adverse effects related to MON 810 cultivation in 2017. Taken together, these results demonstrate that there are no indications of adverse effects to be attributed to the cultivation of MON 810 in Europe in 2017.

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 or renewal in 2017. Nevertheless, Monsanto has been reporting on its activities for this non-hypothesis based monitoring on a voluntary basis since 2005. Over the years, several approaches to monitor unanticipated adverse effects were developed and their methodologies improved substantially. Several complementary approaches initially developed by Monsanto were taken up by EuropaBio in an effort to harmonize proportional and workable 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).

The weight of evidence available to date confirms the initial conclusions of the EU risk 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 13 post-market environmental monitoring (PMEM) reports covering 15 years of MON 810 cultivation in the EU and all reports confirm consistently its safety. These reports describe the activities undertaken by Monsanto to identify and analyse anticipated and allegedly unanticipated effects related to MON 810 cultivation (Bayer Agriculture BVBA, 2018; Monsanto Europe S.A., 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2015, 2016, 2017). The resulting weight of confirmatory 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 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. For the farmer questionnaires, a sample size of 2 436 interviews was calculated to achieve the demands as specified in Appendix 1. These demands are very stringent in order to reduce false test decisions to a minimum. To achieve this sample size even in the case of questionnaires having to be excluded from the survey *e.g.* because of low quality, this number was rounded to 2 500 questionnaires. Since the first implementation of farmer interviews, more than 3000 farmers have been questioned about their experience with MON 810 and in particular about any observations or effects in the field that were different for MON 810

compared to conventional maize hybrids. As this years' PMEM report aims to describe the outcomes of the 2017 growing season, the results of the farmer questionnaires conducted in 2017 are provided. None of the reports, for which the results were statistically analysed, identified a statistically meaningful effect that indicated adverse effects to human or animal health, or the environment. The intended beneficial effects were observed in those reports as being evaluated in MON 810 fields compared to conventional maize fields.

The Council Decision 2002/811/EC and the EFSA guidance on PMEM of genetically modified plants (EFSA, 2011), state that "*monitoring plans should not be viewed as static*" and "*it is fundamental that the monitoring plan and associated methodology are reviewed at appropriate intervals and* ***may need to be modified and adapted depending on the results of the monitoring information collected***". Following EFSA guidance, "*the monitoring results and experience may lead to adjustments of certain parts of the original monitoring plan"*. In 2015, a total of 2 500 farmer questionnaires, which was the aimed sample size at the start of the farmer questionnaires' survey to run meta-analysis covering the authorisation period, was reached after 10 years of the survey (Monsanto Europe S.A., 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2015, 2016). Based on the meta-analysis with the pooled multiyear data, the results confirmed once again, as reported in every separated annual report, the initial conclusions of the risk assessment that MON 810 is as safe as conventional maize and no adverse effect of MON 810 cultivation on human or animal health, or the environment was identified. The outcome has been submitted for publication in a peer reviewed journal (Bertho *et al.*, 2018) and is expected to be accepted soon. The data collected in the subsequent MON 810 growing seasons (Bayer Agriculture BVBA, 2018; Monsanto Europe S.A., 2017) also confirmed that no adverse effects are associated with MON 810 cultivation. Based on this extensive information, the spirit of Directive 2001/18/EC that states PMEM should be reviewed based on the gathered information, the Council Decision 2002/811/EC and the EFSA guidance that indicates results and experience may lead to adjustments in the PMEM, our proposal would be to adapt the conditions for the general surveillance and limit this for MON 810 cultivation to literature searches and the farmer complaint systems.

In addition to the results from the farmer questionnaires conducted in 2017, Monsanto's company-internal processes for managing product related incidents and complaints did not identify adverse effects caused by the MON 810 event. Furthermore, as a third pillar of the implemented GS, 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 425 articles of which the vast majority is authored by independent academics and scientists. Allegations about the safety of the 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, the value of using the reports of EENs to confirm the safety of GM crops in general and MON 810 in particular was assessed, 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).

The aforementioned 13 PMEM reports, covering 15 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, Egypt, EU, Honduras, Paraguay, the Philippines, South Africa, Uruguay and the USA[6]. More specifically in the EU, independent scientific panels, such as the EFSA have reviewed our regulatory submissions (EFSA, 2012c, 2012d), new scientific publications published from 2009 onwards (EFSA, 2012e, 2015a, 2015c, 2016a, 2016b, 2017b, 2018), Monsanto's monitoring reports (Bayer Agriculture BVBA, 2018; Monsanto Europe S.A., 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2015, 2016, 2017) as well as challenges raised by various Member States related to human and animal health or the environment (EFSA, 2004, 2005, 2006, 2008a, 2008b, 2008c, 2008d, 2012a, 2012b, 2013a, 2013b, 2014b). 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 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 unintended 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 scientific risk assessment data and local safety opinions,
- hundreds of peer-reviewed publications relevant to the risk assessment of MON 810 and the expressed Cry1Ab protein,
- more than 14 years of experience with MON 810 cultivation in the EU,
- more than 20 years of experience worldwide on millions of hectares,
- multiple PMEM reports for the EU reporting on the commercial experience confirming the initial conclusions of the risk assessment (and endorsed by EFSA),
- absence (in the EU and on a global scale) of demonstrated field resistance for the targeted pests,
- absence of evidence indicating adverse effect related to the event.

