Annual monitoring report on the cultivation of MON 810 in 2020

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[1], now Bayer CropScience LP, developed insect-protected YieldGard®[2] 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, Monsanto Company 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"*[3]. 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)[4] 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 nationalisation 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 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 authorisation for (1) existing food and food ingredients produced from MON 810;

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[1] On August 1st, 2020, Monsanto Company converted its legal form and changed its name to Bayer CropScience LP.

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

[3] Opinion of the Scientific Committee on Plants Regarding the Genetically Modified, Insect Resistant Maize Lines Notified by the Monsanto Company - https://ec.europa.eu/food/system/files/2020-12/sci-com_scp_out02_en.pdf (Accessed 8 October 2020)

[4] 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.

feed consisting of 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 authorisation 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 authorising 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 2020, MON 810 was planted in the EU on approximately 102 367 hectares in two countries: 4 216 ha and 98 152 ha in Portugal and Spain, respectively (DGAV, 2020; MAPA, 2020).

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 BV, 2020; Bayer Agriculture BVBA, 2018, 2019; Monsanto Europe S.A., 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017). Since 2010, the reports follow the format as laid out in Annex I to Commission Decision 2009/770/EC (European Commission, 2009) and confirm consistently the initial conclusions on the safety of MON 810.

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 2020 - June 2021

1.6 Other monitoring reports have been/ will be submitted in respect of:

- **Import and Processing** Yes voluntary (October 2021)
- **Food/Feed** Not applicable

2. EXECUTIVE SUMMARY

In 2020, MON 810 was planted in the EU on approximately 102 367 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 2020 cultivation of MON 810 maize in Europe is detailed in this report.

The planting of MON 810 in the 2020 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 2020. The success of these initiatives was reflected in acknowledgment of all the farmers about their awareness for compliance with requirements for refuge implementation and the high levels of compliance observed again in the 2020 season. A comprehensive IRM program demonstrated that there were no changes in susceptibility of either *O. nubilalis* or *S. nonagrioides* to the Cry1Ab protein in the major MON 810 growing regions in Europe in 2020. No complaint allegedly caused by reduced target pest susceptibility to MON 810 was received from farmers in 2020.

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 2020, 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 252 additional questionnaires from a survey of farmers cultivating MON 810 in two European countries in 2020 did not reveal any adverse effects associated with the genetic modification in MON 810, consistent with the similar conclusions in the 15 precedent years and the ones from the join meta-analysis of the surveys gathered during the first 10 years of commercial cultivation (Bertho *et al.*, 2020). Furthermore, a detailed analysis of 5 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 2020. Taken together, these results demonstrate that there are no indications of adverse effects attributable to the cultivation of MON 810 in Europe in 2020.

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 authorisation 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 CropLife Europe[5] in an effort to harmonise 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, (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 16 post-market environmental monitoring (PMEM) reports covering 18 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 BV, 2020; Bayer Agriculture BVBA, 2018, 2019; Monsanto Europe S.A., 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017). The resulting weight of confirmatory safety evidence is summarised 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 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 3 750 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 year's PMEM report aims to describe the outcomes of the 2020 growing season, the results of the farmer questionnaires conducted in

[5] Please note that CropLife Europe has taken over all the responsibilities of EuropaBio in coordinating activities of technology providers on the post-market environmental monitoring of GM crops as of 1st January 2021.

2020 are provided. None of the reports for which the results were statistically analysed identified a statistically meaningful effect indicating 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 targeted 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, 2014). 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 (Bertho *et al.*, 2020). The data collected in the subsequent MON 810 growing seasons (Bayer Agriculture BV, 2020; Bayer Agriculture BVBA, 2018, 2019; Monsanto Europe S.A., 2015, 2016, 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 is 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 2020, 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 publications on the safety of MON 810. Across our regulatory submissions and monitoring reports, Bayer has reported on more than 465 publications of which the vast majority are 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 authorisation 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. CropLife Europe[5] identified and characterised 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 (Henrys *et al.*, 2014).

