Annual monitoring report on the cultivation of MON 810 in 2022

Portugal and Spain

Submitted by

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1. GENERAL INFORMATION

Using modern biotechnology, Bayer CropScience LP developed insect-protected maize MON 810 (YieldGard®[1] maize) that produces the naturally occurring *Bacillus thuringiensis (Bt)* protein, Cry1Ab. MON 810 is protected from feeding damage by the European corn borer (*Ostrinia nubilalis*) and the pink stem borer (*Sesamia nonagrioides*).

In 1995, Bayer CropScience LP, then Monsanto Company[2], 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[4]. 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)[5] 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[6]. 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

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1 YieldGard is a registered trademark of Monsanto Technology LLC.

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

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 25 July 2023)

4 European Commission, 1998. Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON 810), pursuant to Council Directive 90/220/EEC (Accessed 25 July 2023).

5 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.

6 EFSA, 2009, Scientific opinion on applications (EFSA-GMO-RX-MON 810) for renewal of authorisation for the continued marketing of (1) food containing, consisting of, or produced from genetically modified maize MON 810; (2) feed containing, consisting of, or produced from maize MON 810; (3) other products containing or consisting of maize MON 810 with the exception of cultivation, all under Regulation (EC) No 1829/2003 from Monsanto. (Accessed 25 July 2023).

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; 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 [7]. 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 of 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[8].

In 2022, MON 810 was planted in the EU on approximately 69 910 hectares in two countries: 2 290 ha and 67 620 ha in Portugal and Spain, respectively[9,10].

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, since 2005 Bayer 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 (please refer to Annex 1). Since 2010, the reports follow the format as laid out in Annex I to Commission Decision 2009/770/EC [11] and confirm consistently and repeatedly the initial conclusions on the safety of MON 810.

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[7] European Commission, 2016. Commission implementing decision (EU) 2016/321 of 3 March 2016 adjusting the geographical scope of the authorisation for cultivation of genetically modified maize (Zea mays L.) MON 810 (MON-ØØ81Ø-6). (Accessed 25 July 2023).

[8] European Commission, 2017. Commission implementing decision (EU) 2017/1207 of 4 July 2017 renewing the authorisation for the placing on the market of genetically modified maize MON 810 (MON-ØØ81Ø-6) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. (Accessed 25 July 2023).

[9] DGAV, 2022. Cultivo de milho geneticamente modificado em 2022 - Resumo dos dados nacionais (Accessed 26 July 2023)

[10] MAPA, 2022. Estimación de la superficie total de variedades omg cultivadas en España. (Accessed 26 July 2023)

[11] European Commission, 2009. Commission Decision of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (Accessed 25 July 2023).

1.1 Crop/trait(s): Maize/insect protection

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 2022 - June 2023

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

- **Annual general surveillance report in 2022/2023 season for MON 810 maize authorised in accordance with Commission Implementing Decision (EU) 2017/1207 …… November 2023**

2. EXECUTIVE SUMMARY

In 2022, MON 810 was planted in the EU on approximately 69 910 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 2022 cultivation of MON 810 maize in Europe is detailed in this report.

The planting of MON 810 in the 2022 season was accompanied by a rigorous IRM plan involving five main elements: farmer education, refuge implementation, a farmer complaint system, susceptibility monitoring and good stewardship practices. The initiatives developed to educate farmers about the importance of the implementation of IRM measures were continued in 2022. The success of these initiatives was reflected in repeatedly 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 2022 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 2022. No complaint allegedly caused by reduced target pest susceptibility to MON 810 was received from farmers in 2022.

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 2022, Bayer continued its General Surveillance monitoring program, implemented on a voluntary basis, aiming 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 farmer questionnaires, one of the implemented General Surveillance monitoring programs, were revised in 2022 growing season considering the EFSA recommendations and the experiences gained over the past 16 years. From the two European countries cultivating MON 810, the farmer questionnaires survey also concentrated on Spain. It was considered no longer necessary to conduct the farmer questionnaires in Portugal as an independent annual survey is conducted by the authorities.

In 2022, the analysis of 250 farmer questionnaires survey in Spain did not reveal any adverse effects associated with the genetic modification in MON 810. This is consistent with the conclusions of the 16 precedent annual farmer questionnaires surveys and the 10-years meta-analysis (Bertho *et al.*, 2020) conducted since the MON 810 commercial cultivation. Furthermore, a detailed analysis of five publications related to MON 810 did not reveal any new scientific evidence that would invalidate the conclusions of the initial risk assessment. Also, company stewardship activities did not reveal any adverse effects related to MON 810 cultivation in 2022. Taken together, these results demonstrate that there are no indications of adverse effects attributable to the cultivation of MON 810 in Europe in 2022.

3. MONITORING RESULTS

3.1 General Surveillance

3.1.1 Introduction

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[12] 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 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 on the one hand, and implementation of practicalities and proportionality (hypothesis driven) on the other hand.

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 18 post-market environmental monitoring (PMEM) reports covering 19 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 (Annex 1). 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. Bayer's

[12] 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.

company-internal processes for managing product related incidents and complaints did not identify adverse effects caused by MON 810.