The weight of evidence described above confirms that MON 810 is as safe as conventional maize with respect to human and animal health and the environment. Taking into consideration that GS is not a condition of the current authorization for MON 810 issued in

[6] CropLife International: www.biotradestatus.com (Accessed on 27 August 2018).

1998 (Commission Decision, 1998), reporting on GS activities of each growing season becomes disproportional to the available weight of evidence demonstrating the safety of MON 810.

However, the European Commission has stated on several occasions the necessity to report on GS activities for MON 810 on an annual basis. Even though Monsanto's position as explained above remains unchanged, the results of the 2017 GS activities are included in this report. Monsanto reiterates the need for adaptation of the monitoring plan and associated methodology based on the comprehensive experience and the information collected, and aligned with the spirit of the EFSA guidance on PMEM of genetically modified plants (EFSA, 2011).

The types of GS monitoring that were implemented by Monsanto as well as the methodologies followed and the reporting conducted has not been an individual applicant's work. During the years, Monsanto always has communicated to different stakeholders and has informed and consulted, amongst others, the European Commission, EFSA GMO unit, Member States and biotech industry on its approach. Through feedback from a variety of workshops, meetings and reports, but also based on gained monitoring experience over time Monsanto has gradually improved the way it implemented GS monitoring. For these adjustments, Monsanto aims to secure the balance between information maximization at the one hand, and implementation practicalities and proportionality (to the perceived risk) at the other hand.

Monsanto acknowledges the fact that EFSA made several recommendations to improve the methodology on how to perform GS, *i.e.*, in their general guidance document for PMEM of GM crops in August 2011 (EFSA, 2011) and seven specific opinions on MON 810 monitoring in the 2009, 2010, 2011, 2012, 2013, 2014, 2015 and 2016 growing seasons (EFSA, 2012e, 2015a, 2015c, 2016a, 2016b, 2017b, 2018). Monsanto has adapted its monitoring approaches where possible and feasible, taking into consideration the gained expertise on MON 810 monitoring and already established methodologies, in order to report on a voluntary basis on the results for the 2017 growing season. EFSA concluded that no adverse effects on human or animal health or the environment were identified due to MON 810 cultivation during the 2009, 2010, 2011, 2012, 2013, 2014, 2015 or 2016 growing seasons and that the outcomes of the monitoring reports did not invalidate the previous risk assessment conclusions (EFSA, 2012e, 2015a, 2015c, 2016a, 2016b, 2017b, 2018). This confirms that Monsanto's methodologies are fit for the purpose of identifying adverse effects. In case an adverse effect is observed to the environment, human or animal health and confirmed to be caused by the MON 810 trait, it will immediately be reported to the European Commission and a mitigation plan will be developed in collaboration with the European Commission and the competent authorities of relevant member states (*see* also Section 1).

3.1.1 Description of General Surveillance

In 2017, Monsanto continued the GS monitoring program initiated in 2005 on a voluntary basis. The objective of GS is to identify the alleged 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 GS 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 (EFSA, 2011).

GS 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 allegation of an 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 be complex to establish a causal link between a potential adverse effect and use of a particular GM crop.

The GS monitoring program performed by Monsanto in 2017 consisted of four elements:

- a farmer questionnaire designed to assess unusual observations in the areas where MON 810 has been cultivated,
- data collected from peer-reviewed 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 benefits 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, plant health and product performance) 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 GS 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 (EFSA, 2011). The questionnaire approach has also proven its applicability with other industries, *e.g.*, the pharmaceutical industry.

A farmer questionnaire has been developed as a 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 2009 (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 unambiguous, easily understood and not to be too burdensome. Also, it is 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. The 2017 GS for MON 810 focused on the Iberian geographical regions where the majority of MON 810 was grown in 2017 (Portugal and Spain, countries accounting for 100% of the MON 810 plantings in the EU in 2017), 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 2017, 14 farmers in Portugal and 236 farmers in Spain were asked to complete the questionnaire (250 in total). The farmers/fields were randomly selected 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 January and March 2018. In Spain, which represented the largest market, the survey was performed by Markin[7] while in Portugal, it was performed by Agro.Ges[8], two qualified, independent companies with a vast experience in the conduction of farmer surveys. 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).

[7] Instituto Markin (Spain): https://markin.org/ (Accessed on 28 August 2018).
[8] Agro.Ges (Portugal): http://www.agroges.pt/?lang=en (Acessed on 28 August 2018).

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.

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, and fertiliser.

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, and yield.

