Annual monitoring report on the cultivation of MON 810 in 2018

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®[1] 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 tunnelling damage by the European corn borer (*Ostrinia nubilalis*) and the pink stem borer (*Sesamia nonagrioides*).

In 1995, Bayer 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 favourable 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, Bayer 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, Bayer 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 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, Bayer requested the European

[1] YieldGard is a registered trademark of Monsanto Technology LLC.

[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 19 September 2019)

[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.

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 2018, MON 810 was planted in the EU on approximately 120 979 hectares in two countries: Portugal (5 733 ha[4]) and Spain (115 246 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, Bayer always has also 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, Bayer will immediately inform the European Commission. Bayer, 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 (Bayer Agriculture BVBA, 2018; 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 19 September 2019)
[5] Ministry of Agriculture, Fishing and Food of Spain: https://www.mapa.gob.es/es/ (Accessed on 19 September 2019)

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 2018 - June 2019

1.6 Other monitoring reports have been submitted in respect of:

- **Import and Processing** Yes voluntary (December 2019)
- **Food/Feed** Not applicable

2. EXECUTIVE SUMMARY

In 2018, MON 810 was planted in the EU on approximately 120 979 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 2018 cultivation of MON 810 maize in Europe is detailed in this report.

The planting of MON 810 in the 2018 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 2018 and the success of these initiatives was reflected in the high levels of compliance with requirements for refuge implementation observed again in the 2018 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 2018. No complaint allegedly caused by reduced target pest susceptibility to MON 810 was received from farmers in 2018.

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 2018, Bayer 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 2018 did not reveal any adverse effects associated with the genetic modification in MON 810. Furthermore, a detailed analysis of 21 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 2018. 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 2018.

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, Bayer 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 Bayer were taken up by EuropaBio in an effort to harmonize proportional and workable monitoring approaches across the technology providers. Bayer 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, Bayer submitted 14 post-market environmental monitoring (PMEM) reports covering 16 years of MON 810 cultivation in the EU and all reports confirm consistently its safety. These reports describe the activities undertaken by Bayer 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 Bayer 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 Bayer'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 3250 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 2018 growing season, the results of the farmer questionnaires conducted in 2018 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 of the meta-analysis was submitted for publication in a peer-reviewed journal and is under review. 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 limit the conditions for the general surveillance to literature searches and the farmer complaint systems.

In addition to the results from the farmer questionnaires conducted in 2018, Bayer'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, Bayer reported on the peer-reviewed articles that were published on the safety of MON 810. Across our regulatory submissions and monitoring reports, Bayer has reported on more than 446 articles of which the vast majority is authored by independent academics and scientists. Allegations about the safety of the product were thoroughly reviewed, allowing Bayer 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 14 PMEM reports, covering 16 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, 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, 2015b, 2016a, 2016b, 2017b, 2018, 2019), Bayer'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, 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 15 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),
- 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 19 September 2019).

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 Bayer's position as explained above remains unchanged, the results of the 2018 GS activities are included in this report. Bayer 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 Bayer as well as the methodologies followed and the reporting conducted has not been an individual applicant's work. During the years, Bayer 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 Bayer has gradually improved the way it implemented GS monitoring. For these adjustments, Bayer 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.

Bayer 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 eight specific opinions on MON 810 monitoring in the 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016 and 2017 growing seasons (EFSA, 2012e, 2015a, 2015b, 2016a, 2016b, 2017b, 2018, 2019). Bayer has adapted its monitoring approaches where possible and feasible, taking into consideration the EFSA recommendations and gained expertise on MON 810 monitoring and already established methodologies, in order to report on a voluntary basis on the results for the 2018 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, 2016 or 2017 growing seasons and that the outcomes of the monitoring reports did not invalidate the previous risk assessment conclusions (EFSA, 2012e, 2015a, 2015b, 2016a, 2016b, 2017b, 2018, 2019). This confirms that Bayer methodologies are fit for 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.

3.1.1 Description of General Surveillance

In 2018, Bayer 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 Bayer in 2018 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 2018 GS for MON 810 focused on the Iberian geographical regions where the majority of MON 810 was grown in 2018 (Portugal and Spain, countries accounting for 100% of the MON 810 plantings in the EU in 2018), 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 2018, 12 farmers in Portugal and 238 farmers in Spain were asked to complete the questionnaire (250 in total). The farmers/fields were randomly selected depending on the market distribution 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 December 2018 and March 2019. 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' developed previously was used (*see* Appendix 4).