For the farmer questionnaires, a sample size of 2 436 interviews was calculated to achieve the demands as reported previously (Annex 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. During 2005-2021 growing seasons, **more than 4 100 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**. None of the farmer questionnaires survey reports identified any statistically meaningful effect indicating adverse effects of MON 810 to human or animal health, or the environment. The intended beneficial effects were rather observed as being evaluated in MON 810 fields compared to conventional maize fields. In 2015, a meta-analysis was conducted since a total of 2 500 farmer questionnaires, the targeted sample size at the start of the farmer questionnaires' survey, was reached after 10 years of the survey (Annex 1: Monitoring reports 1.1 to 1.10). The results of the meta-analysis confirmed once again, as reported in every annual report, the initial conclusions of the risk assessment: MON 810 is as safe as conventional maize and there are no adverse effect on human or animal health, or the environment due to MON 810 cultivation (Bertho *et al.*, 2020). The data collected in the subsequent MON 810 growing seasons (Annex 1: Monitoring reports 1.11 to 1.18) also confirmed that no adverse effects are associated with MON 810 cultivation. Therefore, based on this extensive information, and the spirits of Directive 2001/18/EC, the Council Decision 2002/811/EC, and the 2011 EFSA guidance which advise adaptations in the PMEM as necessary, we reiterate our proposal to limit the conditions for the general surveillance to literature searches and the farmer complaint systems.

In 2022 growing season, Bayer continued with conducting the farmer questionnaire surveys regardless of the existing extensive weight of evidence demonstrating that such monitoring activity is disproportionate and unjustified to the risks associated with the MON 810 cultivation. The 2022 farmer questionnaires were, however, revised considering the EFSA recommendations, the experiences gained over the past 16 years of the survey and the stage of the MON 810 technology since its commercialisation. The farmer questionnaires survey also concentrated on Spain from the two European countries cultivating MON 810. Since an independent annual survey is conducted by the Portuguese authorities, it is considered no longer necessary to conduct the farmer questionnaires in Portugal. As in the previous years, the 2022 farmer questionnaires survey report identified no statistically meaningful effect indicating adverse effects of MON 810 to human or animal health, or the environment.

As a third pillar of the implemented GS, Bayer has identified and reported more than 499 relevant publications on the safety of MON 810. Most of the publications are authored by independent academics and scientists. Allegations on the safety of MON 810 were thoroughly reviewed to confirm in case they might influence the risk assessment of MON 810 for food and feed uses and on the environment. No relevant publications were identified that would invalidate the initial conclusions of the MON 810 risk assessment.

Finally, the value of using the EENs reports 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[12] 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).

Overall, all the previous 18 PMEM reports, covering 19 years of MON 810 cultivation in the EU, support the initial conclusions in the initial application of the MON 810 authorisation, *i.e.*, MON 810 is as safe as conventional maize for food and feed uses and the environment (Annex 1). After reviews of these Bayer monitoring reports, other regulatory submissions on MON 810, relevant scientific literatures published since 2009 and various Member State comments related to the safety of MON 810, EFSA also consistently concluded that there is no specific scientific evidence that would invalidate the initial conclusions of the EFSA GMO Panel risk assessments of MON 810, *i.e.* "*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*" (Annex 2). 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 20 years of experience with MON 810 cultivation in the EU,
- more than 25 years of experience worldwide on millions of hectares of MON 810 cultivation,
- 18 PMEM reports for the EU reporting on the commercial experience confirming the initial conclusions of the MON 810 risk assessment (and endorsed by EFSA),
- absence of demonstrated field resistance in the EU for the targeted pests, and
- absence of evidence indicating adverse effect related to MON 810.

Bayer acknowledges the several recommendations made by EFSA to improve the methodology on how to perform GS on MON 810 monitoring (Annex 2: EFSA statements 2.3 to 2.13). For the 2022 growing season, Bayer has adapted its monitoring approaches where feasible, taking into consideration the EFSA recommendations, the experiences gained on MON 810 monitoring and the already established methodologies. Considering the accumulated experience after 20 years of extensive cultivation and the 18 years voluntary GS activities[4], it is evident that the current annual PMEM has become disproportionate to the available weight-of-evidence. Therefore, Bayer calls for a fit for purpose adaptation on MON 810 GS monitoring program. Bayer reiterates the need for adaptation of the monitoring plan and associated methodology based on the extensive information aligned with the spirits of Directive 2001/18/EC, the Council Decision 2002/811/EC, and the 2011 EFSA guidance[13] which advise adaptations in the PMEM as necessary.

3.1.2 Description of General Surveillance

Bayer continued in 2022 the GS monitoring program initiated on a voluntary basis in 2005. The objective of the 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

[13] EFSA, 2011. Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. (Accessed on 26 July)

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[13].

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 2022 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.

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

3.1.3.1 Farmer questionnaire

Since 2005, more than 4100 farmers have been questioned on their experience with MON 810 and in particular on any observations or effects in the field that were different for MON 810 compared to conventional maize hybrids. None of the farmer questionnaires survey reports identified any statistically meaningful effect indicating adverse effects of MON 810 to human or animal health, or the environment. The intended beneficial effects were rather observed as being evaluated in MON 810 fields compared to conventional maize fields. In 2015, a total of 2 500 farmer questionnaires, the targeted sample size at the start of the farmer questionnaires survey, was reached after 10 years of the survey which allowed to run a meta-analysis (Annex 1: Monitoring reports 1.1 to 1.10). The results of the meta-analysis confirmed also the initial conclusions of the risk assessment: MON 810 is as safe as conventional maize and there are no adverse effect on human or animal health, or the environment due to MON 810 cultivation (Bertho *et al.*, 2020). The data collected in the subsequent MON 810 growing seasons (Annex 1: Monitoring reports 1.11 to 1.18) also confirmed that no adverse effects are associated with MON 810 cultivation.