The aforementioned 16 PMEM reports, covering 18 years of MON 810 cultivation in the EU, all support the original conclusion reached in the initial application of authorisation, *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 authorised 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, 2012e), new scientific publications published from 2009 onwards (EFSA, 2012d, 2015a, 2015b, 2016a, 2016b, 2017, 2018, 2019a, 2020, 2021), Bayer's monitoring reports (Bayer Agriculture BV, 2020; Bayer Agriculture BVBA, 2018, 2019; 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.

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 maximisation 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 10 specific opinions on MON 810 monitoring in the 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 growing seasons (EFSA, 2012d, 2015a, 2015b, 2016a, 2016b, 2017, 2018, 2019a, 2020, 2021). 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 2020 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, 2017, 2018 and 2019 growing seasons and that the outcomes of the monitoring reports did not invalidate the previous risk assessment conclusions (EFSA, 2012d, 2015a, 2015b, 2016a, 2016b, 2017, 2018, 2019a, 2020, 2021). This confirms that Bayer 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

[6] CropLife International: www.biotradestatus.com (Accessed on 12 August 2021).

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.

In addition, Bayer takes note of EFSA's recommendation that "*the consent holder includes and explicitly considers in the future annual PMEM reports all scientific evidence relevant for the environmental risk assessment and risk management of maize MON810 in relation to teosinte*" (EFSA, 2021). In line with Article 13(6) of Directive 2001/18/EC and Articles 9 and 21 of Regulation (EC) No 1829/2003, Bayer monitors and reports any new information that has become available with regard to the safety of MON 810 to human and animal health or the environment, and that might influence the evaluation of the MON 810 safety in all uses as conventional maize, including cultivation. Bayer reiterates that, for the reasons laid down in our letter of 1 July 2016 to the European Commission (Response to the Commission letter dated 16 June 2016 (Ref. Ares(2016)2799314)), the emergence/occurrence of teosinte in Spain cannot be classified as information linked to the safety of MON 810 to human and animal health or the environment, nor can it be regarded as information that influences the evaluation of the MON 810 safety in all uses as conventional maize, including cultivation. Bayer is of the opinion that reporting the activities of teosinte monitoring in Spain limited to MON 810 alone or scientific literature on teosinte would not bring any additional value to the environmental risk assessment of MON 810 maize. The appearance of teosinte in Spain is a generic agronomic problem that concerns all commercial, MON 810, conventional and organic, maize fields. The monitoring of its occurrence and the management of teosinte by related good agronomic practices are relevant for conventional commercial maize, organic maize (specific measures might be needed) as well as MON 810 commercial cultivated fields. It should also be noted that the existing GS methodologies for MON 810 PMEM have been in place on a voluntary basis for 18 years and are confirmed to be fit for the purpose of identifying any potential adverse effects linked to all uses of MON 810 as conventional maize, including cultivation. The occurrence of teosinte in Spain is not an adverse effect originated by MON 810 introduction. Therefore, as stated in the letter of 1 July 2016, Bayer reiterates that there is no reason to report on teosinte emergence/occurrence in light of the safety assessment of MON 810 maize.

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 scientific publications relevant to the risk assessment of MON 810 and the expressed Cry1Ab protein,
- more than 18 years of experience with MON 810 cultivation in the EU,
- more than 23 years of experience worldwide on millions of hectares,
- 16 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 authorisation for MON 810 issued in 1998 (Commission Decision, 1998), the accumulated experience after 18 years of extensive cultivation and voluntary 16 years reporting on GS activities, Bayer views is that current annual PMEM becomes disproportional to the available weight-of-evidence demonstrating the safety of MON 810 and call for a fit for purpose adaptation. 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).