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. Stewardship activities include *1)* assessment of the safety of the products, *2)* management practices to endorse sustainability of the products, *3)* absolute respect of all the regulations in place, and *4)* explanation and promotion of the proper and responsible use of products and technologies. Details on growers' education in this context is given in Section 3.2.1.4.

As part of product stewardship and responsible use, Monsanto urges users to notify 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 Technical User Guides (TUGs), (*see* Appendix 3.1 and Appendix 3.2). Alternatively, EuropaBio[9] and Monsanto[10] websites offer a contact point.

[9] EuropaBio contact webpage - http://www.europabio.org/contact (Accessed 28 August 2018)

[10] Monsanto product stewardship webpage - http://www.monsanto.com/products/pages/product-stewardship.aspx (Accessed 28 August 2018)

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:

- 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 risk 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)[11].

Alerts on environmental issues by existing networks

The EuropaBio Working Group on monitoring coordinated a harmonized effort to map EENs in Europe and to set up a unique reporting system (Smets *et al.*, 2014). The work done by EuropaBio resulted in the identification of numerous suitable EENs established in different individual EU Member States, as well as on a European level. The selection and identification was done in line with EFSA recommendations. The identified networks were divided into four groups, 1) governmental networks; 2) academic networks; 3) nature conservation networks and 4) professional networks. Whereas the monitoring expertise of these identified networks was recognized, it was concluded that it would not be possible for such a network to establish a relationship between a cause and an effect. More specifically, none of the identified EENs measured GM crop cultivation as an influencing factor, making it difficult to establish accurate correlations based on the collected data. Furthermore, additional limitations in the use of EENs as an early warning system part of GS efforts are 1) technical constraints (*e.g.* delayed publication of monitoring data); 2) lack of public availability of (raw) data; 3) harmonization between networks (*e.g.* data collection and processing). As also concluded in Smets *et al*. (2014), plant biotechnology companies have no authority to modify the practices used by EENs today, nor is there an interest to do so as this would influence their independence.

In addition, the EFSA has published a scientific opinion on the use of EENs for PMEM reports based on internal expertise and a report issued by a contracted consortium (Henrys *et al.*, 2014). EFSA's opinion concluded that "*In compliance with these assessment criteria, several existing ESNs have been identified as potentially suitable for GS of GMPs subject to further examination. However, the EFSA GMO Panel also identified several limitations pertaining to ESNs such as limited data accessibility, data reporting format and data connectivity with GMO registers*" (EFSA, 2014a).

[11] The Monsanto website for communication to external stakeholders - http://www.monsanto.com/newsviews/Pages/Issues-and-Answers.aspx (Accessed on 28 August 2018)

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 2017 season can be found in Appendix 3 (see Appendix 3.1 and Appendix 3.2). Additional details on growers' education in the context of refuge implementation is given in Section 3.2.1.4.

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 250 questionnaires from the survey of farmers cultivating MON 810 in Spain and Portugal during the 2017 growing season did not reveal any 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 adverse effects directly associated with MON 810 cultivation that require risk mitigation, these will be reported immediately to the Commission.

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 confirmed adverse effects related to MON 810 were reported in 2017.

3.1.5 Additional information

Not applicable as no adverse effects were observed.

3.1.6 Review of peer-reviewed publications

A literature search that complies with the recommendations outlined in the EFSA explanatory note on literature searching (EFSA, 2017a) has been conducted on a monthly basis covering the time span June 2017 – May 2018 and is provided along with the checklist for literature search (Annex 2) in Appendix 5. Note that additional recommendations provided by the EFSA GMO panel in EFSA (2018) on the literature searching and published on 8 May 2018 will be considered as of the 2018 season since most tasks of the literature search for the 2017 season were already completed by the time of the EFSA publication.

Monsanto confirms that the literature search, conducted in accordance with the 2017 EFSA explanatory note on literature searching (EFSA, 2017a) and within the context of general surveillance for MON 810 in the EU, identified no relevant publications that would invalidate the initial conclusions of the MON 810 risk assessment.

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 have the potential to adapt, sometimes quickly, when exposed to insecticides via a selection process of existing resistant individuals in natural populations. 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[12] established the European Union working group on IRM 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[13] and practical experience gained during the implementation of IRM plans in other parts of the world.

Meanwhile, EFSA published an updated guidance document on PMEM of GM crops as well as eight specific opinions on the monitoring conducted by Monsanto on MON 810 in the 2009, 2010, 2011, 2012, 2013, 2014, 2015 and 2016 growing seasons (EFSA, 2012e, 2015a, 2015c, 2016a, 2016b, 2017b, 2018). One of the elements described in the original plan was to update it in view of the findings and new scientific information. Taking into account the related EFSA´s opinions, the historical data on *Bt*-maize cultivation, 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 2017 (*see* Appendix 6). The purpose of the IRM plan is to proactively monitor the potential development of target pests resistance to the Cry protein(s) expressed in single *Bt* maize events in the EU. This harmonized IRM plan contains guidance on the following key elements: (1) refuge implementation; (2) resistance monitoring in the target pests; (3) farmers complaint system; (4) remedial plan in case of *Bt* maize failure to protect against target pests; and (5) communication and Grower education.

