Annex 1 of EFSA (2020) – EFSA's response to comments and opinions submitted by EU Member States to the annual post market environmental monitoring (PMEM) report on the cultivation of maize MON 810 in 2019 during the consultation period

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
AT	Umweltbundesamt (Environment Agency Austria) on behalf of the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection	2. Executive summary	The monitoring report submitted by the current consent holder Bayer is highly similar in structure, approach and conclusions to the reports submitted in the previous years. The monitoring outlined in the report is based on the insect resistance management (IRM) plan for cultivation of Bt maize in the EU which was revised in 2017 and updated in April 2019 (Appendix 6). The monitoring approach which was implemented over the last years was critically evaluated on many occasions by EFSA as well as EU Member States (MS), including Austria (see e.g. our comments to the previous annual monitoring reports submitted in the years 2011 to 2019). These reviews identified a range of aspects needing to be improved in order to achieve scientific strength and to provide an adequate monitoring of unexpected environmental effects as required by Directive 2001/18/EC. However some important recommendations by EFSA (EFSA 2019) and MS were not addressed sufficiently in the monitoring report at hands. In addition the results of scientific research (Camargo et al. 2018) regarding the increase of frequencies of resistance alleles present in European field populations of a target pest (*Sesamia nonagrioides*) were	EFSA thanks AT for the comment. EFSA assessed the dataset provided by the consent holder in the 2019 PMEM report. The evidence from the 2019 PMEM report and the additional information provided by the consent holder upon EFSA's request does not indicate any adverse effects on human and animal health or the environment arising from the cultivation of maize MON 810 during the 2019 growing season. Consequently, EFSA concludes that no new evidence has been reported that would invalidate previous EFSA/GMO Panel evaluations on the safety of maize MON 810 (EFSA, 2009; EFSA GMO Panel, 2012a,b). However, EFSA notes that the monitoring strategy implemented in the 2019 growing season is not sensitive enough to detect the recommended 3% resistance allele frequency. Consequently, EFSA urges the consent holder to increase the sensitivity of the monitoring strategy in the future. EFSA identifies some other methodological and reporting limitations pertaining to insect resistance monitoring, farmer questionnaires and literature searching that should be resolved by the consent holder in future PMEM reports. Recommendations to resolve these limitations are listed in Section 5 of the EFSA Statement.

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			again not considered nor discussed in the monitoring report at hands. As a general conclusion Bayer states that the monitoring as conducted in 2019 did not identify adverse effects on the environment, human and animal health. Based on this outcome Bayer concludes that this is demonstrating that the applied methodologies are fit for the purpose of identifying adverse effects. We again reiterate that this argument is not appropriate, science-based reasoning: An absence of evidence cannot be taken as a confirmation of the appropriateness of the applied methodology. This absence of evidence might just as well reflect methodological shortcomings and the difficulties to obtain robust evidence, which are acknowledged both in the monitoring report and in the recent review provided by EFSA (EFSA 2019). Such methodological shortcomings were indeed identified by EFSA, in particular with a view to monitoring the increased potential of development of resistance in a relevant target pest towards the Bt toxin Cry1Ab, as indicated by Camargo et al. (2018). We therefore request a further revision of the monitoring approach by the consent holder to address all remaining concerns raised by EFSA and Member States. Steps should be taken to ensure that the recommendations which were meant to be implemented this year, but could not due to difficulties caused by the COVID-19 pandemic will be implemented as soon as possible. Camargo, A. M., et al. (2018). "First detection of a Sesamia nonagrioides resistance allele to Bt maize in	

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			Europe." Scientific Reports (Nature Publisher Group) 8: 1-7. EFSA Panel on Genetically Modified Organisms (2015): 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, Álvarez F., Devos Y., Georgiadis M., Messéan A., Weigmann E. (2018): Statement on annual post-market environmental monitoring report on the cultivation of genetically modified maize MON 810 in 2016. EFSA Journal 2018; 16(5):5287, httpd://doi.org/10.2903/j.efsa.2018.5287. EFSA, _Alvarez F., Camargo A.M. and Devos Y. (2019): Assessment of the 2017 post-market environmental monitoring report on the cultivation of genetically modified maize MON 810. EFSA Journal 2019;17(6):5742, https://doi.org/10.2903/ j.efsa.2019.5742	
AT	Umweltbundesamt (Environment Agency Austria) on behalf of the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection	3.1.2.1 Farmer questionnaire; Appendix 1	We – again - reiterate our concern 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 MON810 as required by Annex VII of Directive 2001/18/EC. In our view this monitoring approach thus needs to be complemented with thorough scientific assessment strategies. Specifically long-term impacts of GM maize MON810 cultivation on biota other than pests directly interacting with the crop cannot be reliably monitored by means of farmer questionnaires. In order to attain scientifically meaningful results these data need to be complemented	EFSA thanks AT for this comment and refers to Section 3.1.2.1 of the EFSA Statement for further information on the farmer questionnaires submitted as part of the 2019 PMEM report on maize MON 810

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			by scientific data, i.e. generated by additional investigations and experiments conducted by experts using appropriate scientific methods. The current approach cannot be considered appropriate, specifically for the assessment of long¬term impacts on non-target organisms and biodiversity in general. We thus reiterate our request that an independent scientific evaluation is provided to validate the results gathered by farmer questionnaires.	
AT	Umweltbundesamt (Environment Agency Austria) on behalf of the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection	3.1.2.3 Alerts on environmental issues	As noted previously the use of data from existing environmental networks (EENs) in the framework of environmental monitoring is important for PMEM issues, which cannot be addressed sufficiently by expertise collected via the farmers questionnaires, e.g. impacts on non-target species and biodiversity. However the monitoring report at hand again does not address this issue sufficiently in spite of the recurrent recommendations by EFSA that a methodological framework to enable making best use of such networks should be implemented (EFSA 2019). Tthe consent holder fails to take any concrete steps (e.g. the case-specific identification of suitable EENs for the Aragon region in Spain) to implement a methodological framework that enables the use of EENs on the basis of the respective opinion by EFSA (2014) and the supplementary external scientific report (Henrys et al. 2014). EFSA Panel on Genetically Modified Organisms (2014): Scientific Opinion on the use of existing environmental surveillance networks to support the post-market	EFSA thanks AT for the comment. An external report commissioned by EFSA (Centre for Ecology and Hydrology et al., 2014) and associated publications (e.g., Smets et al., 2014) have identified several existing networks as potentially suitable for the general surveillance of GM plants. EFSA acknowledges that the use of existing systems raises several methodological challenges around the feasibility of exploiting existing environmental monitoring networks and linking agricultural practices with global impacts. These challenges include data heterogeneity, incompleteness, accessibility to data, exploitation methodologies, data reporting format, and data connectivity with GMO registers (EFSA GMO Panel, 2014b). Also, the lack of a clear definition of the protection goals in each EU Member State or region is a significant obstacle. However, there exist networks adapted to such an exercise (e.g., monitoring of butterflies). EFSA encourages the EU Member States and relevant stakeholders to engage in the pooling of systems and the development of a methodological framework that enables to make the best use of existing networks involved in environmental monitoring. It is