3.1.1 Description of General Surveillance

In 2020, 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 2020 consisted of four elements:

- a farmer questionnaire designed to assess unusual observations in the areas where MON 810 has been cultivated,
- data collected from scientific publications or reports relating to MON 810 and its comparative safety (to conventional counterparts) with respect to human, and animal health and the environment,
- company stewardship activities designed to ensure and maintain the 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 2020 GS for MON 810 focused on the Iberian geographical regions (Portugal and Spain) where they account for 100% of the MON 810 plantings in the EU in 2020, 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 2020, 12 farmers in Portugal and 240 farmers in Spain were asked to complete the questionnaire (252 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). Despite the challenges triggered by the COVID pandemic to conduct a comprehensive questionnaire that requires personal interviews the interviews did a remarkable effort to meet farmers and were able to complete the targeted numbers between February and March 2021. 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 vast experience in the conduct of farmer surveys. All interviewers have been involved since the beginning of the farmer questionnaires and are well trained and equipped to conduct the interviews. Here also

[7] Instituto Markin (Spain): https://markin.org/ (Accessed on 12 August 2021).
[8] Agro.Ges (Portugal): http://www.agroges.pt/?lang=en (Accessed on 12 August 2021).

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:

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 constitute 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, CropLife Europe[5,9] and Bayer[10] websites offer a contact point.

3.1.2.3 Alerts on environmental issues

Internal procedure on alerts on environmental issues

Since the commercial introduction of MON 810, attention to potential environmental issues has been raised through a number of sources. An issue management process has been put in place by 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).

Alerts on environmental issues by existing networks

The CropLife Europe[5] Working Group on monitoring coordinated a harmonised effort to map EENs in Europe and to set up a unique reporting system (Smets *et al.*, 2014). The work done by CropLife Europe[5] 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 were 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 recognised, 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. 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) harmonisation 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).

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[9] CropLife Europe contact webpage - https://croplifeeurope.eu/contact-us/ (Accessed 12 August 2021)

[10] Bayer product stewardship webpage - https://www.bayer.com/en/product-stewardship.aspx, www.dekalb.es and www.dekalb.pt (Accessed 12 August 2021)

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 2020 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 252 questionnaires from the survey of farmers cultivating MON 810 in Spain and Portugal during the 2020 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 2020.

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, 2019b) has been conducted on a quarterly basis covering the time span June 2020 – May 2021 and is provided along with the Appendix E completeness checklist in Appendix 5.

Overall, Bayer confirms that the literature search, conducted in accordance with the 2019 EFSA explanatory note on literature searching (EFSA, 2019b) 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)

3.2.1.1 Background

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 two other companies[11] established the European Union working group on IRM and developed together a harmonised 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 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 10 specific opinions on the monitoring conducted by Bayer on MON 810 in the 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 growing seasons (EFSA, 2012d, 2015a, 2015b, 2016a, 2016b, 2017, 2018, 2019a, 2020, 2021). 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 CropLife Europe[5] Monitoring working group 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 pest resistance to the Cry protein(s) expressed in single *Bt* maize events in the EU. This harmonised 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.

3.2.1.2 Refuge compliance

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.

Bayer is strongly committed since the beginning of the cultivation of MON 810 to educate farmers and advocate for refuge compliance directly and through other influential ag stakeholders, like cooperatives, farmers' advisors, National Breeders associations and authorities. Many initiatives have been taken to educate farmers on the importance of implementing IRM measures since the first days of cultivation within the EU (*see* Section 3.2.1.4). Due to the absence of direct sales between end-users and seed companies, the seed industry has also put emphasis on the development of communication tools. The awareness of farmers is currently very high on the refuge compliance requirements and as in previous seasons 100% of the farmers interviewed acknowledged have been informed about the IRM obligations as well as the associated impacts of non-compliance, as this is clearly highlighted in the documentation that is accompanying the seed bags. From the continued communication

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

efforts by the different stated stakeholders (*see* Section 3.2.1.4), structured refuge compliance has reached 90% or above in the high adoption areas over the past years. This results in the reported extreme high levels of structured refuge implementation which is considered one of the best compliance records to be found worldwide. Modelling studies have demonstrated that levels of compliance with structured refuge as high as 90% with structured refuge delay resistance evolution to a greater extent than can be achieved with seed mixtures (Carroll *et al.*, 2012). Therefore, the high level of refuge compliance achieved by the Spanish farmers needs to be acknowledged and encouraged.