After 16 years of comprehensive monitoring activities in Europe and millions of hectares grown globally there is no plausible hypothesis to suspect adverse effects associated with MON 810 cultivation will occur. The Council Decision 2002/811/EC and the 2011 EFSA guidance on PMEM of genetically modified plants[13] 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 the EFSA guidance, "*the monitoring results and experience may lead to adjustments of certain parts of the original monitoring plan"*. Therefore, based on the extensive information on MON 810 farmer questionnaires, and the spirits of Directive 2001/18/EC, the Council Decision 2002/811/EC, and the 2011 EFSA guidance[13] which advise adaptations in the PMEM as necessary, it is evident that further farmer questionnaire surveys would have of limited value to the MON 810 GS monitoring program. In line with this, Bayer has requested the European Commission and the national authorities of MON 810 cultivating countries to consider a science-based approach for monitoring MON 810 cultivation in the following years and to demonstrate consistency on not adding unjustified barriers to the use of technologies that could contribute to the Farm to Fork and Biodiversity strategies.

In 2022 growing season, Bayer continued with conducting the farmer questionnaire surveys regardless of the existing extensive weight of evidence demonstrating that continuing with such monitoring activity is disproportionate and unjustified to the risks associated with the MON 810 cultivation. The 2022 farmer questionnaires were, however, revised considering the EFSA recommendations (Annex 2: EFSA statements 2.24, 2.25, 2.26), the experiences gained over the past 16 years of the survey and the stage of the MON 810 technology since its commercialisation. The 2022 revised farmer questionnaires featured a new set of questions, two-waves interview structure that covered timely specific questions (after sowing: July 2022; and after harvesting: January 2023), improved comparison between MON 810 and conventional maize, and a transition to digital data collection, while maintaining the original goal of monitoring MON 810 cultivation's influence on safeguarding objectives (*see* Appendix 2).

The 2022 farmer questionnaires for MON 810 focused on Spain which accounted for 95,81% of the MON 810 plantings in the EU in 2021, 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 extension services (insect pest pressure). Considering the limited MON 810 cultivation area in Portugal and that the annual farmer interviews are conducted in Portugal by the Portuguese authorities, additional farmer questionnaire survey in Portugal was considered not necessary.

In 2022, 250 farmers in Spain were asked to complete the questionnaire. As in the previous years, the sample size 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). The farmers/fields were randomly selected depending on the market distribution (*see* Appendix 1 for details on methodology).

The interviewers were able to complete the targeted numbers of the farmer questionnaires in two waves of interviews as indicated above during the growing season. The interviews were performed by bithA[14], a qualified, independent company incorporating personnel with vast experience in the conduct of farmer questionnaires surveys including those associated to post-market monitoring of MON 810 cultivation. All interviewers have been involved since the beginning of the farmer questionnaires and are well trained and equipped to conduct the interviews. Experience gained during surveys (uncertainties, misinterpretation of questions) were shared and resolved as necessary. The 'user manual' developed previously was amended

[14] bithA - Bio_Investigation to Health for Animal and Agriculture - https://www.bitha.org/ (Accessed on 03 October 2023).

to appropriately assist the interviewers in filling in the revised questionnaires with the farmers (*see* Appendix 4).

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

Part 1: Maize growing area

Responses to this section will enable records of general/ basic data on maize cultivation, local insect and weed pressure (independent from GM or non-GM cultivation – background and possible influencing factors). It includes questions on location, size and number of fields of the maize cultivated areas, maize varieties grown, local insect pest and weed pressure in maize fields.

Part 2: Observations on integrated pest management (IPM) practices in MON 810 maize (compared to conventional maize)

Questions in this section aim to establish the IPM practices employed to control corn borer in MON 810 maize compared to conventional maize. The data collected in this section constitute a baseline against which the IPM practices in conventional and MON 810 maize can be compared. It includes questions on 'adjustable factors', *e.g.* crop rotation, maize sowing and harvesting periods, and corn borer control practices.

Part 3: Observations on development and performance of MON 810 maize (compared to conventional maize)

Questions in this section collect information to assess the development and performance of MON 810 maize compared to conventional maize. It includes questions on 'monitoring parameters' for comparison with conventional maize, *e.g.* any unusual observation on growth performance (germination, emergence, flowering, incidence of stalk/root lodging, maturity, yield, volunteers, non-target organisms, susceptibility to diseases, susceptibility to *Bt* non-target insect pests, etc.

Part 4: Implementation of insect protected maize event specific measures

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

For further details on the above specific areas, *see* Appendix 4.

3.1.3.2 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 3.2.1.5.

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[12,15] and Bayer[16] websites offer a contact point.

3.1.3.3 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 3.1.5.5)),
- 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[12] 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[12] 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*" [17].