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

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[7] Instituto Markin (Spain): https://markin.org/ (Accessed on 18 October 2019).
[8] Agro.Ges (Portugal): http://www.agroges.pt/?lang=en (Accessed on 18 October 2019).

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

Bayer 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, Bayer 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 Bayer[10] websites offer a contact point.

[9] EuropaBio contact webpage - http://www.europabio.org/contact (Accessed 18 October 2019)
[10] Bayer product stewardship webpage - https://monsanto.com/products/product-stewardship/; www.dekalb.es and www.dekalb.pt (Accessed 18 October 2019)

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 Bayer 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 Bayer website for communication to external stakeholders - http://www.monsanto.com/newsviews/Pages/Issues-and-Answers.aspx (Accessed on 28 November 2019)

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 2018 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 2018 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 2018.

3.1.5 Additional information

Not applicable as no adverse effects were observed.

3.1.6 Literature search

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 2018 – May 2019 and is provided along with the checklist for literature search (Annex 2) in Appendix 5. Note that additional recommendations provided by the EFSA (2019) on the literature searching will be considered as of the 2019 season since all tasks of the literature search for the 2018 season were already completed by the time the EFSA statement was published on 13 June 2019.

Bayer 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, Bayer 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, Bayer 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 Bayer on MON 810 in the 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016 and 2017 growing seasons (EFSA, 2012e, 2015a, 2015b, 2016a, 2016b, 2017b, 2018, 2019). 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 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 and amended in 2019 (*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) growers complaint system; (4) remedial plan in case of *Bt* maize failure to protect against target pests; and (5) communication and grower education.

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

[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 18 October 2019)

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.

Bayer takes note of EFSA's recommendation that "*the consent holder should strive to increase the level of compliance in high adoption areas (North-eastern Spain, see Appendix B). Spanish National Competent Authorities and other relevant stakeholders, including farmers' associations, could contribute to reinforce farmers' awareness of refuge compliance*". It should be noted that given the continued communication efforts by the different stated stakeholders (*see* Section 3.2.1.4), the high-dose/structured refuge compliance has reached 90% or above in the high adoption areas over the past years. Studies demonstrated that levels of compliance with high-dose/structured refuge compliance as high as 90% with 20% of structured refugee provide product sustainability in delaying resistance evolution that exceeds what can be achieved with seed mixtures (Carroll *et al.*, 2012). Therefore, Bayer believes that the high-level refuge compliance achieved by the Spanish farmers needs to be acknowledged and encouraged. Other alternative strategies to delay the resistance evolution for the target pests would have been the implementation of multiple modes of action (different Cry proteins) to complement the MON 810 technology. There are currently, and likely not in the near future, no such solutions available because of the negative political context related to new biotech approvals for cultivation in Europe. Another strategy proposed by EFSA to "*ensure that structured refuges are planted in clustered areas greater than 5 ha*" is also not possible to implement in practice since such information is not publicly available for the growing season.

In the context of Bayer's 2018 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.

91.2% of the farmers indicated that they followed the technical guidelines regarding the implementation of a refuge (79.2% planted a refuge and 12% 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 Bayer 2018 Farmer Questionnaire Survey show that 90.8% of

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

the farmers in Spain were compliant with refuge planting while 22 farmers out of 238 (*i.e.*, 9.2%) indicated they did not meet the refuge requirement for the following two main reasons: (1) the farmers felt it complicates the planting and/or they did not have enough time (14/21, 63.3 %), and (2) they feared yield losses in conventional maize (6/21, 28.6 %).

In Portugal, an independent monitoring report on the planting of MON 810 varieties (including IRM communication and refuge implementation) during the 2018 growing season was prepared by the Portuguese authorities[15]. In addition to the farmers trained in previous seasons, and in compliance with the Portuguese law, 6 new farmers[16] were trained in 2018 on national and EU legislations that regulate the cultivation of GM varieties and to learn about the main characteristics of MON 810 maize. Furthermore, 54 inspections were performed on farmers planting MON 810 maize out of the total 172 cultivation notifications registered in 2018. 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, 35 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 Bayer) during the 2018 season are consistent and do show a high level of refuge 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 2019 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

[15] DGAV 2019. http://www.dgv.min-agricultura.pt/xeov21/attachfileu.jsp?look_parentBoui=33743502&att_display=n&att_download=y (Accessed on 30 October 2019)

[16] So far, 1823 farmers have been trained on national and EU legislations since 2005.