An additional strategy to delay resistance evolution in the target pests would have been the implementation of multiple modes of action (different Cry proteins) to complement the MON 810 technology. There are not currently, and likely not in the near future, any such solutions available because of the negative political context related to new biotech approvals for cultivation in Europe. The 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 due to the following reasons: (1) the necessary exchange of information between companies about MON 810 cultivating farmers is against anti-trust policies and competition rules[12]; and (2) farmers make their planting decisions based on several factors that are not known and in many cases cannot be predicted before planting because they are subjected to variables that are out of their control (e.g. water availability for irrigation, prices, etc.).

In the context of Bayer's 2020 GS, 252 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.

During the 2020 growing season, 97.6% of the farmers indicated that they followed the technical guidelines regarding the implementation of a refuge (88.5% planted a refuge and 9.1% had less than 5 ha planted with MON 810 on their farm[13]). 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 2020 Farmer Questionnaire Survey show that 97.5% of the farmers in Spain were compliant with refuge planting while 6 farmers out of 240 (*i.e.*, 2.5%) indicated they did not meet the refuge requirement for the following three main reasons: (1) the farmers feared the yield losses in conventional maize (3/6), (2) they had conventional maize as neighbouring plots (2/6), and (3) one farmer stated that the planting would be too complicated (1/6).

In Portugal, an independent monitoring report on the planting of MON 810 varieties (including IRM communication and refuge implementation) during the 2020 growing season was prepared by the Portuguese authorities (DGAV, 2021). In 2020 due to the COVID-19 pandemic situation Portuguese authorities were not able to conduct additional training sessions but all farmers cultivating MON 810 varieties in Portugal were subjected to training sessions before. Since 2005, 1887 farmers have been trained to learn about the main characteristics of MON 810 maize and the national and EU legislations that regulate the cultivation of GM varieties. Furthermore, 42 inspections were performed on farmers planting

[12] European Commission: https://ec.europa.eu/info/business-economy-euro/doing-business-eu/competition-rules_en - Accessed on 17 September 2021

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

MON 810 maize out of the total 123 cultivation notifications registered in 2020. 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, 12 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. All the interviewed farmers reported a positive balance of the cultivation of MON 810 maize and a significant number refer to better control of corn borers without need to apply insecticides as the main driver for adoption. None of them found a negative effect associated to the cultivation.

In conclusion, the results from the presented surveys (Portuguese authorities and Bayer) during the 2020 season are consistent and show a high level of refuge compliance, due to the growers' high awareness on refuge compliance and the continued efforts on grower education. Regardless of these results, the message on the importance of refuge implementation was repeated to Spanish and Portuguese farmers growing MON 810 in the 2020 cultivation season. It is important to continue reminding the farmers on the necessity to implement refuges and align them with responsible use of the technology.

Integrated Pest Management (IPM) is mandatory in EU countries as enforced by the Sustainable Use Directive 2009/128/EC and its transposition to member states' regulations (*e.g.* Real Decreto 1311/2012 in Spain). Implementation of good agricultural practices including refuge compliance is prescribed in the guidance documents for IPM[14]. Bayer continues also encouraging authorities to enforce the adoption of refuges in the MON 810 cultivating countries. It is recommended that refuge planting be integrated as a 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.

3.2.1.3 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 (Farinos *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

[14] Ministry of Agriculture (Spain): https://www.mapa.gob.es/es/agricultura/temas/sanidad-vegetal/productos-fitosanitarios/guias-gestion-plagas/cultivos-herbaceos/default.aspx (Accessed on 16 September 2021).

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 (Farinos *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 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 harmonised IRM plan is to keep it updated based on new learnings and scientific information, and CropLife Europe[5] 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 harmonised IRM plan, additional amendments to the monitoring protocol and sampling criteria were made based on field experiences from past years.