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			environmental monitoring of genetically modified plants. EFSA Journal 12(11):3883. EFSA, _Alvarez F., Camargo A.M. and Devos Y. (2019): Assessment of the 2017 post-market environmental monitoring report on the cultivation of genetically modified maize MON 810. EFSA Journal 2019;17(6):5742, https://doi.org/10.2903/ j.efsa.2019.5742 Henrys et al. (2014) – Review of statistical methods and data requirements to support post-market environmental monitoring of agro-ecosystems (see http://www.efsa.europa.eu/en/efsajournal/doc/3883ax1.pdf	recommended that the consent holder evaluates the EENs in a transparent manner according to EFSA 2014 (opinion on the use of existing EENs to support PMEM of GMPs https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3883)
AT	Umweltbundesamt (Environment Agency Austria) on behalf of the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection	3.2.1 Description and results of case-specific monitoring; Appendix 6	Similar to our comments directed to the monitoring reports submitted in the previous years, we are of the opinion that the ERA conducted for GM maize MON810 is lacking adequate strength and is associated with significant uncertainties (see previous AT comments for reference). 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). Thus the implemented CSM should provide 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	EFSA thanks AT for the comment. 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 (see also the model development supported by EFSA: https://www.efsa.europa.eu/en/supporting/pub/en-6443); 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

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			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, were proposed (see AT comments from previous years for reference). 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 monitoring potential adverse effects of genetically modified plants to the environment: the legal and conceptional framework for implementation. Euphytica, DOI: 10.1007/s10681-007-9475-9476.	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.
AT	Umweltbundesamt (Environment Agency Austria) on behalf of the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection	3.2.1.1 Refuge	In accordance with EFSA we again recommend that the consent holder takes further action to reduce non-compliance by farmers cultivating GM maize MON810 on fields > 5 ha and to ensure that structured refuges are established for clustered cultivation of GM maize MON810 by farmers who are not individually obliged to plant refuges themselves (EFSA 2019). EFSA, _Alvarez F., Camargo A.M. and Devos Y. (2019): Assessment of the 2017 post-market environmental monitoring report on the cultivation of genetically	EFSA thanks DE for the comment. EFSA agrees that the consent holder should strive to increase the level of compliance in high adoption areas in Spain. Spanish National Competent Authorities and other relevant stakeholders, including farmers' associations, could also contribute to reinforcing farmers' awareness of refuge compliance. EFSA reiterates that refuge requirements also apply to clusters of small maize MON 810 fields in which the aggregate area planted with *Bt* maize is greater than 5 ha, irrespective of individual field and farm size (EFSA,

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			modified maize MON 810. EFSA Journal 2019;17(6):5742, https://doi.org/10.2903/ j.efsa.2019.5742	2009). See also section 3.1.1 of the current EFSA statement.
AT	Umweltbundesamt (Environment Agency Austria) on behalf of the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection	3.2.1.2 Baseline studies and resistance monitoring in the target pests;	We reiterate our concerns that the consent holder did not specifically implement the recommendation by EFSA to address the lack of sensitivity of the insect resistance monitoring put in place (EFSA 2018, 2019). EFSA suggested increasing the sensitivity to reliably detect the resistance allele frequencies occurring at a level of 3% or below after a resistance allele to Cry1Ab maize was detected for the first time in a field population of Sesamia nonagrioides in the Ebro valley in Spain, applying an F2 screening method (Camargo et al. 2018). This study was identified during the literature review by the consent holder during the 2017 monitoring season and also considered to be relevant by EFSA (EFSA 2018). However, the consent holder did neither discuss nor consider any complementary measures (e.g. increasing refuge compliance or size, application of refuge requirements to clusters of small fields as recommended by EFSA 2018) from these scientific findings. Albeit the resistance allele frequency detected in this study was below the detection level of 3% resistance allele frequency set by the IRM plan, such findings clearly constitute an early warning signal and should not be ignored. We again recommend that the consent holder adapts his objective of sampling to collect higher numbers of target pest larvae per population in the areas selected for monitoring. This way a sufficient number of individuals could be tested by the implemented diagnostic bioassays	EFSA thanks AT for the comment. The analysis of the resistance monitoring data does not show a decrease in susceptibility to the Cry1Ab protein in the *Ostrinia nubilalis* populations collected from north eastern Spain during the 2019 maize growing season. For *Sesamia nonagrioides*, moulting inhibition observed in the diagnostic concentration bioassays was lower than the expected >99% in one of the three populations tested. Additional studies with plant material indicate that none of the *S. nonagrioides* larvae tested from that population could complete development on maize MON 810 leaves. EFSA encourages the consent holder to apply the step-wise approach recommended by the US Environmental Protection Agency for confirming resistance of lepidopteran pests of *Bt* plants updating the harmonised IRM plan accordingly. Based the estimated numbers of *O. nubilalis* and *S. nonagrioides* field collected larvae represented in the diagnostic concentration bioassays, the monitoring strategy implemented in the 2019 growing season was not sensitive enough to detect the recommended 3% resistance allele frequency (EFSA, 2015). Consequently, EFSA considers that a more sensitive alternative testing method should be used so that alternative management measures can be implemented timely to delay resistance evolution.