[12] Syngenta Seeds, Corteva (formerly called Pioneer Hi-Bred International Incorporated and Dow AgroSciences).

[13] Opinion of the Scientific Committee on Plants on *Bt* resistance monitoring (Opinion expressed on March 04, 1999), *Document SCP/GMO/094-Rev.5* - https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out35_en.pdf (Accessed on 28 August 2018)

3.2.1.1 Refuge

According to the *Harmonised insect resistance management (IRM) plan for cultivation of Bt maize (single insecticidal trait) in the EU* (*see* Appendix 6), 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 3.2.1.4). 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. Consequently, the seed industry has put emphasis on the development of communication tools.

In the context of Monsanto's 2017 GS, 250 farmers across Spain and Portugal where MON 810 was commercially cultivated were surveyed for their implementation of a refuge (*see* Appendix 1). This GS took place in representative environments, reflecting the range and distribution of farming practices and environments exposed to MON 810 plants and their cultivation.

93.2% of the farmers indicated that they followed the technical guidelines regarding the implementation of a refuge (85.6% planted a refuge and 7.6% had less than 5 ha planted with MON 810 on their farm[14]). Both countries reported a very high level of compliance with refuge requirements. The farmers in Portugal were all in compliance with refuge requirements. Responses of the Monsanto 2017 Farmer Questionnaire Survey show that 92.8% of the farmers in Spain were compliant with refuge planting while 17 farmers out of 236 (*i.e.*, 7.2%) indicated they did not meet the refuge requirement for the following three main reasons: (1) lack or not enough information about the technical guidelines and fear of yield losses in conventional maize (8/17, 47.1 %); (2) having two or three plots smaller than 5 ha (5/17, 29.4 %) and (3) the refuge was smaller than 20% of MON 810 area (4/17, 23.5).

In Portugal, an independent monitoring report on the planting of MON 810 varieties (including IRM communication and refuge implementation) during the 2017 growing season was prepared by the Portuguese authorities (DGAV, 2017) . In addition to the farmers trained in previous seasons, and in compliance with the Portuguese law, 44 new farmers[15] were trained in 2017 on national and EU legislations that regulate the cultivation of GM varieties and to learn about the main characteristics of MON 810 maize. Furthermore, 78 inspections were performed on farmers planting MON 810 maize out of the total 213 cultivation notifications registered in 2017. These inspections showed high compliance in general terms, with minor changes compared to the information declared in the notification, and no sanctions were needed. Full compliance with refuge and labelling requirements was found. In addition,

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

[15] So far, 1817 farmers have been trained on national and EU legislations since 2005.

61 farmer questionnaires were completed by farmers growing MON 810 maize in Portugal. None of them declared that any 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 (Portuguese authorities and Monsanto) during the 2017 season are consistent and do show a high level of compliance, probably due to the high effectiveness of the growers' education. Regardless of these results, the message on the importance of refuge implementation is being repeated to Spanish and Portuguese farmers growing MON 810 in the 2018 cultivation season. It is important to continue reminding the farmers on the necessity to implement refuges and align them with a responsible use of the technology.

It would be also recommended that refuge planting would be integrated as requirement for direct payments under the Common Agricultural Policy or other national rules. Compliant farmers would be encouraged to continue implementing refuges, whereas those farmers reluctant to be compliant could be subjected to reductions or exclusions from direct support schemes.

3.2.1.2 Baseline studies and resistance monitoring in 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 justifies 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 also established for the French and Portuguese field populations of *S. nonagrioides* and for the Portuguese populations of *O. nubilalis* (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, 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 MON 810 adoption. During this period, levels of susceptibility to Cry1Ab have been determined for one laboratory colony and several field collected *O. nubilalis* populations in maize fields in the Czech Republic, France, Germany, Italy, Hungary, Slovakia, Poland, Portugal and Romania (Monsanto Europe S.A., 2006, 2007, 2008).

Resistance monitoring in the target pests

Monitoring for changes in susceptibility to Cry1Ab in *O. nubilalis* and *S. nonagrioides* across the Ebro Valley, central Spain and Extremadura-Andalucia since 1999 was in place following the commercialisation of *Bt*176 maize varieties 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 a European Union Working Group on Insect Resistance Management in those geographical areas with considerable commercial plantings of MON 810. During 2012-2015, monitoring for *O. nubilalis* and *S. nonagroides* susceptibility to Cry1Ab expressed in MON 810 was performed following the 2012 EuropaBio harmonised IRM plan updated in the view of the related EFSA's opinions, historical data on *Bt*-maize cultivation, scientific literature and worldwide experiences on IRM plans.

