Annual post-market environmental report on the cultivation of maize MON 810 in 2016
Comments and opinions submitted by EU Member States (MS) during the consultation period

| EU MS | Organization | Reference¹ | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | EFSA’s response                                                                                                                                                                                                                                                                                                                                                     |
|-------|--------------|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AT    | Environment Agency Austria | General comment | The monitoring report was submitted in September 2017 by the consent holder Monsanto to the European Commission. The report summarizes the results of monitoring as conducted by the consent holder in 2016. The monitoring report at hands is similar in structure, approach and conclusions to the reports submitted in previous years. However, it includes a revised version of the insect resistance management (IRM) plan for cultivation of Bt maize in the EU (Appendix 6). Recommendations of EFSA suggested in the framework of their review of previous monitoring reports (EFSA 2011, 2012, 2013, 2014a, 2015b, 2016, 2017), or from Member States (MS), including Austria, were not taken fully into account by the consent holder. Overall the monitoring approach developed by the consent holder, which was criticized by EFSA and MS in many ways, was pursued again. Some improvements, however, were made to the revised IRM plan, which incorporates a number of recommendations previously provided by EFSA (2015a).
As a general conclusion Monsanto states that the monitoring as conducted did not identify adverse effects on the environment, human and animal health. Based on this outcome Monsanto concludes that this is demonstrating that the applied methodologies are fit for the purpose of identifying adverse effects (see Chapter 3.1). Austria considers that this argument is unfounded and not based on appropriate, science-based reasoning: An absence of evidence due to methodological shortcomings in our view cannot be considered as evidence for an absence of adverse effects.
Austria therefore reiterates his concern, that potential adverse effects might be overlooked due to the apparent methodological shortcomings of the monitoring as conducted by the consent holder. We also underline our previously notified concern that the repeated requests submitted by Austria as well as by other Member States asking for a substantial revision of the monitoring plan and the implemented monitoring measures are disregarded by EFSA assessed the dataset provided by the consent holder in the 2016 PMEM report and an additional relevant publication identified by EFSA (Camargo et al., 2018). The assessed information did not indicate any adverse effects on human and animal health or the environment arising from the cultivation of maize MON 810 during the 2016 growing season. EFSA therefore concluded that no new evidence has been reported in the context of the 2016 PMEM report that would invalidate previous GMO Panel evaluations on the safety of maize MON 810 (EFSA, 2009; EFSA GMO Panel, 2012a,b). However, EFSA identified some methodological and reporting limitations pertaining to insect resistance monitoring, farmer questionnaires and literature searching, and therefore updated its previous recommendations (e.g., EFSA, 2015; EFSA GMO Panel 2016, 2017) that should be implemented by the consent holder. |
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|       |              |            | the consent holder. | |
|       |              |            | In summary, the report provided by the consent holder for monitoring of cultivation of GM Maize MON 810 in 2016 lacks scientific strength and cannot be considered adequate for the monitoring of unexpected environmental effects as required by Directive 2001/18/EC. | |
|       |              |            | We therefore request further revision of the monitoring approach by the consent holder to address all remaining concerns raised by EFSA and Member States. | |
|       |              |            | EFSA Panel on Genetically Modified Organisms (2011a): Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 9(8), 2316. | |
|       |              |            | EFSA Panel on Genetically Modified Organisms (2011b): Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2009. EFSA Journal 9(10), 2376. | |
|       |              |            | EFSA Panel on Genetically Modified Organisms (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. EFSA Journal 10(4), 2610. | |
|       |              |            | EFSA Panel on Genetically Modified Organisms (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. EFSA Journal 11(12):3500. | |
|       |              |            | EFSA Panel on Genetically Modified Organisms (2014a): 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. EFSA Journal 12(6):3704. | |
|       |              |            | EFSA Panel on Genetically Modified Organisms (2015b): 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 2015. EFSA Journal 13(6):3909. | |

¹ Reference numbers correspond to the EFSA publications listed above.
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| AT    | Environment Agency Austria | 3.1. General Surveillance | maize MON 810 in 2013. The EFSA Journal 13(3), 1-11. EFSA Panel on Genetically Modified Organisms (2016): Scientific Opinion on the annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2014. The EFSA Journal 14(4): 4446, 26pp. EFSA GMO Panel (2017): Scientific Opinion on the annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2015 from Monsanto Eurpoe S.A. EFSA Journal 2017; 1585):4805, 27pp. | The GS measures reported in the revised report are associated with shortcomings, e.g., as detailed below for specific components of the system. We note that comparable shortcomings were identified and notified in previous years. To our disappointment the respective requests for improvement were not taken into account by the consent holder for preparation of the monitoring report at hands. We therefore consider the GS as conducted by Monsanto to be inappropriate. EFSA took note of the comment raised by Austria. During the assessment of the 2016 PMEM report, EFSA identified some limitations pertaining to general surveillance of maize MON 810 that need further consideration by the consent holder. Details on the recommendations for farmer questionnaires and literature searching can be found in Section 5.2 of the EFSA Statement. |
| AT    | Environment Agency Austria | 3.1. General Surveillance | As noted previously the use of data from existing environmental networks (EENs) in the framework of environmental monitoring is a crucial issue for PMEM. However the monitoring report at hand again fails to address this issue satisfactorily. Concerning the use of information from EENs for environmental monitoring the consent holder is primarily referring to Smets et al. (2014) as a source to conclude that EENs are not well suited as primary tools for GS. The consent holder argues that it is not possible for such a network to establish a relationship between a cause and an effect. This however is not the primary objective of GS, but rather the task of subsequent follow up activities in case adverse effects are identified, which may be due to the cultivation of MON 810. In addition the consent holder fails to take into account the implications of the opinion by In an external report commissioned by EFSA (Centre for Ecology and Hydrology et al., 2014) and in associated publications (e.g., Smets et al., 2014), several existing networks have been identified as potentially suitable for the general surveillance of genetically modified plants. Although the usefulness of such networks requires resolving issues pertaining to data accessibility, data reporting format, and data connectivity with GMO registers (EFSA GMO Panel, 2014), EFSA encourages relevant stakeholders to implement a methodological framework that enables the use of existing networks in the broader context of environmental monitoring (see Section 3.2.2.2 of the EFSA Statement). |
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|       |              | EFSA (2014b) providing a way forward to identify relevant EENs, which may be used in an improved monitoring approach. In spite of the fact that EENs are listed in the report as information sources in the general description of the implemented General Surveillance, no specific results are presented in Chapter 3.1.4.3. Nevertheless the consent holder concludes in the report that “No confirmed adverse effects related to MON 810 were reported in 2016”. This statement needs to be considered as unsubstantiated. Furthermore the significance of the statement ‘confirmed adverse effects’ should be explained. In our opinion a comprehensive system for involvement of environmental monitoring networks needs to be put in operation as soon as possible and should be designed to adequately address the specific needs of GMO monitoring (Züghart et al. 2011). If this cannot be achieved by the consent holder, he needs to suggest and implement an alternative strategy for monitoring of environmental parameters. |

EFSA Panel on Genetically Modified Organisms (2014b): Scientific Opinion on the use of existing environmental surveillance networks to support the post-market environmental monitoring of genetically modified plants. EFSA Journal 12(11):3883.