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			to achieve a detection limit for resistance allele frequency equal or lower than the recommended 3% for both target pests. In that matter EFSA strongly recommends the consent holder to increase the sensitivity and precision of the monitoring strategy so that alternative management measures can be implemented timely to delay resistance evolution (EFSA 2019). As GM maize events with pyramided Bt-toxins are not available for this purpose in the EU (Camargo et al. 2018), other measures which are less easy to implement would be required. Wwe note that the EFSA recommendations to either (1) increasing the sampling size of field populations and/or reducing the mortality during the laboratory rearing of field-collected populations or (2) replacing diagnostic bioassays by more sensitive testing methods (EFSA 2019) was not sufficiently implemented . Camargo, A. M., et al. (2018). "First detection of a *Sesamia nonagrioides* resistance allele to Bt maize in Europe." Scientific Reports (Nature Publisher Group) 8: 1-7. EFSA, Álvarez F., Devos Y., Georgiadis M., Messéan A., Weigmann E. (2018): Statement on annual post-market environmental monitoring report on the cultivation of genetically modified maize MON 810 in 2016. EFSA Journal 2018; 16(5):5287, 34 pp. EFSA, Alvarez F., Camargo A.M. and Devos Y. (2019): Assessment of the 2017 post-market environmental monitoring report on the cultivation of genetically modified maize MON 810. EFSA Journal 2019;17(6):5742, https://doi.org/10.2903/ j.efsa.2019.5742	Given that no resistant *O. nubilalis* and *S. nonagroides* populations are available for F1screens EFSA recommends performing periodic F2-screens. EFSA considers that it is timely to perform an F2 screen on *S. nonagroides* populations from the same area where the Cry1Ab resistance allele was detected by Camargo et al. (2018) as well as on *O. nubilalis* populations from north eastern Spain, where the frequency of resistance alleles has never been estimated (for more details see Section 3.1.2 of EFSA Statement). EFSA noted that the consent holder has not followed several recommendations to resolve previously identified shortcomings and to improve the monitoring plan (for a summary of these, see Section 5 of EFSA Statement).

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AT	Umweltbundesamt (Environment Agency Austria) on behalf of the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection	3.3 Concluding remarks	Unfortunately the consent holder again does not address the issue of the occurrence of teosinte in Spain in his education program for MON810 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 2016). Teosinte occurs in particular in the northern part of Spain (Trtikova et al. 2017), e.g. in the Ebro Valley, an area with high MON810 adoption rate, which was selected as a focus area for monitoring activities. Recent studies indicate that it is reasonable to expect hybridization between this invasive weed and the maize crops and that after a few generations the population quickly drifts towards weediness (Diaz et al 2020). Since such maize like weeds as found in Spain share morphological similarities with the maize crop the chances of their detection and for them being removed by farmers decrease (Diaz et al. 2020). These issues should be taken into account by the consent holder. In particular, the consent holder should address whether measures, such as the monitoring of infested fields and measures to control the emergence and the establishment of teosinte, were implemented and whether information concerning these measures was disseminated among adopters of the cultivation of MON810 in Spain. 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	EFSA thanks AT for the comment. EFSA notes the existence of monitoring activities of national authorities directly linked to maize cultivation, such as the monitoring of teosinte populations in Spain and in France. The As part of general surveillance and given their potential relevance for MON 810, EFSA is of the opinion that the consent holder should include the outcome of such monitoring activities in the PMEM report. Details on the available information on teosinte monitoring and its implications on the PMEM of MON 810 was discussed by the EFSA WG on 4 May 2021[1]. It is recommended that the consent holder includes and explicitly considers in the future annual PMEM reports all scientific evidence relevant for the environmental risk assessment and risk management of maize MON810 in relation to teosinte, including the outcome of existing monitoring activities as mentioned above. In addition, EFSA recommends that the farmer questionnaires are revised to include the reporting of both the occurrence of teosinte and teosinte hybrid plants and the corresponding level of infestation. The consent holder and the Competent Authorities of the EU Member States where maize MON810 is grown should ensure that robust information systems are in place to promote the sharing of relevant information on teosinte.

[1]Minutes of the 225th meeting of the working group on comparative analysis and environmental risk assessment: https://www.efsa.europa.eu/sites/default/files/wgs/gmo/gmocompera2019.pdf

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			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 (2016): Relevance of new scientific evidence on the occurrence of teosinte in maize fields in Spain and France for previous environmental risk assessment conclusions and risk management recommendations on the cultivation of maize events MON810, Bt11, 1507 and GA21. EFSA supporting publication 2016: EN- 1094.http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2016.EN-1094/full Díaz, A., Taberner, A. & Vilaplana, L. (2020) The emergence of a new weed in maize plantations: characterization and genetic structure using microsatellite markers. Genet Resour Crop Evol 67, 225–239. https://doi.org/10.1007/s10722-019-00828-z Trtikova M., Lohn A., Binimelis R., Chapela I., Oehen B., Zemp N., Widmer A. and Hilbeck A, 2017. Teosinte in Europe – Searching for the origin of a novel weed. Scientific Reports, 71, 1560.	
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 MON810. However, uncertainty remains that potential adverse	EFSA thanks DE for the comments on the 2019 PMEM report on maize MON 810.

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			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 repetitively that GS is conducted by Bayer on a voluntary basis and therefore Bayer elects to continue its current modus operandi and furthermore proposes to reduce the GS to literature searches and the farmer questionnaires only. Ommiting the stewardship activities and the existing networks would not meet the requirements of the Directive 2001/18/EC. The consent holder collaborates within EuropaBio towards a harmonized post-market environmental monitoring plan, which, once agreed with the different 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	