One of the elements described in the harmonized IRM plan is to keep it updated based on new learnings and scientific information. Accordingly, EuropaBio updated the IRM plan in 2017 taking into account recent EFSA opinions, the large amount of additional data generated in the scientific literature, and the experience gained from IRM plans established in Europe and in other world areas (*see* Appendix 6). In the 2017 harmonized IRM plan, the sampling approach and monitoring protocol were revised. The sampling approach as defined in Table 3 of the EuropaBio harmonised IRM plan was implemented to connect sampling frequency to the MON 810 adoption rate and the ecology of the target pests (*i.e.*, multivoltine versus univoltine life cycles). The monitoring protocol as described in the IRM plan was implemented to consider as many larval samplings as possible, ultimately targeting a detection level of 3% resistance allele frequency in the target pest population, and the recurring practical limitations to meet this requirement.

Monsanto acknowledges that EFSA made several recommendations to improve the methodology for resistance monitoring in the target pests (EFSA, 2012e, 2015a, 2015c, 2016a, 2016b, 2017b, 2018). EFSA provided recommendations for the sampling of the target pests, suggesting to "*increase sampling efforts and ensure that as many field-collected larvae as possible are represented in the laboratory assays as F_1 larvae in order to provide sufficient detection sensitivity (i.e. 3% resistance allele frequency)*"(EFSA, 2015b, 2016c, 2017b). Monsanto followed previously fit-for-purpose methodologies gained through experience and in line with harmonized IRM plans allowing EFSA to conclude that no adverse effects related to the target pests have been identified due to MON 810 cultivation and that the findings do not invalidate the previous risk assessment conclusions (EFSA, 2012e, 2015a, 2015c, 2016a, 2016b, 2017b, 2018). The monitoring studies performed with *O. nubilalis* and *S. nonagrioides* from 2004 to 2016 showed that the susceptibility of the collected insect samples to Cry1Ab were within what is considered the normal historical range, demonstrating no change in susceptibility. The findings were further affirmed by scientific literature which demonstrated the absence of resistance development in the target pests (*O. nubilalis* and *S. nonagroides*) to the Cry1Ab protein after years of MON 810 cultivation in the EU (Castañera *et al.*, 2016; Farinós *et al.*, 2017; Thieme *et al.*, 2018). Nevertheless, in light of all the continued EFSA recommendations (EFSA, 2015b, 2016c, 2017b), Monsanto has extensively increased the

efforts to sample larvae since 2016 (EFSA, 2018), although EFSA acknowledged also the difficulties and uncertainties of being able to meet the above recommendation (EFSA, 2017b, 2018).

The area identified in the entire EU region where adoption of MON 810 in the 2017 maize growing season was expected to be greater than 60% was the Ebro valley (Northeast Iberia) in Spain. MON 810 adoption in other regions (Central Iberia, the Southwest of Spain and Portugal) was well below 60%. According to EFSA's opinion, the Ebro valley is where adoption rate of MON 810 is the highest, field resistance to Cry1Ab has the highest potential to evolve and where annual monitoring of the both target pest populations should be exclusively implemented (EFSA, 2016c, 2017b, 2018) Therefore, larvae sampling of *O. nubilalis* and *S. nonagrioides* for the monitoring activities in the 2017 maize growing season concentrated in the Ebro valley as described in the revised IRM plan (Appendix 6) and as recommended by EFSA. No larval samples for *O. nubilalis* and *S. nonagrioides* were collected from the other growing areas for the reasons explained above.

Aligned with the newly revised EuropaBio harmonised IRM plan, the objective of the sampling efforts in the 2017 growing season was to collect approximately 1 000 larvae per population in the Ebro valley, which ultimately target the detection of 3% (recessive) resistance allele frequency, as suggested by EFSA (EFSA, 2016c). From the experience gained in 15 years of MON 810 PMEM and information from independent resources[16], it was demonstrated that such collections may not be always feasible because the target pests' pressure and the number of larvae in the region have decreased drastically since MON 810 introduction and as a result of MON 810 performance. Consequently, despite intensified efforts of larvae collection, the significant reduction of the pest population over the years as well as occurrence of further drops in the pest population due to various reasons in certain growing seasons may make collecting 1 000 larvae impossible. Therefore, as indicated in the EFSA opinions (EFSA, 2017b, 2018), flexibility on the number of larvae samples should be granted provided that the responsible parties can demonstrate to have undertaken the necessary steps to ensure the collection of as many larvae as possible.