Züghart, W., Raps, A., Wust-Saucy, A.-G., Dolezel, M., Eckerstorfer, M. (2011): Monitoring of Genetically modified Organisms. A policy paper representing the view of the National Environment Agencies in Austria and Switzerland and the Federal Agency for Nature Conservation in Germany. Umweltbundesamt Wien, Reports, Volume |
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| AT    | Environment Agency Austria | 3.1.2.1. Farmer questionnaires | A main concern is that the survey conducted by the consent holder by means of farmer questionnaires does not adequately address environmental effects of the cultivation of GM maize MON 810 as required by Annex VII of Directive 2001/18/EC. The monitoring of unexpected environmental effects in our view needs thorough scientific assessment strategies rather than a "general interview format" addressed to farmers. Specifically impacts of GM maize MON 810 cultivation on biota other than pests directly interacting with the crop cannot be reliably monitored by means of farmer questionnaires, but need to be addressed by additional monitoring tools. If such an approach includes data generated by farmers, it needs to be assured that these data are quality assessed and complemented by scientific data generated by experts using appropriate scientific methods.

We thus reiterate our request that an independent scientific evaluation is provided to validate the results gathered by farmer questionnaires. Such a validation could be provided, e.g. by data gathered from existing environmental monitoring networks which are deemed relevant for GMO monitoring and operated in the focus areas of monitoring by farmer questionnaires. However no such validation was conducted by the consent holder (cf. Chapters 3.1.2.3 & 3.1.4.3). The current approach therefore cannot be considered appropriate, specifically for the assessment of impacts on non-target organisms and biodiversity in general. | The farmer questionnaire and the approach followed to identify unanticipated adverse effects caused by the cultivation of maize MON 810 are similar to those in previous annual PMEM reports. EFSA therefore reiterates previous observations on the methodology (e.g., sampling, comparator (non-GM) fields, type of questions and possible responses) and the analysis of data from the farmer questionnaire survey (EFSA GMO Panel, 2016, 2017). |

| AT    | Environment Agency Austria | 3.1.4.1 Farmer questionnaires & Appendix 1 | Moreover the results of the survey by farmers’ questionnaires conducted for the commercial use in 2016 (Appendix 1) seem to challenge the claims regarding the environmental benefits associated with cultivation of GM maize MON 810 made in the notification by Monsanto (see | The benefits associated with the cultivation of maize MON 810 are outside the remit of EFSA. |
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| AT    | Environment Agency Austria | 3.1.6 Review of peer-reviewed publications & Appendix 5 | It is appreciated that the consent holder presents extended information concerning the procedure of the literature review (extended data base search, list of all hits prior to selection of relevant publications, selection criteria applied) | EFSA assessed the systematic literature search performed by the consent holder according to the guidelines given in EFSA (2010, 2017). The overall quality of the performed literature search is acceptable. However, EFSA considers |
|       |              |           |         |                 |

EFSA-GMO-RX-MON 810, technical dossier, p. 28).
According to these data only 19 out of 250 farmers indicated a change in the use of insecticides compared to cultivation of conventional maize and attributed this specifically to a lack of need for control of corn borers in crops of GM maize MON 810. However no further specific information concerning the respective changes in pest control practice and no further discussion of the facts is presented. Overall the consent holder concludes that compared to conventional maize the farmers use nearly the same pest control practices for cultivating MON 810 (Appendix 1, p.80) which is in contradiction to prior claims by the consent holder concerning the assumed environmental benefits of the product.

Furthermore we note that no analysis of the pooled data from more than 10 years of surveys with farmers’ questionnaires is presented by the consent holder. Since data from multiple years are required to attain a sample size which allows to identify potential adverse effects, the assessment of pooled annual data, which was repeatedly requested by EFSA (e.g., EFSA 2016, 2017), is more appropriate to provide a robust analysis than the analysis of annual data. A respective analysis of pooled data should be presented by the consent holder.

EFSA Panel on Genetically Modified Organisms (2016): Scientific Opinion on the annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2014. The EFSA Journal 14(4): 4446, 26pp.

EFSA GMO Panel (2017): Scientific Opinion on the annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2015 from Monsanto Europe S.A. EFSA Journal 2017; 1585):4805, 27pp.
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| AT    | Environment Agency Austria | 3.2. Case specific monitoring & Appendix 6 | As in our comments directed to the monitoring reports submitted in the previous years, we are of the opinion that the ERA conducted for GM maize MON 810 is lacking adequate strength and is associated with significant uncertainties (see e.g. Eckerstorfer et al. 2007, Dolezel et al. 2011, Hilbeck et al. 2012, Holst et al. 2013). The implemented CSM should aim to adequately address remaining uncertainties of the risk assessment and the question whether the risk assessment conclusions are valid. Appropriate monitoring, e.g. of any adverse effects on non-target Lepidoptera and water dwelling organisms is thus regarded necessary to implement the precautionary approach in a case specific manner (compare Züghart et al. 2011 & 2008). Furthermore the conducted CSM should be based on an adequate monitoring of exposure of the various receiving environments to the transgenic Cry1Ab-toxin under cultivation conditions as recommended by Züghart et al. (2011). Lack of appropriate data on exposure under realistic conditions is one of the reasons why different approaches to modeling of the adverse effects of GM maize MON810 on non-target organisms, e.g. butterflies, are proposed and no consensus regarding the conclusions of the modeling exercises has been reached (cf. Holst et al. 2013, Lang et al. 2011, Perry et al. 2011, Lang et al. 2015, Hofmann et al. 2016, EFSA 2016b, Kruse-Plass et al. 20117, Perry et al. 2017). | that the methodology and reporting of literature searches on maize MON 810 could be improved further and therefore provided recommendations for future searches (see Section 3.2.3.2 of the EFSA Statement for further details). In addition, EFSA advises that future literature searches on maize MON 810 performed in the context of annual PMEM reports should follow the guidelines given in EFSA (2017). |

In its Scientific Opinion on the continued marketing of maize MON 810 (EFSA, 2009), the GMO Panel identified two areas of risk requiring risk management:

1) The potential exposure of non-target (NT) lepidopteran larvae to Bt-maize pollen deposited on their host plants in or near Bt-maize fields;

2) The potential for the target insect pests *Ostrinia nubilalis* (European corn borer) and *Sesamia nonagrioides* (Mediterranean corn borer) to evolve resistance to the Cry1Ab proteins expressed in maize MON 810.