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			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.	
DE	Federal Office of Consumer Protection and Food Safety (BVL) German CA	3.1 General Surveillance	The German CA did not share the view of the consent holder that EENs are not suited as a primary tool for GS in GM crop monitoring and are of less value than the other approaches. It is true, that the focus of these EENs is not directly related the GM crop monitoring, but some are linked to agriculture or agricultural landscapes. Several national research projects demonstrated the value of EENS for GMO monitoring (Pascher et al. 2011, Glandorf 2012, Lang & Bühler 2012; DEFRA 2013, Römbke et al. 2014). These papers and EFSA also identified limitations in using EENs for GMO monitoring, but showed also ways forward to use EENs for GS. The German CA is of the opinion that the consent holder should reconsider his strategy to implement EENs into GS. Nevertheless, certainly collaboration with operators of EENs and Member States is needed. 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.	EFSA thanks DE for the comments on existing environmental networks. EFSA acknowledges that the use of such networks raises a major methodological challenge, namely the feasibility of linking a given agricultural practice, such as GM cultivation, with global impacts while many other stressors may explain the observed changes. Other challenges include data heterogeneity, incompleteness, accessibility to data, exploitation methodologies, data reporting format, and data connectivity with GMO registers (EFSA GMO Panel, 2014b). Also, the lack of a clear definition of the protection goals in each EU Member State or region is a significant obstacle. However, there exist networks adapted to such an exercise (e.g., monitoring of butterflies). These systems would equally inform the potential effect of other agricultural practices (e.g., pesticides). While EFSA acknowledges the challenges of using EENs to identify impacts of GM crops, EFSA encourages the EC, the consent holder, the National Competent Authorities and relevant stakeholders to discuss how to make the best use of EENs.

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			Lang, A. & Bühler, C. (2012) Estimation of required sampling effort for monitoring the possible effects of transgenic crops on butterflies: Lessons from long-term monitoring schemes in Switzerland. *Ecological Indicators*, 13, 29–36. Glandorf, D.C.M. (2012) General surveillance of genetically modified plants. *RIVM Report 601040001/2012*. Römbke, J., Jänsch, S., Roß-Nickoll, M. & Toschki, A. (2014) Nutzungsmöglichkeiten der Boden-Dauerbeobachtung der Länder für das Monitoring der Umweltwirkungen gentechnisch veränderter Pflanzen. *BfN Skripten* 369. DEFRA (2013) Post Market Environmental Monitoring of Genetically Modified Crops. https://www.gov.uk/government/publications/genetically-modified-crops-post-market-monitoring.	For transparency reasons, itis suggested that the consent holder provides a list of EENs identified as being active in the areas where GM maize is cultivated and an evaluation of the EENs according to the assessment criteria outlined under point 3 on p. 8-9 in EFSA 2014c. Overall, as part of the general framework on general surveillance that could also include a robust farmer alert system as outlined above, EFSA encourages the concerned EU Member States and relevant stakeholders to engage in the pooling of networks and the development of a methodological framework that enables making the best use of existing ones involved in environmental monitoring of agricultural practices.
DE	Federal Office of Consumer Protection and Food Safety (BVL) German CA	3.1.6 Literature Search	The consent holder stated that all publications resulting from the search - as described in Step 4 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 thanks DE for the comment on the literature search. Overall the quality of the literature review performed by the consent holder is acceptable. EFSA acknowledges the efforts made by the consent holder to take into consideration EFSAs recommendations and to comply with the guidance given in EFSA 2019. However, some areas of improvement of future literature searches were identified. It is recommended that the consent holder provides a discussion/justification for the selection of the searched databases and the exclusion of other databases (e.g. EMBASE) and what might be the impact of their

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				non-inclusion. Furthermore, the consent holder should provide details on the outcome of the pilot study and explain and list the criteria which were used for assessing the reliability of publications identified in the literature search. Relevant information on teosinte should be also be retrieved in future literature searches. None of the publications point to new hazards, modified exposure or new scientific uncertainties that would change the former risk assessment conclusions on and risk management recommendations for maize MON 810.
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, the German CA suggests for better comparability to report LC and MIC values for ECB and MCB, as well.	EFSA thanks DE for the comment and took note of the comment.
DE	BfN	1. General information	The Federal Agency for Nature Conservation considers that the current monitoring report on the cultivation of MON810 in 2019 as well as the underlying monitoring plan does not meet the objectives defined in Annex VII of Directive 2001/18/EC and the supplementing guidance notes (2002/811/EC). Furthermore, the EFSA Guidance on the Post-Market Environmental Monitoring (2011) has not been taken into account. The monitoring report at hand fails to provide sufficient sound and relevant data to support its conclusion that there are no adverse effects	EFSA thanks DE for the comment and took note of the comment.

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			attributed to the cultivation of MON810 in Europe. The Federal Agency for Nature Conservation reinforces its conclusion that substantial improvement of the monitoring plan as well as the monitoring report is needed. We would like to refer to our previous comments and confine ourselves to the following subjects.	
DE	BfN	3.2 Case-specific monitoring	As stated in the monitoring report on the cultivation of MON810 in 2019 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 MON810 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 non-target aquatic organisms (see comments on application for renewal of MON810 (EFSA-GMO-RX-MON810), Bundschuh et al., 2019, Pott et al., 2020). According to the monitoring report Bayer 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 which occurs in the Ebro valley (CSCV 2016), the same region where the monitoring activities for MON810 were concentrated on. Evidence for the occurrence of gene flow from crop maize to teosinte has been reported recently (Le Corre et al., 2020).An introgression of the Bt	EFSA thanks DE for the comment. 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

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			trait of MON810 into teosinte could boost its fitness and increase its weediness. 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. The question whether volunteer maize MON810 plants (Pascher 2016) occur on former MON810 fields needs to be addressed in the case-specific monitoring to initiate eradication procedures and thereby reduce the potential for introgression of the Bt trait into teosinte. Also, measures need to be established to control and eradicate teosinte. The efficacy of these management measures should be surveyed in case-specific monitoring.	(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 notes the existence of monitoring activities of national authorities directly linked to maize cultivation, such as the monitoring of teosinte populations in Spain and in France. As part of general surveillance and given their potential relevance for MON 810, EFSA is of the opinion that the consent holder should include the outcome of such monitoring activities in the PMEM report. Details on the available information on teosinte monitoring and its implications on the PMEM of MON 810 was discussed by the EFSA WG on 4 May 2021 . It is recommended that the consent holder includes and explicitly considers in the future annual PMEM reports all scientific evidence relevant for the environmental risk assessment and risk management of maize MON810 in relation to teosinte, including the outcome of existing monitoring activities as mentioned above. In addition, EFSA recommends that the farmer questionnaires are revised to include the reporting of both the occurrence of teosinte and teosinte hybrid plants and the corresponding level of infestation. The consent holder and the Competent Authorities of the EU Member States where maize MON810 is grown should ensure that robust information systems are in place to promote the sharing of relevant information on teosinte.