During the 2017 growing season, Monsanto continued its effort to collect for both target pests larvae for the laboratory assays. The details of the sampling efforts and laboratory assay are presented in Appendix 7 (insect resistance monitoring report for *S. nonagrioides* associated with MON 810 maize cultivation in the EU) and Appendix 8 (Cry1Ab susceptibility in European origins of *O. nubilalis*). In 2017, a bioassay based on a single diagnostic concentration (DC) estimated from MIC_{99} values was used to evaluate changes in susceptibility of the target pests to the Cry1Ab protein. The use of a diagnostic concentration assay is found appropriate based on the experience gained as well as scientific literature (Roush and Miller, 1986; Sims *et al.*, 1996). This method increases the effectiveness and sensitivity of the assay for detecting changes in susceptibility to the Cry protein. In addition,

[16] Catalunya Research Institute, IRTA, 2014; https://www.ruralcat.net (Accessed 10 October 2018)

comprehensive details of the larvae used and the data generated in the bioassays are clearly elaborated based on appropriate statistical analysis in both reports.

As reported in Appendix 7, from the 1452 larvae of *S. nonagrioides* collected in the Ebro valley Spain, 788 adults (54%) emerged, and the offspring of 95% of these adults (749) were used in the bioassays and treated with the DC of 1091 ng Cry1Ab/cm^2. The treatment with the DC caused moulting inhibition of 94.14% ± 1.4% to the F1 neonates, which was significantly lower than the expected value of 99 %. However, the same DC applied to neonates of the laboratory strain of *S. nonagrioides* caused moulting inhibition of 97.69% which was not significantly lower than the 94.14% value (t = -2.5373, df = 2, p = 0.063). Fluctuations of about 6-fold for both LC_{50} and MIC_{50} were found in the laboratory strain during the period that monitoring was performed by means of dose-response bioassays (2004–2016), but no trends were observed over time. To account for these fluctuations related to experimental conditions (protein bath, testing conditions, etc.), MIC_{50} and LC_{50} values of field populations were compared with the susceptible laboratory strain (Farinós *et al.*, 2017). This finding highlights the importance of maintaining a susceptible laboratory strain against which the field populations should be compared, enabling the correct interpretation of the results. In addition, all the *S. nonagrioides* larvae (10 650) died after continuous feeding on leaves of *Bt* maize (99.91% died before reaching 2nd larval stage and 0.09% before reaching 3rd larval stage). To confirm that the 0.09% larvae are not resistant to MON 810, 1 000 F2 neonates of their siblings coming from the same oviposition cage were fed with MON 810 leaves and all died before reaching the 2nd larval stage. In conclusion, no evidence was detected of a decrease in Cry1Ab susceptibility of *S. nonagroides* during the monitoring duration.

As shown in Appendix 8, of the 1111 larvae of *O. nubilalis* collected in the Ebro valley Spain, 628 adults survived the diapause period, reached the adult stage and mated. Of the 1488 *O. nubilalis* larvae exposed to the discriminating concentration 138 larvae died, 1338 survived but did not reach the 2nd larval stage, and 12 reached the second larval stage. The resulting effect of Cry1Ab on moulting inhibition (this criterion used accounts for both death and complete moulting (growth inhibition) was 99.19%. In addition, all of the *O. nubilalis* larvae that survived in the bioassays died after feeding on leaves of *Bt* maize. In conclusion, no evidence was detected of a decrease in Cry1Ab susceptibility of *O. nubilalis* during the monitoring duration.

3.2.1.3 Farmer complaint system

Monsanto and the seed companies offering MON 810 varieties have a robust farmer complaint systems which provide means for farmers to report any complaint related to maize seeds performance, including failure in protection against corn borers in MON 810 varieties. Farmers are first in line to detect a change in product performance, including reduced target pest insect control. Farmer complaint systems are available without any limitations for the entire farming community and for every field where MON810 is commercially cultivated. Therefore, the farmer complaint system serves as the primary tool to detect insect resistance development (Sumerford *et al.*, 2015). The farmer complaint system is a primary venue for the farmer to record any unexpected effect when cultivating *Bt* maize in their field. As a result, Monsanto believes based on gained experiences that incidence of reduced susceptibility

to Cry1Ab protein in the target pest populations is most likely to be detected and reported rather via the farmer complaint system as the laboratory bioassay can only be performed on limited field samples.

Farmers can complain to the seed suppliers about product related issue via the local sales representatives or customer service routes. The specific procedure can slightly differ between seed suppliers, but in all of them, once a validated product-specific complaint is received, an internal procedure for verification, potential analysis, and follow up is triggered. In the case of Spain, all companies offering MON 810 varieties have committed to monitor insect protection during the cultivation, as part of the Monitoring Plan requested by the registration in the Spanish variety catalogue. In case the analysis of the complaint indicates potential insect resistance development, a procedure will be followed that includes on-site follow-up by company representatives and additional testing of the larvae susceptibility to the protein Cry1Ab and plants expressing MON 810. If this assessment would confirm insect-resistance development, a remedial plan as described in the EuropaBio harmonized IRM plan will be implemented without prejudice to specific actions that may be required by country or local authorities. In Spain the mitigation plan would be compulsory and established at the Monitoring Plan associated to MON 810 varieties registration.