For these two areas of risk, the GMO Panel advised that appropriate risk management measures to mitigate and monitor possible exposure of NT Lepidoptera, and insect resistance management strategies are or continue to be employed, in order to delay and monitor resistance evolution. The GMO Panel updated its Scientific Opinion on maize MON 810 accounting for new relevant scientific literature, and considered that its previous risk assessment conclusions on maize MON 810, as well as its previous recommendations for risk mitigation measures and monitoring, remained valid and applicable (EFSA GMO Panel, 2012a,b). Therefore, EFSA is of the opinion that a case-specific monitoring plan for non-target organisms (including non-target Lepidoptera and water-dwelling organisms) is not necessary.

EFSA assessed the methodology and results of the insect resistance monitoring activities performed in the 2016 growing season. EFSA noted that the IRM plan has been...
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|       |              |           | We appreciate that several important recommendations of EFSA (2011b, 2012, 2014, 2015 a&b) for improvement of the methodology for resistance monitoring were finally taken into account by the consent holder in his revision of the IRM plan (Appendix 6, published by EuropaBio in September 2017). The proposed changes will allow detecting resistance alleles at lower frequencies in the target pest population and thus increasing the time for mitigation measures to prevent resistance from spreading throughout the pest population: | revised with regards to the sampling strategy and monitoring protocol of ECB and MCB populations, accounting for some of the previously made EFSA recommendations, the experience gained with the implementation of the initial IRM plan, and relevant scientific publications. The analyses of the dataset provided by the consent holder do not indicate a decrease in susceptibility to the Cry1Ab protein of the corn borer samples tested in the 2016 growing season. However, EFSA identified some methodological and reporting limitations pertaining to the resistance monitoring that need further consideration by the consent holder. Detailed recommendations are provided in Section 3.1.2.2 of the EFSA Statement. | |
|       |              |           | - In areas where Bt maize adoption is high (i.e. above 80%) annual monitoring of both target pests will be implemented in subsequent years | EFSA also identified some limitations pertaining to the implementation of non-Bt-maize refuges, farmer questionnaires and literature searching, and therefore updated its previous recommendations that should be implemented by the consent holder (see Section 5 of the EFSA Statement). | |
|       |              |           | - In areas where multiple generations of target pests occur an annual sampling frequency will be implemented in case the adoption rate reaches 60% | | |
|       |              |           | - Additionally the consent holder commits to the sampling of 1000 larvae per area (i.e. about 350 larvae in each of the three sampling zones) as suggested by EFSA (EFSA 2015a), however states his concerns, that such an approach might not be feasible for all areas. | | |
|       |              |           | However we are concerned that other important recommendations by EFSA were not implemented as well. For example no attempts have been made by the consent holder to use the information recorded in national cultivation registers. This information could however be used to increase the representativeness of the farmers participating in the survey by farmers questionnaires or to establish data on adoption rates thus increasing the focus of monitoring activities. Such information would also be important for assessing compliance with the refuge requirements, especially in areas where the aggregated area planted with GM maize MON 810 is greater than 5 ha. This would be specifically important for EU MS with a | |
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|       |              |             | small-scale farmland structure, where the maize cropping area of individual farms typically would be less than 5 ha. In this respect it is noted that information on the compliance with the refuge requirements is once more only presented for Spain and Portugal as the survey based on farmers’ questionnaires was only conducted in those two MS and did not cover all MS with MON810 cultivation. Furthermore we regret that the consent holder did not comply with EFSA’s request to provide the raw data of the insect bioassays in future PMEM reports as well as LC-values in addition to MIC-values (EFSA 2017). Dolezel, M., Miklau, M., Hilbeck, A., Otto, M., Eckerstorfer, M., Heissenberger, A., Tappeser, B. & Gaugitsch, H. (2011): Scrutinizing the current practice of the Environmental Risk Assessment of GM Maize Applications for Cultivation in the EU. Environmental Sciences Europe 23: 33. Eckerstorfer, M., Heissenberger, A. & Gaugitsch, H. (2007): Supplementary Risk Assessment for GM maize MON 810 with regard to the conclusions of the WTO-Panel in the case “EC Biotech” on Austrian safeguard measures for GM maize. Band 4/2007. Wien, Bundesministerium für Gesundheit, Familie und Jugend, Sektion IV. Forschungsberichte der Sektion IV. EFSA Panel on Genetically Modified Organisms (2011b): Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON810 in 2009. EFSA Journal 9(10), 2376. EFSA Panel on Genetically Modified Organisms (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. EFSA Journal 10(4), 2610. EFSA Panel on Genetically Modified Organisms (2014a): Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified corn MON 810 in 2014. EFSA Journal 12(6), 4061. | No raw data from the bioassays conducted with the European and the Mediterranean corn borer were provided as part of the 2016 PMEM report. EFSA considers that raw data are necessary to further evaluate and verify data quality and recommends that the consent holder supplies the raw data of the different resistance monitoring bioassays conducted with both target pests as part of future PMEM reports. |
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|       |              |            | maize MON 810 in 2012. EFSA Journal 12(6):3704. EFSA Panel on Genetically Modified Organisms (2015a): Clarifications on EFSA GMO Panel recommendations on the Insect Resistance Management plan for genetically modified maize MON 810. EFSA Supporting publication 2015:EN-842. EFSA Panel on Genetically Modified Organisms (2015b): 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 2013. The EFSA Journal 13(3), 1-11. EFSA (2016b): 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 MON810, Bt11 and 1507. EFSA Supp Publ; EN-1070. EFSA GMO Panel (2017): Scientific Opinion on the annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2015 from Monsanto Europoe S.A. EFSA Journal 2017; 1585):4805, 27pp. Hilbeck, A., McMillan, J.M., Meier, M., Humbel, A., Schlaepfer-Miller, J. & Trtikova, M. (2012): A controversy revisited: Is the coccinellid Adalia bipunctata adversely affected by Bt toxins? Environmental Sciences Europe 2012, 24:10; doi:10.1186/2190-4715-24-10. Hofmann, F., Kruse-Plass, M., Kuhn, U., Otto, M., Schlechtriemen, U., Schröder, B., Vögel, R., Wosniok, W. (2016): Accumulation and variability of maize pollen deposition on leaves of European Lepidoptera host plants and relation to release rates and deposition determined by standardised technical sampling. Environ Sci Eur 28:14 Holst, N., Lang, A., Lovei, G. & Otto, M. (2013): Increased mortality is predicted of Inachis io larvae caused by Bt-maize pollen in European farmland. Ecological Modelling, 250, 126-133. Kruse-Plass, M., Hofmann, F., Kuhn, U., Otto, M., |