3.1.4 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

[15] CropLife Europe contact webpage - https://croplifeeurope.eu/contact-us/ (Accessed 26 July 2023).
[16] Bayer product stewardship webpage - https://www.bayer.com/en/product-stewardship.aspx, www.dekalb.es and www.dekalb.pt (Accessed 26 July 2023).
[17] EFSA, 2014. Scientific Opinion on the use of existing environmental surveillance networks to support the post-market environmental monitoring of genetically modified plants. (Accessed 26 July 2023).

guidelines. Examples of the documents distributed in the 2022 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 3.2.1.5. The TUG and other education materials jointly created by the National Spanish Breeder Association (ANOVE) have been also used by Spanish officials in their education and training activities on good agricultural practices for maize cultivation (*see* Section 3.2.1.5). In the case of Portugal, any farmer willing to start using MON 810 technology needs to accomplish with a training by officials or accredited trainers[18].

3.1.5 Results of General Surveillance

3.1.5.1 Farmer questionnaires

The analysis of 250 questionnaires from the survey of farmers cultivating MON 810 in Spain during the 2022 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. Note that 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.

In Portugal, an independent monitoring report on the planting of MON 810 varieties was prepared by the Portuguese authorities for the 2022 growing season[19]. The authorities interviewed a total of 16 farmers growing MON 810 maize. None of the farmers declared that any adverse effect related to the GM crop was observed. All the interviewed farmers reported rather a positive balance of the cultivation of MON 810 maize and a significant number referred 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 overall surveys (Portuguese authorities and Bayer) during the 2022 season show no adverse effects of MON 810 to human or animal health, or the environment.

3.1.5.2 Company stewardship activities

To date, no unexpected potential adverse effects related to MON 810 have been reported or confirmed.

3.1.5.3 Alerts on environmental issues

No confirmed adverse effects related to MON 810 were reported in 2022.

3.1.5.4 Additional information

Not applicable as no adverse effects were observed.

3.1.5.5 Literature search

A literature search that complies with the recommendations outlined in the 2019 EFSA explanatory note on literature searching [20] has been conducted on a quarterly basis covering the

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[18] DGAV. https://www.dgav.pt/wp-content/uploads/2021/02/Decreto-Lei-160-2005.pdf (Accessed on 26 July 2023).

[19] DGAV, 2023, Relatório De Acompanhamento de 2022. Coexistência entre Culturas Geneticamente Modificadas e outros Modos de Produção Agrícola. (Accessed 26 July 2023)

[20] EFSA, 2019. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market. (Accessed on 26 July 2023).

time span June 2022 – May 2023 and is provided along with the Literature checklist in Appendix 5.

Bayer confirms that the literature search, conducted in accordance with the 2019 EFSA explanatory note on literature searching[20] and within the context of general surveillance for MON 810 cultivation in the EU, identified no relevant publications that would invalidate the initial conclusions of the MON 810 risk assessment.

3.1.5.6 Information on MON 810 x teosinte hybrid interactions

Bayer takes note of EFSA's recommendation that the consent holder explicitly considers all new scientific evidence on teosinte relevant for the environmental risk assessment and risk management of maize MON 810, and revises farmer questionnaires in order to include the reporting of both the occurrence of teosinte and corresponding levels of infestation[21]. 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. Bayer reiterates our position explained in our letter of 14 January 2022 to the European Commission (Response to the Commission letter dated 30 September 2021 (Ref. Ares(2021)5946514)), and in our letter of 12 October 2022 to the European Commission (Response to the Commission letter dated 13 May 2022 (Ref. Ares(2022)3656126)) the emergence/occurrence of teosinte in Spain cannot be classified as information linked to the safety of MON 810, nor can it be regarded as information that influences the evaluation of the MON 810 safety in all uses as conventional maize, including cultivation. Also, a potential development of reduced susceptibility to MON 810, by the target insect pests, is highly unlikely to be affected by potential presence of teosinte or maize x teosinte hybrid plants as the impact would not be different from the presence of adventitious conventional maize.

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 general 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 19 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 consistent results of the farmer questionnaires conducted on a voluntary basis since 2005, do not provide any reason for concern as the observations related to weeds by all interviewed farmers stated to be not different for MON 810 versus conventional maize. The occurrence of teosinte in Spain is not an adverse effect originated by MON 810 introduction. Therefore, as stated in the letters of 14 January 2022 and 12 October 2022, Bayer reiterates that there is no reason to report on teosinte emergence/occurrence in light of the safety assessment of MON 810 maize. The management of this weed that affects maize fields in general should be addressed and reported with a separate action plan, considering the eradication measures already put in place by the authorities of the involved regions in Spain and with the collaboration

[21] EFSA, 2022. Update of environmental risk assessment conclusions and risk management recommendations of EFSA (2016) on EU teosinte (Accessed on 23 October 2023)

of the authorities and the companies marketing maize seeds. The collaboration frame has been established and Bayer highlights its willingness to continue contributing to it.

Regardless of the above, considering the repeated EFSA recommendations, Bayer confirms that the general surveillance, including the farmer questionnaires and the literature searches, did not identify any adverse effects attributable to MON 810 cultivation in the EU due to a potential presence of teosinte weeds in maize fields in the 2022 growing season.

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[22] 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* Annex 1: Monitoring report 1.8). 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 11 specific opinions on the monitoring conducted by Bayer on MON 810 in the 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019 and 2020 growing seasons (Annex 2: EFSA statements 2.9 to 2.26). 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[12] Monitoring working group updated the IRM plan in 2017 and amended in 2019, 2021 and 2023 (*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

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

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 3.2.1.5). 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 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 efforts by the different stated stakeholders (*see* Section 3.2.1.5), 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[23]; 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.).