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, and EuropaBio updated the IRM plan in 2017 (and amended in 2019) 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 2019 harmonized IRM plan, additional amendments on the monitoring protocol and sampling criteria were made based on the field experiences from the past years.

Bayer acknowledges that EFSA made several recommendations to improve the bioassays for resistance monitoring in the target pests (EFSA, 2012e, 2015a, 2015b, 2016a, 2016b, 2017b, 2018, 2019). EFSA stated that "*The monitoring strategy implemented in the 2017 growing season is not sensitive enough to detect the recommended 3% resistance allele frequency. Consequently, EFSA strongly recommends to increase the sensitivity and precision of the monitoring strategy so that alternative management measures can be implemented timely to delay resistance evolution*" (EFSA, 2019). Bayer follows 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, 2015b, 2016a, 2016b, 2017b, 2018, 2019). The monitoring studies performed with *O. nubilalis* and *S. nonagrioides* from 2004 to 2017 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). A recent presentation by Sethi *et al.*[17] in the 27th IWGO conference in Switzerland also confirmed the continued performance of *Bt* corn (Cry1Ab) in Canada. Nevertheless, in light of all the continued EFSA recommendations (EFSA, 2015b, 2016c, 2017b), Bayer has extensively increased the field sampling efforts and continuously discussed with experts the best practices for increasing the sensitivity of the strategy since 2016. However, working with field populations of insects (namely collection of larvae and bioassays execution) is subjected to different challenges and unforeseen issues and EFSA has acknowledged also the difficulties and uncertainties of being able to meet the above recommendation (EFSA, 2017b, 2018, 2019).

Bayer takes also note of the EFSA statement that "*Although the consent holder underlines the increasing difficulties to find different fields infested with ECB larvae for sampling, EFSA is not aware of any evidence of area-wide corn borer suppression in North-eastern Spain*" (EFSA, 2019). Aligned with the revised EuropaBio harmonised IRM plan, the objective of the sampling efforts 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, 2016b). From the experience gained in 16 years of MON 810 PMEM, it was demonstrated that such collections may not always be feasible. The target pests' pressure and the number of larvae in the region have decreased drastically as reported by independent sources such as IRTA[18] since the introduction of MON 810 technology in the area (*See* **Figure 1**). Similarly, an area-wide suppression of pest pressure due to *Bt*-maize was also reported in other regions as presented by Hutchison[17] in the 27th IWGO conference in Switzerland. Consequently, despite intensified efforts of larvae collection, the significant reduction of the target pest populations over the years as well as occurrence of further drops in the pest populations due to various natural causes in certain growing seasons may make collecting 1 000 larvae impossible. Therefore, as indicated in the EFSA opinions (EFSA, 2017b, 2018, 2019), 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.

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[17] 27th IWGO conference: https://www.switzerland2019.iwgo.org/WEBS/IWGO2019.pages.download/IWGO_2019_Scientific-Programme.pdf - (Accessed on 28 November 2019)

[18] Catalunya Research Institute, IRTA, 2013; https://ruralcat.gencat.cat/documents/20181/4636355/DT60.+Conreu+de+pan%C3%ADs+per+a+gra%3A+Varietats.+Incid%C3%A8ncia+de+les+virosis+en+la+producci%C3%B3/a6ded890-7f4e-493e-9066-11bf0f69c165 (Accessed 10 December 2019)