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|       |              | Schlechtriemen, U., Schröder, B., Vögel, R., Wosniok, W. (2017): Reply to the EFSA (2016) on the relevance of recent publications (Hofmann et al., 2014, 2016) on environmental risk assessment and management of Bt-maize events (MON810, Bt11 and 1507). Environ Sci Eur 29:12 |
|       |              | Lang, A., Brunzel, S., Dolek, M., Otto, M. & Theißen, B. (2011): Modelling in the light of uncertainty of key parameters: a call to exercise caution in field predictions of Bt-maize effects. Proc. R. Soc. B 278, 980–981. |
|       |              | Lang, A., Oehen, B., Ross, J.-H., Bieri, K., Steinbrich, A. (2015): Potential exposure of butterflies in protected habitats by Bt-maize cultivation: a case study in Switzerland. Biol Cons 192:369–377 |
|       |              | Perry, J.N., Devos, Y., Arpaia, S., Bartsch, D., Gathmann, A., Hails, R.S., Kiss, J., Lheureux, K., Manachini, B., Mestdagh, S., Neemann, G., Ortego, F., Schiemann, J. & Sweet, J.B. (2011): The usefulness of a mathematical model of exposure for environmental risk assessment. Proceedings of the Royal Society of London Series B: Biological Sciences 278, 982–984. |
|       |              | Perry J.N., et al. (2017): Response to Kruse-Plass et al. (2017) regarding the risk to non-target lepidopteran larvae exposed to pollen from one or more of three Bt maize events (MON810, Bt11 and 1507) Environ Sci Eur (2017) 29:21 DOI 10.1186/s12302-017-0119-8 |
|       |              | Züghart, W., Raps, A., Wust-Saucy, A.-G., Dolezel, M., Eckerstorfer, M. (2011): Monitoring of Genetically modified Organisms. A policy paper representing the view of the National Environment Agencies in Austria and Switzerland and the Federal Agency for Nature Conservation in Germany. Umweltbundesamt Wien, Reports, Volume 0305, ISBN: 978-3-99004-107-9; http://www.umweltbundesamt.at/aktuell/publikationen/publikationssuche/publikationsdetail/?pub_id=1903 |
|       |              | Züghart, W., Benzler, A., Berhorn, F., Sukopp, U., Graef, F. (2008): Determining indicators, methods and sites for |
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| AT    | Environment Agency Austria | 4. Summary of results and conclusions | Unfortunately the consent holder does not address the issue of the occurrence of teosinte in Spain in his education program for MON 810 growers as well as in the monitoring report at hand. However teosinte is known to occur in Spain since 2009 and as a novel weed it causes management problems in maize production (see e.g. EFSA 2016a, Testbiotech 2016). Teosinte occurs in particular in the Ebro Valley, an area with high MON 810 adoption rate, which was consequently selected as a focus area for monitoring activities. We are of the opinion that the occurrence and spread of teosinte in Europe does represent an issue of concern for the monitoring of adverse environmental effects ERA of MON 810 since the issue of gene-flow to related plant species, like teosinte, was not addressed during the ERA. Hybrids between maize and teosinte are possible, and this could increase the spread of transgenes in the environment with implications for the exposure of NT organisms to Bt toxins and the establishment of IR plants with weed-like characteristics derived from the teosinte hybrids. Therefore this issue clearly has to be taken into account by the consent holder and must not be ignored. EFSA recently issued a technical report on this topic concluding that the overall environmental risk due to maize x teosinte hybrids expressing insect tolerance transgenes is considered to be low ‘provided that measures are employed to control and / or eradicate teosinte and its progeny in infested agricultural areas’ (EFSA 2016a). The EFSA GMO panel bases its conclusions on the fact that respective compulsory measures, e.g. monitoring of infested fields and measures to control the emergence and the establishment of teosinte, need to be implemented in Spain. The implementation of such monitoring and control measures |
|       |              |            |         | Following a request of the European Commission, EFSA assessed in 2016 the available scientific information on the presence of teosinte in the European Union for its relevance for the environmental risk assessment (ERA) of several genetically modified (GM) maize events, including event MON 810, for cultivation (EFSA, 2016). EFSA assessed whether the documents supplied by the European Commission and any other relevant documents on teosinte contain new information that would change or invalidate its previous ERA conclusions and risk management recommendations on the cultivation of several GM maizes, including event MON 810. Pathways to harm from the cultivation of maize MON 810, were hypothesised for situations where GM maize and teosinte would grow sympatrically, focusing on specific areas of risk typically considered in ERAs of GM plants. For each of these pathways EFSA considered unlikely that environmental harm could occur. In conclusion, there were no data in the scientific information on teosinte supplied by the European Commission that indicated the necessity to revise the previous ERA conclusions and risk management recommendations for maize MON 810. In addition, EFSA is not aware of any scientific report on teosinte that would point to a safety concern. Therefore, EFSA considered that the previous GMO Panel risk assessment conclusions and risk management recommendations on maize MON 810 for cultivation remain valid and applicable. |
therefore is a prerequisite for the validity of the previous conclusions regarding the ERA of a number of GM maize lines, including GM maize MON 810. Thus in our view the consent holder should provide information relating to the implementation of these compulsory measures and contribute to the dissemination of this information among adopters of the cultivation of MON 810. Farmers from infested areas which are participating in the survey by farmer questionnaires should also be specifically alerted to this issue. In case teosinte and maize x teosinte hybrids are found in areas where GM maize MON810 is cultivated appropriate risk management measures should be implemented to mitigate any impact of the cultivation of Bt-maize on the environment.

EFSA Panel on Genetically Modified Organisms (2016): Scientific Opinion on the annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2014. The EFSA Journal 14(4): 4446, 26pp.