EU MS[1]	Organization	Reference[2]	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 2019 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 the implementation of insect protected maize event specific measures. The Federal Agency for Nature Conservation is of the opinion that farmer questionnaires might be a valuable tool to collect data on agronomic issues but must not replace sound investigations of environmental effects of MON810 on farm level as well as on broader environmental scale. Even if farmers possess detailed knowledge on species determination of e.g. insects or birds (see question 3.7 MON810 Farmer questionnaires 2019) the approach of questionnaires applied allows only qualitative and mainly subsequent assumptions. These assumptions need further confirmation using science-based methods and measurements during the growing season. According to the report, the questionnaires were performed in areas reflecting the range and distribution of farming practices and environments exposed to MON810 plants and their **cultivation. It is stated that "This allows for cross**-checking of information indicative of an unanticipated effect, and the possibility to establish correlations either by comparing questionnaires between regions, or associating answers to observations made by existing networks, such as meteorological services (weather conditions) or extension services (pest **pressure)." The report on the cultivation of MON810 in 2019 comprises**	EFSA thanks DE for this comment and refers to Section 3.2.1 of the EFSA Statement for further information on the farmer questionnaires submitted as part of the 2019 PMEM report on maize MON 810.

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			neither any cross-checking of information nor any data correlation with other questionnaires or environmental data. Comparing questionnaires between regions or space-time correlation of data gained during the previous monitoring seasons with environmental data such as meteorological information or environmental surveys would be valuable tools to interpret the results of farmer questionnaires.	
DE	BfN	3.1.2.3 Alerts on environmental issues by existing networks	Existing environmental surveillance programs were not involved in general surveillance of MON810 in 2019, according to the report. The Federal Agency for Nature Conservation is of the opinion that the information of environmental surveillance programs are of great value for general surveillance. Therefore, effords should be made to develop strategies how existing programs 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 programs for the purpose of PMEM. In case significant data gaps exist, additional surveillance methods for the monitoring or environmental parameters need to be established.	EFSA thanks DE for the comment. EFSA acknowledges that the use of such networks raises a major methodological challenge, namely the feasibility of linking a given agricultural practice, such as GM cultivation, with global impacts while many other stressors may explain the observed changes. Other challenges include data heterogeneity, incompleteness, accessibility to data, exploitation methodologies, data reporting format, and data connectivity with GMO registers (EFSA GMO Panel, 2014b). Also, the lack of a clear definition of the protection goals in each EU Member State or region is a significant obstacle. However, there exist networks adapted to such an exercise (e.g., monitoring of butterflies). These systems would equally inform the potential effect of other agricultural practices (e.g., pesticides). While EFSA acknowledges the challenges of using EENs to identify impacts of GM crops, EFSA encourages the EC, the consent holder, the National Competent Authorities and relevant stakeholders to discuss how to make the best use of EENs.

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
				For transparency reasons, it is suggested that the consent holder provides a list of EENs identified as being active in the areas where GM maize is cultivated and an evaluation of the EENs according to the assessment criteria outlined under point 3 on p. 8-9 in EFSA 2014 c. Overall, as part of the general framework on general surveillance that could also include a robust farmer alert system as outlined above, EFSA encourages the concerned EU Member States and relevant stakeholders to engage in the pooling of networks and the development of a methodological framework that enables making the best use of existing ones involved in environmental monitoring of agricultural practices.
DE	BfN	3.1.4.3 Alerts on environmental issues	It is stated in this chapter that "no confirmed adverse effects related to MON810 were reported in 2019". It remains unclear whether any alerts were raised during 2019 and how they were investigated and assessed.	EFSA thanks DE for the comment. The consent holder did not make use of the EENs. Recommendations on improvement of general surveillance and use of EENs are given in the current EFSA statement in sections 3.2.1 and 3.2.2. and section 5.
DE	BfN	3.1.6 Literature search	The literature search ist not complete. Publications regarding teosinte and the spreading of volunteer maize plants are missing, as well as publications regarding the exposure and the effects of the Bt toxin on non-target organisms. The Federal agency for Nature conservations requests to add and analyse: Bundschuh, R., Bundschuh, M., Otto, M, Schulz, R. (2019). Food-related exposure to systemic pesticides and pesticides from transgenic plants: evaluation of aquatic test strategies. Environ Sci Eur 31, 87	EFSA thanks DE for the comment. The quality of the literature review performed by the consent holder is acceptable. A few suggestions for improvement of the literature review were made by EFSA (section 3.2.4.2). However, overall the quality of the literature search was evaluated as acceptable. The literature search performed by the consent holder on maize MON 810 and the Cry1Ab protein for the 2019 post-environmental monitoring report on maize MON 810 covered the time span between May 2019-May 2020.

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			CSCV (2016). Report on the situation of and measures taken to control Teosinte (*Zea mays* spp.) in the autonomous community of Aragon. Le Corre, V.; Siol, M.; Vigouroux, Y.; Tenaillon, M.; Délye, C. (2020): Adaptive introgression from maize has facilitated the establishment of teosinte as a noxious weed in Europe. In: Proceedings of the National Academy of Sciences of the United States of America 117 (41), 25618–25627. Pascher, K. (2016). Spread of volunteer and feral maize plants in Central Europe: Recent data from Austria. Environmental Sciences Europe, 28 (1), 30. Pott, A.; Bundschuh, M.; Bundschuh, R.; Otto, M.; Schulz, R. (2020): Effect of Bt toxin Cry1Ab on two freshwater caddisfly shredders - an attempt to establish dose-effect relationships through food-spiking. In: Scientific Reports 10 (1), 5262. The literature search is not complete. There are publications to teosinte and spreading of volunteer maize plants missing. The Federal agency for Nature conservations requests to add and analyse: - CSCV (2016). Report on the situation of and measures taken to control Teosinte (*Zea mays* spp.) in the autonomous community of Aragon. - Pascher, K. (2016). Spread of volunteer and feral maize plants in Central Europe: Recent data from Austria. Environmental Sciences Europe, 28 (1), 30.	Therefore, the publication of CSCV 2016 and Pascher 2016 were not retrieved by the literature search as they were outside the time frame covered by the search. The article of Pascher 2016 is not linked to MON 810. EFSA is aware of the article and it is cited in several EFSA opinions. The article of Bundschuh et al. 2019 is not related to MON 810. Pott et al. 2020 was evaluated in the EFSA 2020 (EFSA (European Food Safety Authority), Álvarez F, Georgiadis M, Messéan A and Streissl F, 2020. Assessment of the 2018 post-market environmental monitoring report on the cultivation of genetically modified maize MON 810 in the EU. EFSA Journal 2020;18(10):6245, 42 pp. https://doi.org/10.2903/j.efsa.2020.6245) The most up to date report of CSCV and information on teosinte was evaluated by EFSA (see section 3.2.3 in the current EFSA statement). The article of le Corre et al. 2020 was discussed in the WG CompERA. See minutes of 219th CompERA meeting held on 24 November 2020. https://www.efsa.europa.eu/sites/default/files/wgs/gmo/gmocompera2019.pdf