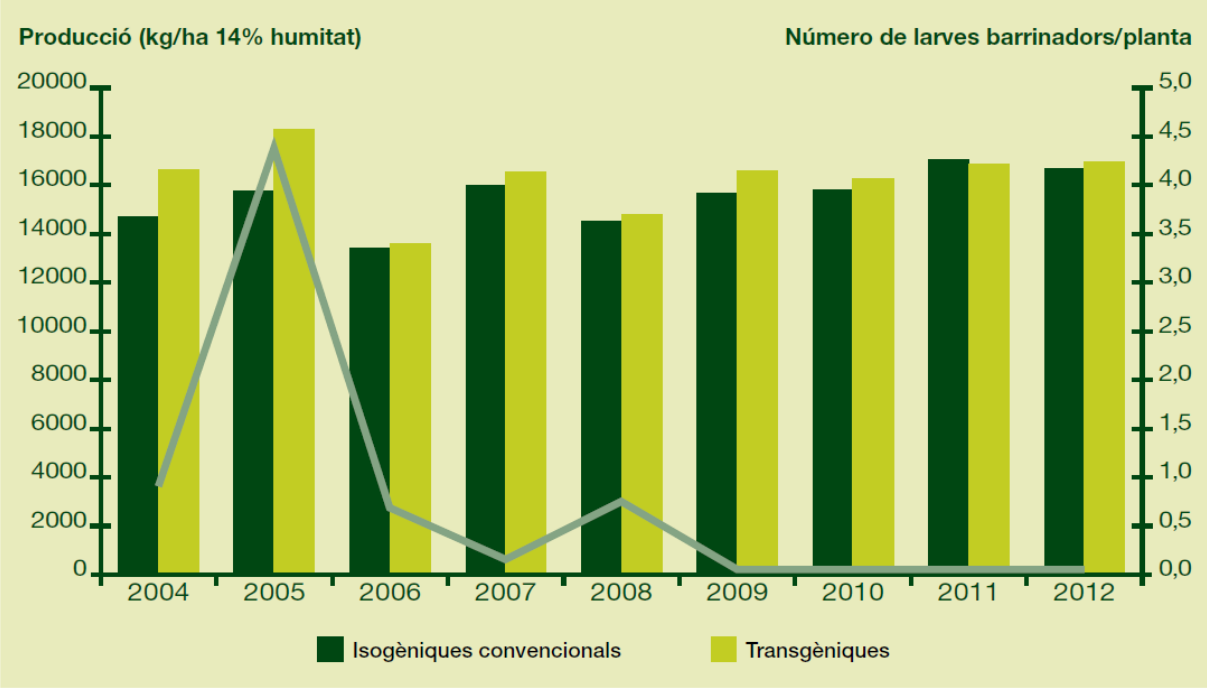

Figure 1. Evidence showing the reduction of corn borers in North Eastern Spain since the introduction of the MON 810 technology (Source: IRTA 2013). Continued effectiveness of the MON 810 technology and low infestation levels of corn borers between 2012 and 2018 have been observed also by IRTA (data not published).

EFSA provided also recommendation regarding the mortality of the field larvae suggesting "*to undertake measures to optimise the rearing process of collected individuals and reduce the pre-imaginal mortality prior to susceptibility testing, so that as many field-collected individuals as possible are represented in the bioassays as F1-larvae*" (EFSA, 2019). Bayer would like to highlight that both laboratories performing the bioassays have a very broad experience working with larvae populations of *O. nubilialis* and *S. nonagroides*. They have qualified staffs and they apply good experimental practices but unfortunately, the mortality prior to susceptibility testing is subjected to many factors that are out of control and cannot be predicted (*e.g.* larvae parasitism; poor fitness as the larvae are collected from areas with high adoption of MON 810 maize).

The area identified in the entire EU region in 2018 where adoption of MON 810 was 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%. Therefore, larvae sampling of *O. nubilalis* and *S. nonagrioides* for the monitoring activities in the 2018 maize growing season concentrated in the Ebro valley as described in the 2019 revised IRM plan (Appendix 6) and as recommended by EFSA (EFSA, 2016b, 2017b, 2018, 2019). No larval samples for *O. nubilalis* and *S. nonagrioides* were collected from the other growing areas as the adoption rate of MON 810 cultivation was below 60%.

During the 2018 growing season, Bayer continued its effort to collect for both target pests field 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 2018, 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.