Testbiotech (2016): Spanish government does not respond to the risk of massive transgenic contamination. Press release on Monday, 4 July 2016; Available at https://www.testbiotech.org/en/node/1676

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| DE    | BfN          | 1. General information | The monitoring report on the cultivation of MON810 in 2016 and the underlying monitoring plan are much the same as previous monitoring plans and reports (e.g. 2009, 2010, 2011, 2012, 2013, 2014, and 2015). For each previous report EFSA and Member States identified more or less similar fundamental shortcomings and made recommendations for improvement in the methodology for case specific monitoring and general surveillance. These recommendations were barely if any implemented in the monitoring on the cultivation of MON 810 in 2016. The Federal Agency for Nature Conservation considers that the current monitoring report on the cultivation of MON 810 in 2016 as well as the underlying monitoring plan does not meet the objectives defined in Annex VII of | EFSA took of the comment raise by BfN. |
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| EU MS | Organization | Reference | Comment                                                                                                                                                                                                 | EFSA’s response                                                                                                                                                                                                 |
|-------|--------------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DE    | BfN          | 3.2 Case specific monitoring | According to the monitoring report on the cultivation of MON 810 in 2016 the implementation of an Insect Resistant Management (IRM) is regarded as stewardship measure and classified as case specific monitoring. Beside the IRM no further case specific monitoring has been conducted. The Federal Agency for Nature Conservation considers that due to incomplete data, high uncertainties concerning the risk assessment of MON 810 and the well-documented susceptibility of a range of lepidopteran larvae to Cry1Ab (EFSA 2009), further case specific monitoring needs to be implemented, particularly the observation of Lepidoptera and aquatic organisms (see comments on application for renewal of MON 810 (EFSA-GMO-RX-MON 810)). | In its Scientific Opinion on the continued marketing of maize MON 810 (EFSA, 2009), the GMO Panel identified two areas of risk requiring risk management:  
1) The potential exposure of non-target (NT) lepidopteran larvae to Bt-maize pollen deposited on their host plants in or near Bt-maize fields;
2) The potential for the target insect pests *Ostrinia nubilalis* (European corn borer) and *Sesamia nonagrioides* (Mediterranean corn borer) to evolve resistance to the Cry1Ab proteins expressed in maize MON 810.  
For these two areas of risk, the GMO Panel advised that appropriate risk management measures to mitigate and monitor possible exposure of NT Lepidoptera, and insect resistance management strategies are or continue to be employed, in order to delay and monitor resistance evolution. The GMO Panel updated its Scientific Opinion on maize MON 810 accounting for new relevant scientific literature, and considered that its previous risk assessment conclusions on maize MON 810, as well as its previous recommendations for risk mitigation measures and monitoring, remained valid and applicable (EFSA GMO Panel, 2012a,b). Therefore, EFSA is of the opinion that a case-specific monitoring plan for non-target organisms (including non-target Lepidoptera and aquatic organisms) |
According to the monitoring report Monsanto has not conducted any monitoring activities specifically addressing the presence of teosinte detection in Spain. The occurrence of teosinte in Europe is reported repeatedly. Teosinte is a wild breeding partner of maize. The Bt trait of MON 810 may introgress in teosinte and boosts its fitness. Against this background the Federal Agency for Nature Conservation is of the opinion that the occurrence of teosinte and the possible outcrossing of the Bt transgene into teosinte plants should be part of case specific monitoring. Measures need to be established to control and eradicate Teosinte. The efficacy of these management measures should be surveyed in case specific monitoring.

Following a request of the European Commission, EFSA assessed in 2016 the available scientific information on the presence of teosinte in the EU for its relevance for the environmental risk assessment (ERA) of genetically modified (GM) maize events MON810, Bt11, 1507 and GA21 for cultivation (EFSA, 2016). EFSA assessed whether the documents supplied by the European Commission and any other relevant documents on teosinte contain new information that would change or invalidate its previous ERA conclusions and risk management recommendations on the cultivation of several GM maize events, including event MON 810.

Pathways to harm from the cultivation of maize MON 810, were hypothesised for situations where GM maize and teosinte would grow sympatiically, focusing on specific areas of risk typically considered in ERAs of GM plants. For each of these pathways EFSA considered unlikely that environmental harm could occur.

In conclusion, there were no data in the scientific information on teosinte supplied by the European Commission that indicate the necessity to revise the previous ERA conclusions and risk management recommendations for maize MON 810. In addition, EFSA is not aware of any scientific report on teosinte that would point to a safety concern. Therefore, EFSA considers that the previous GMO Panel risk assessment conclusions and risk management recommendations on maize MON 810 for cultivation remain valid and applicable, and that case-specific monitoring for teosinte is not needed.

| EU MS | Organization | Reference | Comment | EFSA’s response |
|-------|--------------|-----------|---------|----------------|
| DE    | BfN          | 3.1 General surveillance 3.1.2.1 Farmer questionnaires | As stated in the report on the cultivation of MON810 in 2016 a farmer questionnaire has been performed as one of four elements of general surveillance. The approach of the farmer questionnaire is specifically focused on the farm level and collects data on the maize grown area, on typical agronomic practices to grow maize on the farm, on observations of the insect protected maize event and on | EFSA took note of the comment raised by BfN. |
### Annual post-market environmental report on the cultivation of maize MON 810 in 2016

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| EU MS | Organization | Reference | Comment | EFSA’s response |
|-------|--------------|-----------|---------|-----------------|
| DE    | BfN          | 3.1.2.3 Alerts on environmental issues by existing networks | According to the report, existing environmental surveillance networks were not involved in general surveillance of MON 810 in 2016. The Federal Agency for Nature Conservation is of the opinion that the information of environmental surveillance networks are of great value for general surveillance. Therefore efforts should be made to develop strategies how existing networks can be used for PMEM in an appropriate way. This includes agreements with institutions/representatives of monitoring schemes and networks and the adaptation and enhancement of existing surveillance networks for the purpose of PMEM. In case significant data gaps exist, additional surveillance methods for the monitoring or environmental parameters need to be established. | In an external report commissioned by EFSA (Centre for Ecology and Hydrology et al., 2014) and in associated publications (e.g., Smets et al., 2014), several existing networks have been identified as potentially suitable for the general surveillance of GM plants. Although the usefulness of such networks requires resolving issues pertaining to data accessibility, data reporting format, and data connectivity with GMO registers (EFSA GMO Panel, 2014), EFSA encourages relevant stakeholders to implement a methodological framework that enables the use of existing networks in the broader context of environmental monitoring (see Section 3.2.2.2 of the EFSA Statement). |
| DE    | BfN          | 3.1.4.3 Alerts on environmental issues | Since no existing environmental networks were involved the report provides no information to comprehend the conclusion. | EFSA took note of the comment raised by BfN. |
| DE    | BfN          | 3.1.6 Review of peer-reviewed publications | The outcome of the literature search is incomplete. At least the following peer reviewed publications are missing: Krämer, L. (2016). Teosinte plants in the European environment and its implication for market authorisation of genetically engineered maize. Testbiotech, München. https://www.testbiotech.org/node/1773. 13S. | EFSA confirms that the four publications referred to by BfN were not retrieved by the literature search performed by the consent holder. EFSA considered that there are no data in those publications that indicate the necessity to revise the previous ERA conclusions and risk management recommendations for maize MON 810. |
### Annual post-market environmental report on the cultivation of maize MON 810 in 2016