During the 2022 growing season, 250 farmers across Spain where MON 810 was commercially cultivated were surveyed for their implementation of a refuge in the context of Bayer's GS program (*see* Appendix 1). All the farmers interviewed indicated that they followed the technical guidelines regarding the implementation of a refuge (73.2 % planted a refuge and 26.8 % had less than 5 ha planted with MON 810 on their farm[24]).

In Portugal, an independent monitoring report on the planting of MON 810 varieties (including IRM communication and refuge implementation) was prepared by the Portuguese authorities for the 2022 growing season[19]. In 2022, the Portuguese authorities provided online training sessions to 60 farmers. Since 2005, 1947 farmers have been trained to learn about the main characteristics of MON 810 maize and the national and EU legislations on regulation of cultivating GM varieties. Furthermore, 21 inspections were performed on farmers planting

[23] European Commission: https://ec.europa.eu/info/business-economy-euro/doing-business-eu/competition-rules_en - (Accessed on 25 July 2023)

[24] 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 69 cultivation notifications registered in 2022. These inspections showed full compliance, with no unconformity, with refuge and labelling requirements. In addition, 16 farmer questionnaires were completed by farmers growing MON 810 maize in Portugal. All the interviewed farmers stated that the technical information on the seed bags was sufficient and clear.

In conclusion, the results from the overall surveys (Portuguese authorities and Bayer) during the 2022 season show a high level of refuge compliance due to the growers' high awareness on refuge compliance and the continued efforts on grower education. Regardless, the message on the importance of refuge implementation was repeated in the 2022 cultivation season to Spanish and Portuguese farmers growing MON 810. 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[25]. 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 (Annex 1: Monitoring report 1.1). 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* (Annex 1: Monitoring reports 1.2 and 1.3). 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 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 (Annex1: Monitoring reports 1.2, 1.3, 1.4).

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

[25] 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 25 July 2023).

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[12] updated the IRM plan in 2017 (and amended in 2019, 2021 and 2023) 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 (Annex 2). Bayer follows fit-for-purpose methodologies gained through experience and in line with harmonised IRM plans allowing EFSA to conclude on changes in susceptibility of the targeted pest *O. nubilalis* and *S. nonagrioides* to the Cry1Ab protein in the MON 810 growing regions in the EU (Annex 2). 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)[26] in the 27th IWGO conference in Switzerland also confirmed the continued performance of *Bt* corn (Cry1Ab) in Canada. Nevertheless, considering EFSA recommendations (Annex 2: EFSA statements 2.10, 2.18, 2.21), 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 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 (Annex 2: EFSA statements 2.21, 2.22, 2.23, 2.25, 2.26).

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 (Annex 2: EFSA statement 2.7). From the experience gained in 20 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[27] 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

[26] 27th IWGO conference: https://www.switzerland2019.iwgo.org/WEBS/IWGO2019.pages.download/IWGO_2019_Scientific-Programme.pdf (Accessed on 26 July 2023)

[27] Catalunya Research Institute, IRTA, 2013: CONREU DE PANÍS PER A GRA VARIETATS. INCIDÈNCIA DE LES VIROSIS EN LA PRODUCCIÓ (Accessed 26 July 2023)

Hutchison[26] 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 welcomes also 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 (Annex 2: EFSA statements 2.25 and 2.26).

The only areas identified in the entire EU region in 2022 where adoption of MON 810 was greater than 60% were the Ebro valley and the Girona region (Northeast Iberia) in Spain; MON 810 adoption in other regions (Central Iberia, the Southwest of Spain and Portugal) was well below 60%. Therefore, in line with the harmonised IRM plan (Appendix 6) and the EFSA recommendations (Annex 2: EFSA statements 2.16 to 2.26), larval sampling of *O. nubilalis* and *S. nonagrioides* for the monitoring activities in the 2022 maize growing season concentrated in the Ebro valley and Girona. This was the first season in which larval samples were collected from Girona (new Zone 2). Due to their proximity, the former Zones 1 (Lanaja, Huesca) and 2 (Candasnos, Huesca) have been merged into one zone (Zone 1). Navarra remains as Zone 3. 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. Bayer welcomes also of EFSA's acknowledgment that "*rearing and maintenance of insect populations entails some practical challenges and that many factors contribute to mortality before susceptibility testing, and that it is not possible to control some of those (e.g. parasitism of corn borer larvae by hymenopteran species, insect pathogens)*" (Annex 2: EFSA statement 2.13).

During the 2022 growing season, Bayer continued its field collection efforts for both target pests for the laboratory assays. As in the previous years, in 2022, 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).

As reported previously (Annex 1: Monitoring reports 1.8, 1.9, 1.10), 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, when possible, as recommended by EFSA (Annex 2: EFSA statements 2.23 to 2.26). 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 for both species; 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; 5) 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 6) 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*" (Annex 2: EFSA statements 2.25 and 2.26). 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. 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 (Spain and Portugal) 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 Aragón, one of the Ebro Valley regions, the network Red Fitosanitaria Aragón[28] 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[29], which distributes alerts and information on pest incidences and plant health issues or the Gencat websit[30] in Catalunya, which distributes timely information about pest monitoring and insecticide treatments to provide farmers with information and advice. Other examples in other

[28] Red Fitosanitaria Aragón: https://web.redfara.es/ (Accessed on 10 November 2023)

[29] RAIF: https://www.juntadeandalucia.es/agriculturapescaaguaydesarrollorural/raif (Accessed on 10 November 2023)

[30] Gencat: http://agricultura.gencat.cat/ca/ambits/agricultura/dar_sanitat_vegetal_nou/avisos-fitosanitaris/ and https://ruralcat.gencat.cat/web/guest/avisos.fitosanitaris (Accessed on 10 November 2023)

regions in Spain: INTIA in Navarra[31], JUNTAEX in Extremadura[32], plant health service of Castilla la Mancha[33] and ITACYL in Castilla y León[34].