Bayer acknowledges that EFSA made several recommendations to improve the bioassays for resistance monitoring in the target pests (EFSA, 2012d, 2015a, 2015b, 2016a, 2016b, 2017, 2018, 2019a, 2020, 2021). Bayer follows fit-for-purpose methodologies gained through experience and in line with harmonised 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 are consistent with the previous risk assessment conclusions (EFSA, 2012d, 2015a, 2015b, 2016a, 2016b, 2017, 2018, 2019a, 2020, 2021). 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 presentation by Sethi *et al.* (2019)[15] in the 27th IWGO conference in Switzerland also confirmed the continued performance of *Bt* corn (Cry1Ab) in Canada. Nevertheless, considering EFSA recommendations (EFSA, 2015a, 2016c, 2017b), Bayer has significantly increased field sampling efforts and continued discussions with experts on the best practices for increasing the sensitivity of the strategy since 2016. Working with field populations of

[15] 27th IWGO conference: https://www.switzerland2019.iwgo.org/WEBS/IWGO2019.pages.download/IWGO_2019_Scientific-Programme.pdf - (Accessed on 16 September 2021)

insects (namely collection of larvae and bioassays execution) has proven to present different challenges and unforeseen issues. EFSA acknowledged these difficulties and uncertainties in being able to meet the above recommendations (EFSA, 2017, 2018, 2019a, 2021).

Aligned with the revised harmonised IRM plan, the objective of the sampling efforts was to collect approximately 1 000 larvae per population in the Ebro valley, which ultimately targets the detection of a 3% (recessive) resistance allele frequency, as suggested by EFSA (EFSA, 2016c). From the experience gained in 18 years of MON 810 PMEM, it was demonstrated that such collections are not always feasible. The target pest pressure and the number of larvae in the region have decreased drastically as reported by independent sources such as IRTA[16] since the introduction of MON 810 technology in the area. Similarly, area-wide suppression of pest pressure due to *Bt* maize was reported in other regions as presented by Hutchison[15] in the 27th IWGO conference in Switzerland. Consequently, despite intensified efforts on larvae collection, the significant reduction in the target pest populations over the years, as well as the occurrence of further drops in the pest populations due to various natural causes in certain growing seasons, may make collecting 1 000 larvae impossible. Bayer takes note also of EFSA's acknowledgment that "*under current conditions in north-eastern Spain, it is not feasible to collect enough larvae to reach the targeted threshold*" of the detection of a 3% resistance allele frequency (EFSA, 2021).

The only area identified in the entire EU region in 2020 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, larval sampling of *O. nubilalis* and *S. nonagrioides* for the monitoring activities in the 2020 maize growing season concentrated in the Ebro valley as described in the 2019 revised IRM plan (Appendix 6) and as recommended by EFSA (EFSA, 2016a, 2016b, 2017, 2018, 2019a, 2020, 2021). No larval samples for *O. nubilalis* and *S. nonagrioides* were collected from the other growing areas as the adoption of MON 810 was below 60%.

Bayer also would like to reiterate that mortality prior to susceptibility testing is caused by many factors that cannot be fully controlled or predicted (*e.g.* larvae parasitism; poor fitness as the larvae are collected from areas with high adoption of MON 810 maize). The laboratories performing the bioassays have very broad experience working with larval populations of *O. nubilialis* and *S. nonagroides*. They have qualified staff and apply good experimental practices to generate high-quality data.

During the 2020 growing season, Bayer continued its field collection efforts for both target pests for the laboratory assays. In 2020, bioassays at a single diagnostic concentration (DC) estimated from historical MIC_{99} values were used to evaluate changes in susceptibility of the target pests to the Cry1Ab protein (*see* Appendix 7 and Appendix 8). This method increases the effectiveness and sensitivity of the assay (relative to concentration-response assays) for detecting changes in susceptibility to the Cry protein. Therefore the use of a diagnostic concentration assay is appropriate based on the monitoring goals (detecting resistance at low frequencies), the experience gained, and expert opinions in the scientific literature (Roush and Miller, 1986; Sims *et al.*, 1996).