**Comments and opinions submitted by EU Member States (MS) during the consultation period**

| EU MS | Organization | Reference | Comment |
|-------|--------------|-----------|---------|
| DE    | Federal Office of Consumer Protection and Food Safety (BVL) German CA | 3. Monitoring Results | The consent holder is committed to implement an Insect Resistance Management (IRM) plan according to Decision 98/294/EC. In addition, the consent holder initiated a General Surveillance (GS) on a voluntary basis since 2005. In summary, the monitoring report did not report on any adverse effect related to the cultivation of MON 810. However, uncertainty remains that potential adverse effects might be over-seen due to methodological shortcomings. The German CA assessed these monitoring reports yearly. The previous monitoring reports were partly acceptable, but would need substantial improvement to meet the requirements of the Directive 2001/18/EC. Therefore, the consent holder should still take into account the recommendations given by member states and EFSA in previous opinions. The monitoring report is essentially similar to reports submitted in previous years. New information or insight is not achieved. The consent holder stated that recommendation provided by Member States and EFSA were not considered because of (i) GS is conducted by Monsanto on a voluntary basis and therefore Monsanto elects to continue its current modus operandi and (ii) the consent holder collaborates within EuropaBio towards a harmonized post-market environmental monitoring plan, which, once agreed with the different |

During the assessment of the annual 2016 post-market environmental monitoring report of maize MON 810, EFSA identified some methodological and reporting limitations pertaining to insect resistance monitoring, farmer questionnaires and literature searching, and therefore updated its previous recommendations that should be implemented by the consent holder. Specific recommendations for case-specific monitoring and general surveillance of maize MON 810 are provided in Section 5 of the EFSA Statement.
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| EU MS | Organization | Reference | Comment | EFSA’s response |
|-------|--------------|-----------|---------|------------------|
| DE    | Federal Office of Consumer Protection and Food Safety (BVL) German CA | 3.1 General Surveillance | stakeholders including the European Commission, will be implemented when different GM crops are (re-)approved for cultivation. However, it would be valuable to start a discussion between consent holder and risk managers improving the monitoring activities if the renewal of MON 810 maize takes place and the legal basis requiring GS changes. The applicant should consider whether other existing monitoring networks might be used in particular in the field of human and animal health. In such a case, the selection and evaluation process should be described in detail. In general, the BVL likes to refer to the comments submitted by the German CA in the previous years, but made some specific comments to the current monitoring report. | In an external report commissioned by EFSA (Centre for Ecology and Hydrology et al., 2014) and in associated publications (e.g., Smets et al., 2014), several existing networks have been identified as potentially suitable for the general surveillance of GM plants. Although the usefulness of such networks requires resolving issues pertaining to data accessibility, data reporting format, and data connectivity with GMO registers (EFSA GMO Panel, 2014), EFSA encourages relevant stakeholders to implement a methodological framework that enables the use of existing networks in the broader context of environmental monitoring (see Section 3.2.2.2 of the EFSA Statement). |

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1. Reference: Pascher, K., Moser, D., Dullinger, S., Sachslehner, L., Gros, P., Sauberer, N., et al. (2011) Setup, efforts and practical experiences of a monitoring program for genetically modified plants-An Austrian case study for oilseed rape and maize. *Environmental Sciences Europe*, 23, 1–12. Lang, A. & Bühler, C. (2012) Estimation of required
## Annual post-market environmental report on the cultivation of maize MON 810 in 2016

Comments and opinions submitted by EU Member States (MS) during the consultation period

| EU MS | Organization | Reference | Comment                                                                                                                                                                                                 | EFSA’s response                                                                                                                                                                                                 |
|-------|--------------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DE    | Federal Office of Consumer Protection and Food Safety (BVL) German CA | 3.1.6.1 Peer-reviewed publications on the safety of MON 810 and/or the Cry1Ab protein published in 2016 – 2017 | The consent holder stated that all publications that resulted from the search - as described in Step 3 of the literature search - were screened and relevant publication for risk assessment were subsequently assessed. However, he did not describe the process of screening and selection in detail. A description (e.g., inclusion and exclusion criteria, definition of high quality journals) and presentation of number remaining publications after each selection process would make the literature review more transparent. That may be done in form of a table. | EFSA assessed the systematic literature search provided by the consent holder according to the guidelines given in EFSA (2010, 2017). The overall quality of the performed literature search is acceptable. However, EFSA considers that the methodology and reporting of literature searches on maize MON 810 could be improved further and therefore provided recommendations for future searches (see Section 3.2.3.2 of the EFSA Statement for further details). In addition, EFSA advises that future literature searches on maize MON 810 performed in the context of annual PMEM reports should follow the guidelines given in EFSA (2017). |
| DE    | Federal Office of Consumer Protection and Food Safety (BVL) German CA | 3.2.1.2 Baseline studies and resistance monitoring in the target pests | The consent holder collected Mediterranean corn borer (MCB) and European corn borer (ECB) in one area according on the sampling strategy outlined in the updated EuropaBio harmonized IRM plan. He followed recommendations of EFSA and concentrated the sampling on the Ebro valley. Nevertheless, as asked before by EFSA, the German CA suggest to report LC and MIC values for ECB and MCB. | The harmonised insect resistance management plan has been updated and susceptibility of target pests to the Bt-protein is now assessed in diagnostic bioassays. Concentration -response bioassays have not been performed with progeny of the target pest populations collected in 2016 in north-eastern Spain. EFSA agrees with the proposed testing strategy. Further details are provided in Section 3.1.2.2 of the EFSA Statement. |
| IT    | Ministry of Annual monitoring report on the cultivation of | In 2016, MON 810 was planted in the EU on approximately 136,334 hectares across four countries: Czech Republic | EFSA took note of the comment raised by Italian Ministry | |
Annual post-market environmental report on the cultivation of maize MON 810 in 2016
Comments and opinions submitted by EU Member States (MS) during the consultation period