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
DE	BfN	4 Summary of results and conclusion	The general surveillance of MON810 in 2019 focussed mainly on the farm level. Monitoring of potential environmental effects in the vicinity of the fields planted with MON810 and at landscape level did not take place. Therefore the conclusion in this chapter that "All together, these results demonstrate that there are currently no adverse effects attributed to the cultivation of MON810 in the EU" is unfounded and misleading.	EFSA thanks DE for the comment. The general surveillance consists also of a literature review and should ideally also make us of EENs. Improvements in the general surveillance and use of EENs are proposed in the current EFSA statement (sections 3.2.1, 3.2.2, 3.2.3 and sections 4 and 5).
ES	National Commission on Biosafety (CNB)	General information	The annual monitoring report on the cultivation of MON 810 in 2019 is in line with the proposal for monitoring included in the application for renewal of this event and in accordance to EU regulation. The report also follows the format the reports follow the format provided in Commission Decision 2009/770/EC Main results of the 2019 Report are: - The analysis of 250 questionnaires from the survey of farmers cultivating MON 810 in Spain and Portugal during the 2019 growing season did not reveal any adverse effects that could be associated with the genetic modification in MON 810. - The commercial planting of MON 810 in Europe in 2019 continues to be accompanied after 14 years by a proactive Insect Resistance Management (IRM) plan, involving a farmer complaint system, refuge implementation, target pests susceptibility monitoring, farmer education and company stewardship activities. - The established and reinforced effective education and communication program in countries where MON 810 was grown in 2019, obtained the 100% of farmers interviewed acknowledged and informed about	EFSA thanks ES for the comment.

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			the good agricultural practices applicable to MON 810 and the percentage of farmers implementing refuges in their fields remains very high (94.8%). - The results of the analysis of 2019 farmer questionnaires, Company stewardship activities, farmer complaint systems and issue alerts did not reveal adverse effect related to MON 810 cultivation. The literature search has been arried out and 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 2019 cultivation season as confirmed by the absence of farmer complaints related to allegedly reduced MON 810 target pest product performance. - The latest IRM plan results show that 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 2019. The data presented in the report did not show any scientific evidence that could invalidate the outcome of previous risk assesment. Therefore it is concluded that MON 810 is as safe to human health, animal health and the environmenet as its conventional counterpart. Although the CNB does not have any specific comments on this conclusion, after many years of MON810 maize cultivation, the PMEM Plan should be updated in a legally binding manner, taking into account, first of all, the accumulated experience during these years and that Bayer continues to report 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	

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			which were not anticipated in the environmental risk assessment regarding to General Surveillance monitoring.	
ES	National Commission on Biosafety (CNB)	General surveillance	GS is not a requirement included in the current authorisation for MON 810 issued in 1998, therefore we acknowledege the company´s commitment to report on this activities on a voluntary basis since 2005. The importance of this type of monitoring to support the conclusions on the safety of cultivation of MON 810 is also recognized. Bayer proposes to limit the conditions for the general surveillance to literature searches and the farmer complaint systems. However, in previous EFSA reports this proposal was not supported. The main reasons are that the existing system is not dedicated to monitoring and lacks adequate communication mechanisms and educational programmes (e.g. field scouting techniques and characterisation of the damage caused by corn borers). As described in paragraph 3.2.1.3 "farmer complaint system provide means for farmers to report any complaint related to maize seeds performance, including failure in protection against corn borers in MON 810 varieties".... "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". Those monitoring plan must fulffil specific requirements and they must include programs to inform the farmers with recommendation about good agricultural practices. Ministerial Order on the registration of a variety	EFSA thanks ES for the comment and information.

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			with MON 810 in the national variety catologue also establishes the protocol to inform Competent authorities about the possible detection of resistance insects or other significant evidence and examples of measures that could be implemented if the resistance is finally confirmed.	
ES	National Commission on Biosafety (CNB)	Case specific monitoring	The resistance to cry 1Ab should be analyzed within a broader approach and not only linked to the cultivation of this event. Currently it is not mandatory in the EU law to 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. The high level lof compliance of this voluntary provision shows the comittment of spanish farmers and the effort of the notifier and national CA to explain and recall the importance and advantages of implementing refuges, as a tool for the insect resistance management. However further efforts would be needed to advance towards achieve full compliance with refuge requirements in areas of high adoption of maize MON 810, as reccomended by EFSA in its report assessment 2018. Spanish CA have adopted a national control program on the deliberate release of GMO for food and feed purposes, included in the national plan for oficial control of the food chain which could represent another good opportunity to interact with farmers about the refuges an other good agricultural practices in addition to the existing ones. We acknowledge the effort made by the consent holder to improve the IRM taking into account the difficulties reported to find sampling sites with sufficiente number of larvae	EFSA thanks ES for the comment. EFSA notes that the detection limit for resistance allele frequency achieved in the diagnostic bioassays was higher than the recommended 3% for both target pests. Consequently, EFSA reiterates the recommendation to increase the sensitivity and precision of the monitoring strategy so that the consent holder can implement alternative management measures timely to delay resistance evolution. As indicated in EFSA (2019a), this could be achieved by (1) increasing the sampling size of field populations and reducing the mortality during the laboratory rearing of field-collected populations; or (2) replacing diagnostic bioassays by more sensitive testing methods. Since the consent holder has conveyed the difficulties to find sampling sites with sufficient numbers of corn borer larvae and to reduce the mortality of field-collected individuals before laboratory testing, the only alternative to increase the sensitivity of the monitoring strategy is using a more sensitive method EFSA advocates modifying the current monitoring strategy, primarily based on diagnostic concentration assays, and using a more precise and sensitive testing method, like F_2 screen. EFSA is aware that the F_2 screen is costly and resource-intensive and entails practical challenges. To overcome such limitations, F_2 screens could be performed periodically with ECB and MCB populations. Periodic estimations of resistance alleles