During the 2022 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 the Asociación Nacional de Obtentores Vegetales (ANOVE, the National Breeder Association in Spain)[35] and member companies commercializing MON 810 maize, to have an overview of the farmer complaint schemes (ANOVE, 2022). The effectiveness of the system was demonstrated because a total of 614 complaints were received related to any issue with maize seeds or maize cultivation (GM and non-GM). Only one complaint was received claiming to be related to the efficacy of MON 810. The complaint initially reported by the farmer as poor efficacy performance of MON 810 was further investigated and it was found that the reason for the low efficacy was not related to the MON 810 performance, but to a mixing of MON 810 seeds with conventional maize seeds. The high number of complaints received related to maize cultivation in general 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 Technical User Guide (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 (TUG) (*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 2022 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, 9.3 and 9.4) was included in seed bags and has been extensively distributed by physical and electronic means.

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[31] INTIA: https://estacionavisos.agrointegra.intiasa.es/ (Accessed on 10 November 2023)

[32] JUNTAEX: https://www.juntaex.es/buscador?sort=modified-&category=78612&category=78686&category=78724&tema=122329 (Accessed on 10 November 2023)

[33] Plant health service of Castilla la Mancha: https://www.castillalamancha.es/gobierno/actuaciones/bolet%C3%ADn-fitosanitario-de-avisos (Accessed on 10 November 2023)

[34] ITACYL: https://plagas.itacyl.es/ (Accessed on 10 November 2023)

[35] Asociación Nacional de Obtentores Vegetales: http://www.anove.es/ (Accessed on 26 July 2023)

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 2022, the following actions were taken:

   a. Information about IRM, including a video (Link: La importancia de las BUENAS PRÁCTICAS en la siembra de MAÍZ Bt), was posted in ANOVE website, blog and actively distributed by campaigns in social media targeting planting dates (Appendix 9.1, 9.2, 9.5 and 9.6).
   b. Each selling company (on behalf of ANOVE) committed to send timely reminder of refuge obligations at the planting season (*e.g.* e-postcard or e-poster by SMS to mobile phones) to farmers in their database located in MON 810 growing areas (*see* Appendix 9.1 and 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 9.1, 9.2, 9.3 and 9.4).
   d. Posters reminding the obligation to plant a refuge distributed among seed distributors and point of sales (*see* Appendix 9.2).
   e. Communication plan for cooperatives, small points of sales and farmers: Trained ANOVE inspectors completed 103 interviews to cooperatives and point of sales at planting time in all the 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 (103/103) 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, 9.2, 9.5 and 9.6).

3) As in previous seasons, the 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[36].

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, 94% of farmers

[36] Example IRM advertisement in Aragon (Spain): https://www.aragon.es/-/organismos-modificados-geneticamente (Accessed on 26 July 2023).

interviewed acknowledged they have been informed about the good agricultural practices applicable to MON 810. Users have received information through the TUGs 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

The GS monitoring results obtained via questionnaires (*see* Section 3.1.5.1 and Appendix 1), the scientific literature (*see* Section 3.1.5.5 and Appendix 5), company stewardship activities (*see* Section 3.1.5.2) and alerts on environmental issues (*see* Section 3.1.5.3) demonstrated that there are no adverse effects attributable to the cultivation of MON 810 in the EU.

The 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 2022.

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 2022, 94% 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 (100%).

The results of the analysis of 2022 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 2022 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 2022. This is consistent with the observation that also on a global level there have been no published reports of practical resistance to Cry1Ab 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 18 PMEM reports covering 19 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-year meta-analysis 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. It consists of 1) regulatory safety studies presented in the different EU applications, 2) more than a dozen EFSA opinions concluding on the safety of MON 810, 3) cultivation approvals for MON 810 in multiple countries around the world based on scientific risk assessment data and local safety opinions, 4) hundreds of peer reviewed publications relevant to the risk assessment of MON 810 and the expressed Cry1Ab protein, 5) more than 20 years of experience with MON 810 cultivation in the EU, 6) more than 4100 farmers questionnaires

confirming the safety of MON 810 cultivation in the EU, more than 25 years of experience worldwide on millions of hectares, 7) multiple PMEM reports for the EU reporting on the commercial experience confirming the initial conclusions of the risk assessment (and endorsed by EFSA), and 8) 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 results of the 2022 monitoring efforts are consistent with the results observed since monitoring was started in 2003.