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[16] 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 16 September 2021)

As reported previously (Bayer Agriculture BVBA, 2018, 2019; 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 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 maximise the power of the DC assays, which required focusing resources on the DC assays. Bayer considers, as further clarified in the 2021 post-adoption teleconference (Ref. AA/FS/yog – OC-2021 - 24516820), using this comprehensive data set gives the best estimate of the extremes of the susceptibility distribution which is the target for the DC calculation. If the DC is calculated based on data from a different region, the natural variability may differ between regions leading to an inaccurate calculation. To reinforce the correct interpretation of the DC results, in the 2021 post-adoption teleconference (Ref. AA/FS/yog – OC-2021 - 24516820), Bayer presented also the added value of using the reference population as an additional point of comparison to MIC_{99} in determination of changes in susceptibility of the target pests to the Cry1Ab protein.

As can be seen in Appendix 7 and Appendix 8, a continued effort also has been made to harmonise the methodologies of the diagnostic bioassays between the two species as recommended by EFSA (2019a): 1) The field larvae collected from the different sampling zones were reared separately and tested independently; 2) Reference strains were included as an additional control in the DC assays; 3) All larvae surviving from the DC bioassays were fed with MON 810 leaves in the confirmatory feeding tests with plant material; 4) Conventional maize was included as a control in the confirmatory feeding tests with plant material; 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*); and 5) Testing to determine the expression of the Cry1Ab protein (using commercial test strips) in the *Bt*-maize leaves was conducted before confirmatory studies with plant material.

The results and the associated raw data of the bioassays for the resistance monitoring are reported in Appendix 7 and Appendix 8. No evidence was detected of a decrease in Cry1Ab susceptibility of *O. nubilalis* and *S. nonagrioides* during the monitoring duration.

Alternatives to single DC assays for resistance monitoring

Bayer takes note of the EFSA's recommendation that the consent holder should "*increase the sensitivity and precision of the monitoring strategy by using a more sensitive testing method, like F2 screening. Periodic estimations of resistance alleles through F2 screening, together with a robust farmer complaint system should replace annual diagnostic concentration assays*" (EFSA, 2021). As explained in the 2021 post-adoption teleconference (Ref. AA/FS/yog – OC-2021 - 24516820), F2 screening is resource intensive and expensive because of the need to rear a large number of genetic lines and multiple insect generations IRAC, 2020). In regions outside of the EU, it is used regularly in a few cases with very high resistance risk (*e.g.* millions of hectares cultivation), high value markets, and consequently

well-developed technical capacity (dedicated labs) *e.g.*, maize and soybean pests in Brazil, and cotton pests in Australia. Therefore, the implementation of F2 screening for resistance monitoring of the MON 810 target pests in Iberia is considered disproportionate to the area of MON 810 cultivation in the region and the related risk for resistance development.

Other alternatives to F2 screening such as molecular assays and/or a modified F1 screen are possible if resistance is isolated from field populations, but only detect the relevant resistance allele. As no suitable Cry1Ab-resistant colonies exist for *O. nubilalis* and *S. nonagrioides*, these alternatives cannot be considered as options for the resistance monitoring at this time.

3.2.1.4 Farmer complaint system

Bayer and the seed companies offering MON 810 varieties have a robust farmer complaint system which provide a means for farmers to report any complaint related to 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 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 via the farmer complaint system versus the laboratory bioassay that can only be performed on limited field samples.

Farmers can complain to the seed suppliers about product-related issues 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 larval 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 harmonised IRM plan (Appendix 6) 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 through these networks, especially if it is related to efficacy. 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 performing weekly monitoring of pest incidences, including corn borers, in specific control points across the region. Similarly, in each region there are similar networks, like @RAIF_noticias in

Andalucía, which distributes alerts and information on pest incidences and plant health issues or the Gencat website[17] in Catalunya which distribute timely information about pest monitoring and insecticide treatments to provide farmer's information and advices.