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			We consider the reported efforts to harmonise the methodologies of the diagnostic bioassays between the two species as it was recommended by EFSA. On the other hand, in parallel to this revision, CNB has also review the EFSA report on the PMEM on the cultivation of MON 810 in 2018. EFSA recommends to use a more sensitive method to increase the sensitivity of the monitoring strategy: "perform an F2 screen on corn borer population from north-eastern Spain" This type of monitoring was only implemented in Australia for Bt cotton. This fact, together with the presence of technical limitations and the need of intensive resources to implement this strategy should be acknowledged in a broader context. Therefore, it could be also useful to recommend and analyze with the consent holder the criteria and possibilities to better implement these type of strategies taking into account the previous knowledge and limitations on the development of IRM activities, other measures included in the PMEM and their results.	through F_2 screening, together with a robust farmer complaint system (see Section 3.2.3.3 of the EFSA statement for further insights), should replace annual diagnostic concentration assays. After each F_2 screen, the consent holder should run new simulations with resistance evolution models using the latest resistance frequency estimations and accounting for changes in the model parameters.
IT	Institute for Environmental Protection and Research (ISPRA)	3.1 General Surveillance	General surveillance was also applied in accordance with the provisions of the legislation. Regarding the applicant's proposal to update general surveillance by limiting it exclusively to literature research and the reporting system by farmers, and thus leaving aside the sending and analysis of questionnaires to farmers and the use of existing environmental monitoring networks, we believe that these last two activities should continue to be applied. Even if the existing monitoring networks proposed by EuropaBio are not useful under the PMEM of	EFSA thanks IT for the comment. We agree and propose to maintain the farmer questionnaires and to improve….

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			MON810, the applicant can still continue to check every year if further useful networks have been developed in the meantime. Even the sending of questionnaires to farmers is an activity that should be maintained, despite the fact that the amount of 2.500 questionnaires has been reached in 10 years, a number that allowed the meta-analysis that the applicant performed.	
IT	Institute for Environmental Protection and Research (ISPRA)	3.2 Case-specific monitoring	Regarding the case-specific monitoring named insect-resistant management (IRM), ISPRA retains that this has been adequately conducted in relation to the 2019 agricultural season in Spain and Portugal, following the protocol provided by EuropaBio.	EFSA thanks IT for the comment
IT	Institute for Environmental Protection and Research (ISPRA)	Appendix 7, tables 3 and 4, and Appendix 8,	It able would be appropriate to have more details on the sampling points of the larvae of the two species collected outside the nearest reference Bt field: the report indicates the distances from this field, but not if it is another field cultivated with corn and what type of treatment is used (conventional, organic, etc.).	EFSA thanks IT for the comment. Appendix H which provides minimum recommendations for reporting information for insect resistance monitoring studies has been updated to indicate that information on the type of maize fields where larvae are collected should be provided.
NL	GMO Office, for the Ministry of Infrastructure and Water management	1 General Information	The Dutch CA under 2001/18/EC is of the opinion that the MON 810 monitoring report of 2019 is in line with the proposal for monitoring as provided in the application for renewal of this event (RX-MON810) and in accordance to Regulation (EC) 1829/2003. The 2019 monitoring report also complies with the monitoring format for GM cultivation (Commission Decision 2009/770/EC).	EFSA thanks NL for the comment and takes note of this comment.
NL	GMO Office, for the Ministry of Infrastructure and Water management	3.1 General Surveillance	The General Surveillance monitoring program performed by Bayer in 2019 consists of four elements: · data obtained by 250 farmer questionnaires of farmers from 2 member states (Spain and Portugal)	EFSA thanks NL for the comment. EFSA noted that the farmer questionnaire and the approach followed to identify unanticipated adverse effects caused by the cultivation of maize MON 810 are

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			designed to assess unusual observations in the areas where MON 810 has been cultivated the most; · data collected from 15 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 MON810 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 111 845 hectares in two EU member states (Portugal and Spain) in 2019. With respect to the farmer questionnaire, we refer to COGEMs advice on General Surveillance (CGM/100226-01, https://cogem.net/publicatie/signalering-general-surveillance/)	similar to those in previous annual PMEM reports. EFSA therefore reiterated 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 (See section 3.2.1 of the EFSA Statement).
NL	GMO Office, for the Ministry of Infrastructure and Water management	3.2 Case specific monitoring	We want to point out that the Netherlands does not consider resistance development of the European corn borer (ECB) towards Cry1Ab to pose an environmental risk, but rather an agricultural or economic risk. This is in line with Regulation (EC) No 1107/2009 that considers resistance development to plant protection agents (such	EFSA thanks NL for the comment and took note of this comment.

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			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 GMO.	
RO	Romanian Biosafety Commission	General comments	The Annual Monitoring Report on the cultivation of MON 810 in 2019 growing season in Portugal and Spain was submitted in October 2020 by the Department of Regulatory Science of Bayer Agriculture BV to the European Commission. The report has the similar structure, approach and conclusions as those submitted in previous years (2005-2018) in the layout which follows the format asked by Commission Decision 2009/770/EC. On 4th of July 2017, the European Commission adopted the renewal of the authorisation for the placing on the market of MON 810 for all uses, except for pollen and cultivation (European Commission, 2017). In 2019, MON 810 was planted in the EU on approximately 111 845 hectares only in the two countries, Portugal (4 718 ha) and Spain (107 127 ha). The planting of MON 810 in the 2019 season was accompanied by a rigorous IRM plan involving five main elements: a farmer complaint system, farmer education, refuge implementation, susceptibility monitoring and good stewardship practices. In 2019, Bayer continued its General Surveillance monitoring program, implemented on a voluntary basis and aimed at identifying the occurrence of adverse effects of the GMO or its use on human or animal health or the environment, which were not anticipated in the environmental risk assessment.	EFSA thanks RO for the comment and took note of this comment.