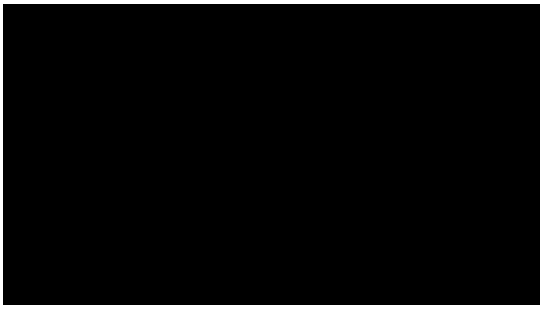
5. ADAPTATIONS OF THE MONITORING PLAN AND ASSOCIATED METHODOLOGY FOR FUTURE YEARS

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 20 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 on the previous monitoring plan (related to the resistance monitoring in the target pests as from the 2016 maize growing season (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. This report includes also adaptations implemented on the previous farmer questionnaires as from the 2022 maize growing season (Section 3.1) considering the EFSA recommendations, the experiences gained over the past 16 years of the farmer questionnaires survey and the stage of the MON 810 technology since its commercialisation.

Taking account of the experiences gained during the past 20 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 further future adaptations on the current general surveillance methodologies so that these will become proportionate to the existing extensive weight of evidence and the risks associated with MON 810 cultivation. We reiterate our proposal to limit the conditions for the general surveillance to literature searches and the farmer complaint systems. This is also in line with the spirits of Directive 2001/18/EC, the Council Decision 2002/811/EC and the 2011 EFSA guidance on PMEM of GM plants that advise adaptations in the PMEM in such circumstances.

Date: 15 November 2023

Signature: 

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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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Annex 1 Bayer monitoring reports

N°	Reference	Title and link to the document
1.1	Monsanto Europe S.A., 2005	Report on the implementation of the Insect Resistant Management plan for MON 810 in the European Union - MON 810 cultivation in Spain in 2003 and 2004.pdf. (Accessed on 26 October 2023)
1.2	Monsanto Europe S.A., 2006	Monitoring report - MON 810 cultivation - Czech Republic, France, Germany, Portugal and Spain - 2005. (Accessed on 26 October 2023)
1.3	Monsanto Europe S.A., 2007	Monitoring report - MON 810 cultivation - Czech Republic, France, Germany, Portugal, Slovakia and Spain - 2006. (Accessed on 26 October 2023)
1.4	Monsanto Europe S.A., 2008	Monitoring report - MON 810 cultivation - Czech Republic, France, Germany, Poland, Portugal, Romania, Slovakia and Spain - 2007. (Accessed on 26 October 2023)
1.5	Monsanto Europe S.A., 2009	Monitoring report - MON 810 cultivation - Czech Republic, Germany, Poland, Portugal, Romania, Slovakia and Spain - 2008. (Accessed on 26 October 2023)
1.6	Monsanto Europe S.A., 2010	Annual monitoring report on the cultivation of MON 810 in 2009: Czech Republic, Portugal, Slovakia, Poland, Romania and Spain. (Accessed on 25 July 2023).
1.7	Monsanto Europe S.A., 2011	Annual monitoring report on the cultivation of MON 810 in 2010: Czech Republic, Poland, Portugal, Romania, Slovakia, and Spain (Accessed on 25 July 2023).
1.8	Monsanto Europe S.A., 2012	Annual monitoring report on the cultivation of MON 810 in 2011: Czech Republic, Poland, Portugal, Romania, Slovakia, and Spain (Accessed on 25 July 2023).
1.9	Monsanto Europe S.A., 2013	Annual monitoring report on the cultivation of MON 810 in 2012: Czech Republic, Portugal, Romania, Slovakia, and Spain. (Accessed on 25 July 2023).

1.10	Monsanto Europe S.A., 2014	Revised annual monitoring report on the cultivation of MON 810 in 2013: Czech Republic, Portugal, Romania, Slovakia, and Spain. (Accessed on 25 July 2023).
1.11	Monsanto Europe S.A., 2015	Annual monitoring report on the cultivation of MON 810 in 2014: Czech Republic, Portugal, Romania, Slovakia, and Spain. (Accessed on 25 July 2023).
1.12	Monsanto Europe S.A., 2016	Annual monitoring report on the cultivation of MON 810 in 2015: Czech Republic, Portugal, Romania, Slovakia, and Spain. (Accessed on 25 July 2023).
1.13	Monsanto Europe S.A., 2017	Annual monitoring report on the cultivation of MON 810 in 2016: Czech Republic, Portugal, Slovakia, and Spain. (Accessed on 25 July 2023).
1.14	Bayer Agriculture BVBA, 2018	Annual monitoring report on the cultivation of MON 810 in 2017: Portugal and Spain. (Accessed on 25 July 2023).
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1.16	Bayer Agriculture BV, 2020	Annual monitoring report on the cultivation of MON 810 in 2019: Portugal and Spain. (Accessed on 25 July 2023).
1.17	Bayer Agriculture BV, 2021	Annual monitoring report on the cultivation of MON 810 in 2020: Portugal and Spain. (Accessed on 25 July 2023).
1.18	Bayer Agriculture BV, 2022	Annual monitoring report on the cultivation of MON 810 in 2021: Portugal and Spain. (Accessed on 25 July 2023).