| EU MS         | Organization | Reference | Comment                                                                                                                                                                                                 | EFSA’s response |
|---------------|--------------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| environment   | MON 810 in 2016 | (75.26 ha), Portugal (7,056 ha), Slovakia (122.13 ha) and Spain (129,081 ha). The PMEM of MON 810 is composed by two different actions: a case-specific monitoring plan, called “insect resistant management (IRM)”, for the onset of insect resistant to the Bt toxin, and a general surveillance, implemented on a voluntary basis. During the growing season 2016, Monsanto continued with the IRM programme, which included activities related to: a farmer complaint system, farmer education, refuge implementation, susceptibility monitoring and good stewardship practices. The notifier states that the data collected by the IRM plan have revealed that there were no changes in susceptibility of neither O. nubilalis nor S. nonagrioides to the Cry1Ab protein in the major MON 810 growing regions in Europe in 2016. Regarding the General Surveillance (GS), the activities conducted by Monsanto were: analysis of farmer questionnaires (250 questionnaires from 2 European countries), literature searches on the safety of MON 810 in peer reviewed journals (37 publications), alerts on the product through stewardship programs, and the use of existing environmental networks (EENs). Based on the analysis conducted within the GS, the notifier states that the evidence available to date confirm the initial conclusions of the safety assessment of 1998, namely that MON 810 is as safe as conventional maize with respect to human or animal health and the environment. Regarding the use of existing environmental monitoring networks, Monsanto has used the work done by EuropaBio, that had identified and characterized potential relevant EENs in Europe for PMEM of GM crop cultivation, but concludes that EENs are not well suited as a primary tool for the general surveillance within the GM crop monitoring. We underline that most of the explanatory documentation, both on IRM and on general surveillance, is provided in the languages of the States where the cultivation took place, but not in English, which would be necessary in order to allow all European risk assessors the evaluation of the strategies implemented by the notifier. Moreover, |


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| EU MS | Organization | Reference |
|-------|--------------|-----------|
| IT    | Ministry of environment | EuropaBio Harmonised IRM YieldGard Technical Guide (Appendix 9.1) |

Regarding the case-specific monitoring named insect-resistant management (IRM), we retain that this has been adequately conducted in relation to the 2016 agricultural season and to Spain and Portugal. Although it is true that Spain and Portugal represent the majority of the area under cultivation with MON 810, in order to perform a complete evaluation of the IRM implemented by Monsanto it is also necessary to have information on the implementation of this case-specific monitoring plan in the other 2 States where cultivation took place.

As shown in the EuropaBio Harmonised IRM, any resistance to *Bt* toxin is likely to be caused by allelic recessive mutations. These mutations are very dangerous because they give an immediate advantage to the homozygote resistant insects, causing a high selective pressure on the original population of lepidopterans. In fact, the use of the refuge areas is aimed to maintain these kind of mutations in heterozygosis condition, so that they cannot be phenotypically expressed. In *Ostrinia nubilalis* and *Sesamia nonagrioides* IRM, the bioassay analyses for the assessment of any Cry1Ab resistance is carried out on F1 larvae generation. However, in order to estimate the allelic frequency of a recessive mutation for the resistance to the toxin in the sampled population *P₀*, it would be more appropriate to evaluate also the phenotypes in the F₂ segregant population.

In the communication material is stated that the refuge areas are mandatory in case of field larger than 5 hectares, but it is not clear how the respect of this disposal is guaranteed, especially in the light of fact that the questionnaire results shows that a little percentage of farmers do not sow refuge areas, even when the field conditions would require their sowing.

In Section 3.1.2.2 of the EFSA Statement, EFSA recommends that the consent holder develops alternative testing methods to improve the sensitivity and precision of the current monitoring strategy. An alternative approach to the current resistance monitoring bioassays (i.e., diagnostic concentration) is the F₂-screen, which allows the detection of recessive resistant alleles. Although F₂-screen is resource intensive and presents some technical limitations, EFSA considers that it could be performed periodically with ECB and MCB populations to confirm the results of the diagnostic bioassays; to validate one of the key assumptions of the “high dose/refuge” strategy (i.e., frequency of resistant alleles is <10⁻³); and to revise the predictions of resistance evolution models.

EFSA took note of this comment. Unlike in Portugal, there is no legal obligation with regards to non-*Bt* refuge planting in Spain and no inspection were performed on farmers planting maize MON 810. One of the elements of the insect resistance management plan implemented by the consent holder for maize MON 810 is a grower education programm to raise awareness on refuge implementation. As shown in Appendix A, compliance with refuge requirements has increased since 2004. Still, The 2016 PMEM report shows partial compliance (89%) with refuge requirements in Spain. EFSA considers that full compliance should be achieved in high adoption areas, and reiterates that the consent holder should strive to increase the level of compliance in those areas.
## Annual post-market environmental report on the cultivation of maize MON 810 in 2016

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| EU MS | Organization | Reference | Comment | EFSA’s response |
|-------|--------------|-----------|---------|-----------------|
| NL    | GMO Office   | General   | The Dutch CA under 2001/18/EC is of the opinion that the MON 810 monitoring report of 2016, submitted on a voluntary basis, is in line with the proposal for monitoring as provided in the application for renewal of this event (RX-MON 810) and in accordance to Regulation (EC) 1829/2003. The 2016 monitoring report also complies with the monitoring format for GM cultivation (Commission Decision 2009/770/EC). | EFSA took note of the comment raised by the Netherlands GMO Office. |
| NL    | GMO Office   | 3.1. General surveillance | The General Surveillance monitoring program performed by Monsanto in 2016 consists of four elements:  
- data obtained by 250 farmer questionnaires of farmers from 2 member states (Spain and Portugal) designed to assess unusual observations in the areas where MON 810 has been cultivated the most;  
- data collected from 37 scientific publications relating to MON 810 and/or Cry1Ab and its safety with respect to human, and animal health and the environment;  
- company stewardship activities designed to ensure and maintain the value of the product;  
- alerts on environmental issues by authorities, existing networks and the press that may reflect potential adverse effects associated with the product.  
The data presented in the report confirm the outcome of the earlier environmental risk assessment of MON 810 cultivation. They are also in line with results of annual post market monitoring that has been performed since 2005. There are no indications of adverse effects on human health and the environment as a consequence of MON810 cultivation on 136 334 hectares in five EU member states (Czech republic, Portugal, Romania, Slovakia and Spain) in 2015. | EFSA took note of the comment raised by the Netherlands GMO Office. |
| NL    | GMO Office   | 3.1.2.1 Farmer questionnaire | Based on COGEMs advice on General Surveillance (CGM/100226-01, http://www.cogem.net/index.cfm/nl/publicaties/publicatie/si | EFSA took note of the comment raised by the Netherlands GMO Office. 
EFSA noted that the farmer questionnaire and the |
### Comments and opinions submitted by EU Member States (MS) during the consultation period