Bayer notes EFSA's statement that "*the consent holder did not provide additional evidence to underpin the appropriateness of the diagnostic concentration selected for MCB*" and that "*the validity of the concentration should be confirmed by comparing it with data generated with MCB larvae collected from areas with low or no selection pressure*" (EFSA, 2019). As previously reported (Bayer Agriculture BVBA, 2018; Monsanto Europe S.A., 2017), the determination of a diagnostic concentration involves using all relevant data available to select a concentration that reasonably distinguishes phenotypically resistant and susceptible insects while balancing the probability of Type I and Type II errors. In essence, the lowest concentration is determined that reliably controls susceptible insects. There are a variety of formulae that have been used in the literature to calculate diagnostic concentrations because there are various ways to meet the criteria outlined above; all of these formulae produce broadly similar values and generally are viewed as acceptable (Halliday and Burnham, 1990; Roush and Miller, 1986). For *S. nonagrioides* (MCB), the diagnostic concentration (DC) was calculated with endpoint moulting inhibition (MI) data of *S. nonagrioides* from the Ebro valley, obtained from concentration-response bioassays in the period 2009-2015. This seven-year period was viewed as adequate to capture the natural variation in *Bt* protein susceptibility, as required for choosing a DC. Concentration-response bioassays have not been performed since that time because of the need to maximize the power of the DC assays, which required focusing resources on the DC assays. Bayer considers that using these comprehensive data set gives the best estimate of the extremes of the susceptibility distribution which is the target for the DC calculation. Additionally, if the DC is calculated based on data from a different region, the natural variability may differ between regions leading to wrong comparison.

Bayer acknowledges also the EFSA statement on "*the harmonisation of the methodology of the diagnostic bioassays used for both target pests*" (EFSA, 2019). As can be seen in Appendix 7 and Appendix 8, a significant effort has been made to harmonise the methodologies of the diagnostic bioassays between the two species as recommended by EFSA (2017b, 2018): 1) The field larvae collected from the different sampling zones were kept separately and independently tested; 2) All larvae surviving from the DC bioassays were fed with MON 810 leaves in the confirmatory feeding tests with plant material; 3) Conventional maize was included as control in the confirmatory feeding tests with plant material; and 4) All assays on the test and control materials for each species were run in parallel and for the same duration (10 days for *O. nubilalis* and 7 days for *S. nonagrioides*). The additional EFSA recommendations stated in EFSA (2019), *e.g.* 1) Including reference strain as an additional control in the DC assays and 2) Confirmatory testing on the expression of the Cry1Ab protein (e.g. by using commercial test strips) in the *Bt*-maize leaves used in studies with plant

material, have been already addressed for the MCB bioassays and for harmonisation, will be considered for ECB bioassays starting next monitoring season (2019 season) since the experiments for the 2018 season were already finalised by the time the 2019 EFSA statement was published on 13 June 2019.

As reported in Appendix 7, from the 1490 larvae of *S. nonagrioides* collected in the Ebro valley Spain, 637 adults (43%) emerged, of whom 584 mated, and the offspring of 95% of these adults (554) were used in the bioassays and treated with the DC of 1091 ng Cry1Ab/cm^2. The treatment with the DC caused a mean moulting inhibition of 98.65% ± 0.40% to the F1 neonates, which was not significantly different from the expected value of 99 % or the value of moulting inhibition (97.75%) caused to neonates of the laboratory strain of *S. nonagrioides* after treatment with the same DC (t = -2.1759, df = 2, p = 0.081). 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 (2004–2015), 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 F1 first-instar larvae *S. nonagrioides* larvae (10 294) died after continuous feeding on leaves of *Bt* maize (100% died before reaching 2nd larval stage). To confirm that the 40 larvae that reached the second larval instar in the DC bioassay are not resistant to MON 810, 128 F2 neonates of their siblings coming from two different oviposition cages were fed with MON 810 leaves and all died before reaching the 3rd 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 1144 larvae of *O. nubilalis* collected in the Ebro valley Spain, 534 adults (46.7%) survived the diapause period, reached the adult stage and mated. Of the 1768 *O. nubilalis* larvae exposed to the discriminating concentration 76 larvae died, 1689 survived but did not reach the 2nd larval stage, and 3 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 99.85%. 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.

Regarding the raw data, Bayer still considers that the data provided in the IRM reports (Appendix 7 and Appendix 8) are sufficient to assess the quality and accuracy of the bioassays. However, with the spirit of transparency and EFSA's repeated recommendation, the raw data for the 2018 bioassays are provided with the reports in Appendix 7 and Appendix 8.

3.2.1.3 Farmer complaint system

Bayer and the seed companies offering MON 810 varieties have a robust farmer complaint system 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 MON 810 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, Bayer 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 is compulsory and marketing companies commit on it at the Monitoring Plan they sign off.