Annex 2 EFSA statements

N°	Reference	Title and link to the document
2.1	EFSA, 2004	Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC1 (Question No EFSA-Q-2004-062). (Accessed on 25 July 2023)
2.2	EFSA, 2005	Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safeguard clause invoked by Hungary according to Article 23 of Directive 2001/18/EC. (Accessed on 25 July 2023)
2.3	EFSA, 2006	Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safeguard clause invoked by Greece according to Article 23 of Directive 2001/18/EC and to Article 18 of Directive 2002/53/EC (Question No EFSA-Q-2006-048). (Accessed on 25 July 2023)
2.4	EFSA, 2008	Request from the European Commission related to the safeguard clause invoked by Greece on maize MON 810 according to Article 23 of Directive 2001/18/EC. (Accessed on 25 July 2023)
2.5	EFSA, 2008	Request from the European Commission related to the safeguard clause invoked by Hungary on maize MON 810 according to Article 23 of Directive 2001/18/EC. (Accessed on 25 July 2023)
2.6	EFSA, 2012	Scientific Opinion on a request from the European Commission related to the emergency measure notified by France on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003. (Accessed on 25 July 2023)
2.7	EFSA, 2012	Scientific Opinion on an application (EFSA-GMO-NL-2012-107) for the placing on the market of maize MON 810 pollen under Regulation (EC) No 1829/2003 from Monsanto. (Accessed on 25 July 2023)
2.8	EFSA, 2012	Scientific Opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations for the cultivation of the genetically modified insect resistant maize Bt11 and MON 810. (Accessed on 25 July 2023)

2.9	EFSA, 2012	Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2010. (Accessed on 25 July 2023)
2.10	EFSA, 2013	Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2011. (Accessed on 25 July 2023)
2.11	EFSA, 2013	Scientific Opinion on a request from the European Commission related to the emergency measure notified by Italy on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003. (Accessed on 25 July 2023)
2.12	EFSA, 2013	Scientific Opinion on a request from the European Commission related to the emergency measure notified by Luxembourg on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003. (Accessed on 25 July 2023)
2.13	EFSA, 2014	Statement on a request from the European Commission related to the emergency measure notified by Greece on genetically modified maize MON 810 according to Article 18 of Directive 2002/53/EC. (Accessed on 25 July 2023)
2.14	EFSA, 2014	Scientific Opinion on the annual post-market environmental monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2012. (Accessed on 25 July 2023)
2.15	EFSA, 2015	Updating risk management recommendations to limit exposure of non-target Lepidoptera of conservation concern in protected habitats to Bt-maize pollen. (Accessed on 25 July 2023)
2.16	EFSA, 2015	Revised annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2013 from Monsanto Europe S.A. (Accessed on 25 July 2023)
2.17	EFSA, 2015	Relevance of a new scientific publication (Trtikova et al., 2015) on previous EFSA GMO Panel conclusions on the risk assessment of maize MON 810 and other Cry1Ab-expressing Bt-maize events. (Accessed on 25 July 2023)

2.18	EFSA, 2016	Annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2014 from Monsanto Europe S.A. (Accessed on 25 July 2023)
2.19	EFSA, 2016	Relevance of a new scientific publication (Bøhn et al., 2016) for previous environmental risk assessment conclusions on the cultivation of Bt-maize events MON 810 and Bt11. (Accessed on 25 July 2023)
2.20	EFSA, 2016	Relevance of a new scientific publication (Hofmann et al., 2016) for previous environmental risk assessment conclusions and risk management recommendations on the cultivation of Bt-maize events MON 810, Bt11 and 1507. (Accessed on 25 July 2023)
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Appendix 1. POST MARKET MONITORING OF INSECT PROTECTED *BT* MAIZE MON 810 IN EUROPE – BIOMETRICAL ANNUAL REPORT ON THE 2022 GROWING SEASON

Appendix 2. 2022 MON 810 FARMER QUESTIONNAIRE

Appendix 3. EXAMPLES OF TECHNICAL USER GUIDES

Appendix 3.1. PORTUGAL_TUG

Appendix 3.2. SPAIN_TUG

Appendix 4. 2022 FARMER QUESTIONNAIRE – USER'S MANUAL

Appendix 5. RESULTS OF ANNUAL LITERATURE SEARCH (JUNE 2022 – MAY 2023)

Appendix 6. HARMONISED INSECT RESISTANCE MANAGEMENT (IRM) PLAN FOR CULTIVATION OF *BT* MAIZE (SINGLE INSECTICIDAL TRAITS) IN THE EU, 2023

Appendix 7. INSECT RESISTANCE MONITORING REPORT FOR *SESAMIA NONAGRIOIDES* (MCB) ASSOCIATED WITH MON 810 MAIZE CULTIVATION IN THE EU: SEASON 2022

Appendix 8. INSECT RESISTANCE MONITORING REPORT FOR *OSTRINIA NUBILALIS* (ECB) ASSOCIATED WITH MON 810 MAIZE CULTIVATION IN THE EU: SEASON 2022

Appendix 9. IBERIAN REFUGE IMPLEMENTATION COMMUNICATION MATERIALS

Appendix 9.1. POSTCARD ON REFUGE REQUIREMENTS

Appendix 9.2. POSTER ON REFUGE REQUIREMENTS

Appendix 9.3. BAYER DEKALB WEBSITES SPAIN AND PORTUGAL

Appendix 9.4. BAYER DEKALB DIGITAL LIBRARY SPAIN AND PORTUGAL – 2022

Appendix 9.5. VIDEO FOR COMMUNICATION OF GOOD PRACTICES

Appendix 9.6. ANOVE COMMUNICATION ON REFUGE REQUIREMENTS IN SOCIAL MEDIA AND ANOVE BLOG