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			The analysis of 250 questionnaires from the 2019 survey of farmers cultivating MON 810 in Portugal (11) and Spain (239), did not reveal any adverse effects associated with the genetic modification in MON 810. Furthermore, a detailed analysis of 17 independent publications (from References) 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 publications confirm 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. An extensive 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 2019. No complaint allegedly caused by reduced target pest susceptibility to MON 810 was received from farmers in 2019. In 2019 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 2019.	
RO	Romanian Biosafety Commission	3.1 General Surveillance	The monitoring plan strategies to identify the occurrence of adverse effects of the GMO, known as General Surveillance (GS), is not a condition of the current authorization for MON 810 issued in 1998 or renewal in 2019.	EFSA thanks RO for the comment and took note of this comment.

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			In 2019, Bayer continued the GS monitoring program initiated in 2005 on a voluntary basis. The objective of GS is to identify the alleged occurrence of adverse effects of the GMO or its use on human or animal health or the environment which were not anticipated in the environmental risk assessment. The main challenge of GS is determining whether 1) an unusual effect has been observed (i.e., an alteration that results in values that are outside the normal variation range given the constant change and flux of agriculture, agricultural practices, the rural environment and the associated biota in the European Union), 2) the effect is adverse, and 3) the adverse effect is associated with the GM plant or its cultivation (EFSA, 2011). GS is focused on the geographical regions within the EU where the GM crop is grown, therefore takes place in representative environments, reflecting the range and distribution of farming practices and environments exposed to GM plants and their cultivation. EFSA concluded that no adverse effects on human or animal health or the environment were identified due to MON 810 cultivation during the 2009 – 2019 growing seasons and that the outcomes of the monitoring reports did not invalidate the previous risk assessment conclusions Bayer 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, (4) the use of existing environmental networks	

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			(EENs) and description and results of case – specific monitoring. We consider the GS conducted by Bayer to be appropriate, confirming that MON 810 is as safe as conventional maize with respect to human and animal health and the environment.	
RO	Romanian Biosafety Commission	3.1.2.1. Farmer questionnaires	EFSA explicitly considers questionnaires as a useful method to collect firsthand data on the performance and impact of a GM plant. The 2019 GS for MON 810 focused on the Iberian geographical regions where most MON 810 was grown (Portugal and Spain), reflecting the range and distribution of farming practices and environments exposed to MON 810 plants and their cultivation. This allows for cross-checking of information indicative of an unanticipated effect, and the possibility to establish correlations either by comparing questionnaires between regions, or associating answers to observations made by existing networks, such as meteorological services (weather conditions) or extension services (pest pressure). The current version of the questionnaire was adapted according to DG Environment feedback (13 March 2009) and discussions within EuropaBio (Appendix 2). As appropriate, in each season adjustments were made to improve the statistical relevance of the collected data. Questions were designed to be unambiguous, easily understood and not to be too burdensome. Also, it is sufficiently pragmatic to consider real commercial situations. In 2019, 11 farmers in Portugal and 239 farmers in Spain were asked to complete the questionnaires (250 in total).	EFSA thanks RO for the comment and took note of this comment.

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			The interviews have been completed between February and March 2020. All interviewers have been trained to understand the background of the questions. The analysis of the 250 questionnaires from the survey of farmers cultivating MON 810 in two European countries in 2019 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	This literature search was conducted to support general surveillance of 2019/2020 annual post market environmental monitoring report in accordance with the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019). Bayer confirms that the literature search, within the context of general surveillance for MON 810 in the EU, identified no relevant publications that would invalidate the initial conclusions of the MON 810 risk assessment.	EFSA thanks RO for the comment and took note of this comment.
RO	Romanian Biosafety Commission	3.2 Case specific monitoring	Starting 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. A harmonized IRM plan specific for the EU was implemented based on published research, current EU	EFSA thanks RO for the comment and took note of this comment.

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			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 opinions, the historical data on Bt-maize cultivation, data in the scientific literature, and the experience gained from IRM plans established in other regions, the EuropaBio Monitoring working group has updated the IRM plan in 2017 and amended in 2019. This harmonized IRM plan contains guidance on the following key elements: (1) refuge implementation; (2) resistance monitoring in the target pests; (3) growers complaint system; (4) remedial plan in case of Bt maize failure to protect against target pests; and (5) communication and grower education. We consider this case specific monitoring as appropriate with the existing monitoring results which demonstrated that there are no adverse effects attributed to the cultivation of MON 810 in Europe.	
RO	Romanian Biosafety Commission	4. Summary of results and conclusions.	The report describes the activities undertaken by Bayer to identify and analyse anticipated and unanticipated effects related to MON 810 cultivation in Europe. The data bring new evidence to support the conclusions and consists of regulatory safety studies, presented in the different EU applications, more than a dozen EFSA opinion concluding 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 opinion and more than 16 years of experience with cultivation of	EFSA thanks RO for the comment and took note of this comment.

EU MS[1]	Organization	Reference[2]	Comment	EFSA's response
			MON 810 in the EU and more than 22 years of experience worldwide on million of hectars. All these results support the initial conclusions of the risk assessment and the absence of confirmed adverse effect related to the event. Considering all these results and the result of the 2019 monitoring plan, as the results observed since monitoring was started in 2003, the conclusion is that there are currently no adverse effects attributed to the cultivation of MON 810 in Europe. In conclusion, we consider that the present methodology used for monitoring the cultivation of MON 810 in Europe is adequate and demonstrates that there are curently no adverse effects attributed to the cultivation of MON 810.	

The full reference of all publications cited in this Annex can be found in the EFSA Statement.

[1] European Union Member States: AT: Austria; DE: Germany; DK: Denmark; ES: Spain; FR: France; NL: The Netherlands; RO: Romania.

[2] Reference to the specific section or appendix of the annual 2019 PMEM report.