During the 2020 growing season, Bayer representatives did not receive any complaint related to MON 810 target pest efficacy. As in previous years, a survey has been performed in Spain among Asociación Nacional de Obtentores Vegetales (ANOVE, the National Breeder Association in Spain)[18] member companies commercializing MON 810 maize to have an overview of the farmer complaint schemes (ANOVE, 2020). The effectiveness of the system was demonstrated because a total of 748 complaints were received related to any issue with maize seeds, by the companies which are marketing MON 810. Two complaints were received related to the efficacy of MON 810. The complaints initially reported by farmers as poor efficacy performance of MON 810 were subjected to further investigation but none of them were related to efficacy on corn borers. In one case it was a misunderstanding on variety planted and it was confirmed that the variety was a conventional one. The other case was an attack of Helicoverpa spp. The high number of complaints indicate that this communication route is well-established within the farming community.

In addition to the independent program to collect farmers complaints that each company commercialising MON 810 has set and committed to report, the TUG in Spain (Appendix 3) encourages farmers to survey regularly their fields and report any suspect of resistant larvae either through the marketing routes or through the common additional contact point "prep@anove.es", managed by ANOVE.

3.2.1.5 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 program 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 2020 planting season in Spain (the main country growing MON 810), a number of activities were taken place to emphasise the importance of refuge implementation. A comprehensive program to maintain the awareness of refuge requirements was continued through education of personnel, distributors, cooperatives and individual farmers, as for all the previous years. The educational 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 by physical an electronic means.
2) Stewardship requirements and IRM compliance for MON 810 cultivation are reviewed and extensively communicated with licensee companies and Bayer sales teams every

[17] Gencat: http://agricultura.gencat.cat/ca/ambits/agricultura/dar_sanitat_vegetal_nou/avisos-fitosanitaris/ - Accessed on 14 October 2021

[18] Asociación Nacional de Obtentores Vegetales: http://www.anove.es/ - Accessed on 12 August 2021

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 2020, the following actions were taken:

a. Advertisement about refuge compliance, articles and references to the TUG were published in key agricultural magazines (*see example in* Appendix 9.1.). Information about IRM was also posted in ANOVE website, blog and actively distributed by campaigns in social media targeting planting dates.

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 9.2).

c. Sales and marketing teams of ANOVE members were encouraged to include IRM requirements in farmer meetings, farmer talks, fairs, exhibitions, etc. As in the previous seasons, summary slide decks, roll up, posters and other communication materials highlighting the farmers obligations were made available and each company committed to widely use it (*see* Appendix 9.3 and 9.4).

d. Posters reminding the obligation to plant a refuge distributed among seed distributors and point of sales (*see* Appendix 9.3).

e. Communication plan for cooperatives, small points of sales and farmers: Trained ANOVE inspectors completed 98 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. The 100% of the interviewed entities (most of them marketing MON 810 varieties but also conventional maize varieties) considered that farmers in their area are 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 9.1).

3) As in previous seasons, ANOVE working group of *Bt* maize continue encouraging authorities in Spain to endorse the IRM plan and refuge obligations in their own communication and education streams. Copies of the IRM materials are sent every season to regional and national authorities to wider distribute among the agricultural

networks and some regional authorities have added them in their technical bulletins and/or other communication materials[19].

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 maintain awareness on refuge implementation (Section 3.2.1.1 of this report). As reported in Appendix 1, 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 attributable to the cultivation of MON 810 in the EU.

[19] Example IRM advertisement in Aragon (Spain)*:* https://www.aragon.es/-/organismos-modificados-geneticamente (Accessed on 16 September 2021).

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 program 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 pest 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 2020, 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 (97.6%).