| EU MS | Organization | Reference | Comment | EFSA’s response |
|-------|--------------|-----------|---------|-----------------|
| NL    | GMO Office   | 3.2. Case-specific monitoring | The Netherlands does not consider resistance development of the European corn borer (ECB) towards Cry1Ab to pose an environmental risk, but rather to pose an agricultural or economic risk. This is in line with Regulation (EC) No 1107/2009 that considers resistance development to plant protection agents (such as Bt proteins) as an efficacy problem, but not as an environmental risk. Given the fact that resistance to Cry1Ab in the ECB can develop regardless the source of the substance, it should not be relevant that the source is a natural one or the result of intentional manipulation of the genetic material. COGEM is also of the opinion that existing networks should be involved in general surveillance. | The consideration made by the Netherlands GMO Office is outside the remit of EFSA. |
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| EU MS | Organization | Reference | Comment | EFSA’s response |
|-------|--------------|-----------|---------|-----------------|
| RO    | Romanian Biosafety Commission | General comments | The monitoring report on the cultivation of MON 810 in 2016 was submitted in September 2017 by Monsanto Europe SA to the European Commission. The report has the similar structure, approach and conclusions as those submitted in previous year (2005-2017) in the laid out which follow the format asked by Commission Decision in 2009.
On 4 July 2017, the European Commission adopted the renewal of the authorisation for the placing on the market of MON 810 for all uses, with the exception of pollen and cultivation (European Commission, 2017).
In 2016, MON 810 was planted in the EU on approximately 136,334 hectares across four countries (Czech Republic, Portugal, Slovakia and Spain).
Monsanto continued in 2016 its General Surveillance monitoring program and the analysis of 250 questionnaires from a survey of farmers cultivating MON 810 in two European countries (Spain and Portugal). The conclusions did not reveal any adverse effects associated with the genetic modification in MON 810. The analysis of 37 publications related to MON 810 and/or Cry1Ab did not reveal any new scientific evidence that would invalidate the conclusions of the risk assessment concluding that MON 810 is as safe to human and animal health as its conventional counterpart. The conclusions confirms that there is negligible impact from the cultivation of MON 810 on biodiversity, abundance or survival of non-target species, and the environmental risk of MON 810 is considered to be negligible compared to conventional maize. In 2016 the company stewardship activities did not reveal any adverse effects related to MON 810 cultivation. These results demonstrate that there are no indications of adverse effects to be attributed to the cultivation of MON 810 in Europe in 2016. | EFSA took note of the comment raised by the Romanian Biosafety Commission. |
### Annual post-market environmental report on the cultivation of maize MON 810 in 2016
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| EU MS | Organization                  | Reference | Comment                                                                                                                                                                                                 | EFSA’s response                                                                                                                   |
|-------|-------------------------------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| RO    | Romanian Biosafety Commission | 3.1 General Surveillance | The monitoring plan strategies to identify the occurrence of adverse effects of the GMO, termed General Surveillance (GS), is not a condition of the current authorization for MON 810 issued in 1998 or renewal in 2017. From 2005 to date, Monsanto submitted 12 post-market environment reports, covering 14 years of MON 810 cultivation in the EU, and all reports confirm consistently its safety. During the years, Monsanto 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. EFSA concluded that no adverse effects on human or animal health or the environment were identified due to MON 810 cultivation during the 2009, 2010, 2011, 2012, 2013, 2014 or 2015 growing seasons and that the outcomes of the monitoring reports did not invalidate the previous risk assessment conclusions. Monsanto acknowledges the fact that EFSA made several recommendations to improve the methodology. The report was focused on four complementary GS activities: (1) analysis of farmer questionnaires, (2) literature searches on the safety of MON 810 in peer-reviewed journals, (3) alerts on the product through stewardship programs, and (4) the use of existing environmental networks (EENs). We consider the GS as conducted by Monsanto to be appropriate confirming that MON 810 is as safe as conventional maize with respect to human and animal health and the environment. | EFSA took note of the comment raised by the Romanian Biosafety Commission. |
| RO    | Romanian Biosafety Commission | 3.1.2.1. Farmers questionnaire | EFSA explicitly considers questionnaires as a useful method to collect first hand data on the performance and impact of a GM plant. A questionnaire addressed to farmers cultivating GM crops was applied by Monsanto Europe S.A. as a monitoring tool specifically focused on the farm level. The results were included in in the Annual Monitoring Report (September 2017 13) on the cultivation of MON 810 in the 2016 growing season compare the GM plant with conventional plants. A total of 250 questionnaires were asked to be | EFSA took note of the comment raised by the Romanian Biosafety Commission. |
| EU MS | Organization | Reference | Comment | EFSA’s response |
|-------|--------------|-----------|---------|-----------------|
|       |              |           | complete by 13 farmers in Portugal and 237 farmers in Spain. In Spain, which represented the largest market, the survey was performed by Markin while in Portugal, it was performed by Agro.Ges, two qualified, independent companies with a vast experience in the conduction of farmer surveys. All interviewers have been trained to understand the background of the questions. The analysis of 250 questionnaires from the survey of farmers cultivating MON 810 in two European countries in 2016 did not reveal any adverse effects associated with the genetic modification in MON 810. We consider the farmer questionnaire as sufficiently pragmatic and appropriate as a monitoring tool for GM crops focused on the farm level. | |
| RO    | Romanian Biosafety Commission | 3.1.6. Review of peer-reviewed publications | A detailed analysis of 37 publications, related to MON 810 and/or Cry1Ab, did not reveal any new scientific evidence that would invalidate the conclusions of the risk assessment concluding that MON 810 is as safe to human and animal health as its conventional counterpart. The conclusions confirms that there is negligible impact from the cultivation of MON 810 on biodiversity, abundance or survival of non-target species, and the environmental risk of MON 810 is considered to be negligible compared to conventional maize. | EFSA took note of the comment raised by the Romanian Biosafety Commission. |
| RO    | Romanian Biosafety Commission | 3.2. Case specific monitoring | Monsanto established, early as 1992, 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. A harmonized IRM plan specific for the EU which was implemented until the 2011, based on published research, current EU legislation, the European Commission’s Scientific Committee on Plants (SCP) opinion on IRM20 and practical experience gained during the implementation of IRM plans in other parts of the world. Taking into account the related EFSA’s opinions, the historical data on | EFSA took note of the comment raised by the Romanian Biosafety Commission. |
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| EU MS | Organization | Reference\(^1\) | Comment | EFSA’s response |
|-------|--------------|-----------------|---------|-----------------|
| RO    | Romanian Biosafety Commission | Summary of results and conclusions. | Bt-maize cultivation, data in the scientific literature, and the experience gained from IRM plans established in other regions, the EuropaBio Monitoring working group has updated the IRM plan in 2017. This harmonized IRM plan contains guidance on the following key elements: (1) Refuge; (2) Resistance monitoring in the target pests; (3) Farmers compliant system; (4) Remedial plan in case of Bt maize failure to protect against target pests; and (5) Communication and Grower education. We consider the presented case specific monitoring as appropriate with the monitoring results demonstrated that there are no adverse effects attributed to the cultivation of MON 810 in Europe. | EFSA took note of the comment raised by the Romanian Biosafety Commission. |

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\(^1\) Reference to the specific section or Appendix of the annual 2016 PMEM report on maize MON 810.

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