During the 2017 growing season, Monsanto representatives did not receive any complaint related to MON 810 target pest efficacy. A survey has been performed in Spain among Asociación Nacional de Obtentores Vegetales (ANOVE, the National Breeder Association in Spain)[17] member companies commercializing MON 810 maize to have an overview of the farmer complaint schemes. The effectiveness of the system was demonstrated because a total of 1703 complaints were received related to any issue with maize seeds, by the companies which are marketing MON 810. However, no complaints were received related to the efficacy of MON 810. The high number of complaints indicate that this communication route is well established within the farming community.

3.2.1.4 Communication and grower education

An extensive annual repeated grower education program is essential for the successful implementation of the IRM plan. Each purchaser of MON 810 receives a Technical User Guide (*see* in Appendix 3 the Technical User Guides used in the countries growing MON 810). 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 2017 planting season in Spain (the main country growing MON 810), a number of initiatives were taken to emphasise the

[17] Asociación Nacional de Obtentores Vegetales: http://web.anove.es/ (Accessed on 4 October 2018)

importance of refuge implementation. A comprehensive program to raise awareness of refuge requirements and educate personnel, distributors, cooperatives and individual farmers was continued. Activities included:

1) Ensuring continuous communication about IRM implementation in all sales tools (leaflets, brochures, catalogues, websites, *etc.*). The TUG (Appendix 3), was included in seed bags and has been extensively distributed. Other, more detailed communication materials like the Guía Técnica YieldGard® (YieldGard Technical Guide) (*see* Appendix 9.1 - Appendix 9.6) were available electronically.

2) Stewardship requirements and IRM compliance for MON 810 cultivation are reviewed and extensively communicated with licensee companies and Monsanto sales teams every season. The working group of *Bt* maize within the ANOVE annually reviews and prepares an updated set of communication materials to be used by individual companies and through the jointly industry activities. This ensures common messages across the market and to the farmers regardless of the seed provider (European-Seed, 2016). In 2017, the following actions were taken:

    a. Advertisement about refuge compliance, articles and references to the TUG were published in key agricultural magazines (*see* Appendix 9.2.) and copies of the IRM materials sent to regional and national authorities, encouraging them to wider distribute among the regional agricultural networks the technical bulletins, etc. Information about IRM was also posted in ANOVE website, blog and other social media.

    b. Each selling company (on behalf of ANOVE) committed to send timely reminder of refuge obligations at the planting season (e.g. e-postcard by SMS to mobile phones) to farmers in their database located in MON 810 growing areas (*see* Appendix 9.3)

    c. Sales and marketing teams of ANOVE members were encouraged to include IRM requirements in farmer meetings/farmer talks. As in the previous seasons, summary slide decks on farmers obligations were available and each company committed to widely use it (*see* Appendix 9.4).

    d. Posters reminding the obligation to plant a refuge distributed among seed distributors and point of sales (*see* Appendix 9.5)

    e. Communication plan for cooperatives, small points of sales and farmers: Trained ANOVE inspectors completed 99 interviews to cooperatives and point of sales at planting time in all the in MON 810 growing areas. The objectives were to check the degree of information and availability of materials, training or complement the information available by seed distributors, as needed offer materials and in the end, ensure that farmers are well informed on refuge implementation when buying MON 810 seeds. 94% of the interviewed entities considered their customers well informed. In general, all the entities expressed

their willingness to support the dissemination of communication materials about refuges and contribute to a sustainable use of the technology.

3) As in previous seasons marketing companies are encouraged to disseminate IRM information during any exhibition at national or regional agricultural fairs attended by maize growers.

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 Technical User Guides (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.

3.2.2 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), 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 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: a farmer complaint system, refuge implementation, target pests 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 2017, the percentage of farmers implementing refuges in their fields remains very high (93.2 %).

The results of the analysis of 2017 farmer questionnaires did not identify potential adverse effects that might be related to MON 810 plants and their cultivation. Company stewardship activities, farmer complaint systems and issue alerts did not reveal 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 2017 cultivation season as confirmed by the absence of farmer complaints related to allegedly reduced MON 810 target pest product performance.

A comprehensive insect resistance monitoring program demonstrated that there were no changes in susceptibility of either targeted pest *O. nubilalis* or *S. nonagrioides* to the Cry1Ab protein in the MON 810 growing regions in Europe in 2017. This is consistent with the observation that also on a global level no resistance is found for *O. nubilalis* and *S. nonagrioides* (Tabashnik *et al.*, 2013) and demonstrates the appropriateness of the implemented IRM plan.