The results of the analysis of 2020 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. The literature search 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 2020 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 the EU in 2020. This is consistent with the observation that also on a global level no Cry1Ab 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 16 PMEM reports covering 18 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. Results from the farmers questionnaires confirmed that the cultivation of MON 810 resulted in a significant reduction in the use of pesticides, efficient protection against the target pests, and healthier, higher yielding crops compared to conventional maize aligned with the EU goals for sustainable food production.

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 18 years of experience with MON 810 cultivation in the EU, more than 3 750 farmers

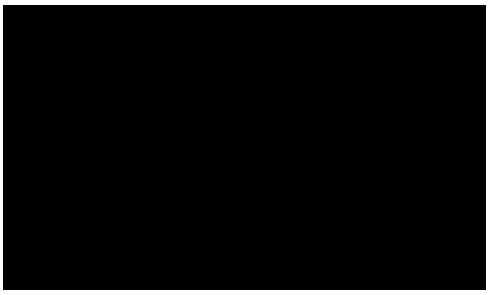
questionnaires confirming the safety of MON 810 cultivation in the EU, more than 23 years of experience worldwide on millions of hectares, multiple PMEM reports for the EU reporting on the commercial experience confirming the initial conclusions of the risk assessment (and endorsed by EFSA), and absence of confirmed adverse effect related to the event. All together, these results demonstrate that there are currently no adverse effects attributable to the cultivation of MON 810 in the EU. The result of the 2020 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 18 years in the EU, 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 harmonised approach for environmental monitoring of these different *Bt* maize events and together developed the harmonised IRM plan (Appendix 6) for case-specific monitoring, which is currently a condition of the MON 810 authorisation in the EU.

Taking account of the experiences gained during the past 16 years from the general surveillance of MON 810 cultivation in Europe and the conclusions of the 10 years meta-analysis (Bertho *et al.*, 2020), 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.

Signed: 

Date: **15 October 2021**

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Copyright protected scientific publications that are cited to support the MON 810 PMEM report are shared only with the regulatory authorities involved in the assessment of the report. Therefore, any further distribution of these publications in a manner not specified in the current copyright order, including posting on websites, and without appropriate authorisation, may be an infringement of copyright rules. Therefore, the full text documents of these scientific publications are provided only in the confidential version of the report.

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Appendix 1. POST MARKET MONITORING OF INSECT PROTECTED *BT* MAIZE MON 810 IN EUROPE – BIOMETRICAL ANNUAL REPORT ON THE 2020 GROWING SEASON

Appendix 2. 2020 MON 810 FARMER QUESTIONNAIRE

Appendix 3. EXAMPLES OF TECHNICAL USER GUIDES

Appendix 3.1. PORTUGAL_TUG

Appendix 3.2. SPAIN_TUG

Appendix 4. 2020 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 2020 – MAY 2021)

Appendix 6. HARMONISED INSECT RESISTANCE MANAGEMENT (IRM) PLAN FOR CULTIVATION OF *BT* MAIZE (SINGLE INSECTICIDAL TRAITS) IN THE EU, April 2020

Appendix 7. INSECT RESISTANCE MONITORING REPORT FOR *SESAMIA NONAGRIOIDES* (MCB) ASSOCIATED WITH MON 810 MAIZE CULTIVATION IN THE EU: SEASON 2020

Appendix 8. INSECT RESISTANCE MONITORING REPORT FOR *OSTRINIA NUBILALIS* (ECB) ASSOCIATED WITH MON 810 MAIZE CULTIVATION IN THE EU: SEASON 2020

Appendix 9. IBERIAN REFUGE IMPLEMENTATION COMMUNICATION MATERIALS

Appendix 9.1. IRM ADVERTISEMENT EXAMPLE (article in Ag magazine)

Appendix 9.2. POSTCARD ON IRM ADVERTISEMENT AND COMMUNICATION 2020

Appendix 9.3. POSTER ON REFUGE REQUIREMENTS

Appendix 9.4. ROLL UP FOR COMMUNICATION ON REFUGES