Farmers and agronomic advisors are also connected to the regional monitoring networks that have been created for integrated pest management (IPM) in Spain. Therefore, they can report any unusual observation, especially if it is related to efficacy breaks through these networks. Examples: in Aragon, one of the Ebro Valley regions, the network @redfaragon is a network by regional authorities, integrated by qualified technical staff, intended to monitor the incidence of pests, distribute information about IPM, good practices on the use of plant protection products (PPPs) and resistance management. Thus, this network is preforming weekly monitoring of pest incidences, including corn borers, in specific control points across the region. Similarly, in Andalucía there is the @RAIF_noticias which distribute alerts and information on pest incidences and plant health issues.

During the 2018 growing season, Bayer 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)[19] member companies commercializing MON 810 maize to have an overview of the farmer complaint schemes (ANOVE, 2018). The effectiveness of the system was demonstrated because a total of 1249 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 2018 planting season in Spain (the main country growing MON 810), 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 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 Bayer 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 (de la Cruz, 2016). In 2018, 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

[19] Asociación Nacional de Obtentores Vegetales: http://www.anove.es/ (Accessed on 21 October 2019)

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. For 2018 season, roll up was created and distributed among companies and ANOVE to have a ready to use material for farmer's talks, fairs, exhibitions, etc about refuges (*see* Appendix 9.4 and 9.7).

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 100 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. 99% 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. ANOVE also continued with an extensive campaign in social media encouraging ag stakeholders to further communicate on the correct use of the technology and the implementation of refuges (*see* Appendix 9.2a).

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 Bayer'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). 100% of farmers interviewed acknowledged they have been informed about the good agricultural practices applicable to MON 810. Users have received information through the Technical User Guides (TUG) attached to the seed bags and went through mandatory 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

Bayer 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 2018, 100% of farmers interviewed acknowledged they have been informed about the good agricultural practices applicable to MON 810 and the percentage of farmers implementing refuges in their fields remains very high (91.2 %).

The results of the analysis of 2018 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 2018 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 2018. 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, Bayer submitted 14 PMEM reports covering 16 years of MON 810 cultivation in the EU and all confirming its safety. These reports describe the activities undertaken by Bayer to identify and analyse anticipated and unanticipated effects related to MON 810 cultivation. Furthermore, the 10 years assessment covering 2006-2015 showed no adverse effects of MON 810 cultivation. The 10 years assessment is submitted for publication and is in review. 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 16 years of experience with MON 810 cultivation in the EU, more than 22 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 2018 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 16 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, Bayer 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 14 years from the general surveillance of MON 810 cultivation in Europe and the conclusions of the 10 years meta-analysis (in review), Bayer 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.

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Appendix 1. POST MARKET MONITORING OF INSECT PROTECTED *BT* MAIZE MON 810 IN EUROPE – BIOMETRICAL ANNUAL REPORT ON THE 2018 GROWING SEASON

Appendix 2. 2018 MON 810 FARMER QUESTIONNAIRE

Appendix 3. EXAMPLES OF TECHNICAL USER GUIDES

Appendix 3.1. PORTUGAL_TUG

Appendix 3.2. SPAIN_TUG

Appendix 4. 2018 FARMER QUESTIONNAIRE – USER'S MANUAL

Appendix 4.1. PORTUGAL USER MANUAL ANNEXES

Appendix 4.2. SPAIN USER MANUAL and ANNEXES

Appendix 5. RESULTS OF ANNUAL LITERATURE SEARCH (JUNE 2018 – MAY 2019)

Appendix 6. EUROPABIO HARMONISED INSECT RESISTANCE MANAGEMENT (IRM) PLAN FOR CULTIVATION OF *BT* MAIZE (SINGLE INSECTICIDAL TRAITS) IN THE EU, April 2019

Appendix 7. INSECT RESISTANCE MONITORING REPORT FOR *SESAMIA NONAGRIOIDES* (MCB) ASSOCIATED WITH MON 810 MAIZE CULTIVATION IN THE EU: SEASON 2018

Appendix 8. INSECT RESISTANCE MONITORING REPORT FOR *OSTRINIA NUBILALIS* (ECB) ASSOCIATED WITH MON 810 MAIZE CULTIVATION IN THE EU: SEASON 2018

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

Appendix 9.7. SPAIN_ROLL UP FOR COMMUNICATION ON REFUGES