The weight of evidence available to date confirms the initial conclusions of the EU risk 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 13 PMEM reports covering 15 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. Furthermore, the 10 years assessment covering 2006-2015 (Bertho *et al.*, 2018) showed no adverse effects of MON 810 cultivation. The 10 years assessment by Bertho *et al.* (2018) is submitted for publication and is expected to be accepted soon. In summary, the weight of evidence continues to support the initial conclusions of the risk assessment and 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 scientific risk assessment data and local safety

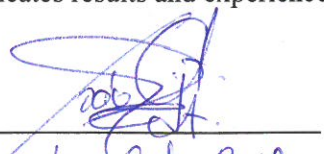
opinions, hundreds of peer reviewed publications relevant to the risk assessment of MON 810 and the expressed Cry1Ab protein, more than 13 years of experience with MON 810 cultivation in the EU, more than 21 years of experience worldwide on millions of hectares, multiple PMEM reports for the EU reporting on the commercial experience confirming the initial conclusions of the risk assessment (and endorsed by EFSA), and absence of confirmed adverse effect related to the event. All together, these results demonstrate that there are currently no adverse effects attributed to the cultivation of MON 810 in Europe. The result of the 2017 monitoring efforts are consistent 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 are subject to adaptation in light of the purpose of the PMEM and the risks associated with MON 810 cultivation. As indicated in the monitoring plan submitted as part of the renewal application EFSA-GMO-RX-MON810 (20.1a), the validity of the monitoring methodologies for the different aspects of the environmental monitoring are continuously evaluated. The improvements that were implemented over the years are based on experiences gained from conducting the environmental monitoring of MON 810 cultivation for fifteen years in Europe, and from discussions with different stakeholders such as the European Commission, EFSA GMO unit, Member States, independent experts and other biotech industries.

This report includes adaptations implemented as from the 2016 maize cultivation season on the previous monitoring plan related to the resistance monitoring in the target pests (Section 3.2). In anticipation of new authorisations for other Lepidopteran-protected *Bt* maize events, Monsanto has collaborated with other applicants towards a harmonized approach for environmental monitoring of these different *Bt* maize events and together developed the harmonized IRM plan (Appendix 6) for the case-specific monitoring, which is currently a condition of the MON 810 authorization in the EU.

Taking account of the experiences gained during the past 13 years from the general surveillance of MON 810 cultivation in Europe and the conclusions of the 10 years meta-analysis in Bertho *et al.* (2018), Monsanto proposes future adaptations on the methodologies currently followed in the general surveillance so that these will become proportionate to the currently still not defined risks associated with MON 810 cultivation. In addition, it is foreseen that the improvements on the methodologies will be based on the extensive available information, the spirit of Directive 2001/18/EC that states that PMEM should be reviewed based on the gathered information, the Council Decision 2002/811/EC and the 2011 EFSA guidance that indicates results and experience may lead to adjustments in the PMEM.

Signed: 

Date: 15 Oct 2018

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Appendix 1. POST MARKET MONITORING OF INSECT PROTECTED *BT* MAIZE MON 810 IN EUROPE – BIOMETRICAL ANNUAL REPORT ON THE 2017 GROWING SEASON

Appendix 2. 2017 MON 810 FARMER QUESTIONNAIRE

Appendix 3. EXAMPLES OF TECHNICAL USER GUIDES

Appendix 3.1. PORTUGAL_TUG

Appendix 3.2. SPAIN_TUG

Appendix 4. 2017 FARMER QUESTIONNAIRE – USER'S MANUAL

Appendix 4.1. PORTUGAL USER MANUAL ANNEXES

Appendix 4.2. SPAIN USER MANUAL ANNEXES

Appendix 5. RESULTS OF ANNUAL LITERATURE SEARCH (JUNE 2017 – MAY 2018)

Appendix 5.1. LIST OF ALL HITS (JUNE 2017 – MAY 2018) – WEB OF SCIENCE™ CORE COLLECTION DATABASE

Appendix 5.2. LIST OF ALL HITS (JUNE 2017 – MAY 2018) – CAB ABSTRACTS® DATABASE

Appendix 5.3. CHECKLIST (ANNEX 2)

Appendix 6. EUROPABIO HARMONISED INSECT RESISTANCE MANAGEMENT (IRM) PLAN FOR CULTIVATION OF *BT* MAIZE (SINGLE INSECTICIDAL TRAITS) IN THE EU, September 2017

Appendix 7. INSECT RESISTANCE MONITORING REPORT FOR *SESAMIA NONAGRIOIDES* (MCB) ASSOCIATED WITH MON 810 MAIZE CULTIVATION IN THE EU: SEASON 2017

Appendix 8. INSECT RESISTANCE MONITORING REPORT FOR *OSTRINIA NUBILALIS* (ECB) ASSOCIATED WITH MON 810 MAIZE CULTIVATION IN THE EU: SEASON 2017

Appendix 9. IBERIAN REFUGE IMPLEMENTATION COMMUNICATION MATERIALS

Appendix 9.1. SPAIN_YIELDGARD TECHNICAL GUIDE

Appendix 9.2. IRM ADVERTISEMENT EXAMPLES

Appendix 9.3. REFUGE POSTCARD

Appendix 9.4. SLIDE DECK ON IRM REQUIREMENTS

Appendix 9.5. IRM POSTER

Appendix 9.6. PORTUGAL_YIELDGARD TECHNICAL GUIDE