Application EFSA-GMO-RX-017 (maize MON 88017 x MON 810)

Comments and opinions submitted by Member States during the three-months consultation period

Country	Organization	Reference	Topic	Comment	GMO Panel responses
Austria	Fed.Ministry_ Labour/Soc.A/ Health	2.3.1. Systematic search and evaluation of literature	AUT Comment_01	As already outlined previously with respect to another renewal notification (EFSA-GMO-RX-015) and agreed by an EFSA GMO Panel Response, the combination of search terms such as the trade name and the newly expressed proteins with the Boolean operator "AND" is considered not to be an adequate search approach. It should be paid more attention to the compliance with EFSA's Explanatory note on literature searching (EFSA 2019), in particular, that "some key elements are less important than others […] or may unnecessarily complicate or restrict a search strategy" and "the number of elements in a search strategy should remain as low as possible" (Chapter 3.2.2.5). [EFSA, 2019. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market. EFSA Supporting Publications EN-1614: 1-62.]	The applicant submitted two systematic literature searches covering the period from January 2009 till September 2020, that were performed in accordance with the recommendations on literature search outlined in EFSA (2010, 2017). The GMO Panel assessed the applicant's literature searches on maize MON 88017 × MON 810 and the newly expressed proteins Cry3Bb1, Cry1Ab, and CP4 EPSPS. The overall quality of the performed literature searches is acceptable; however, the GMO Panel considered that future searches could be fine-tuned. The GMO Panel therefore recommended the applicant for future searches to: (1) ensure that enough search term variation is used (covering possible synonyms, related terms, acronyms, spelling variants, old and new terminology, brand and generic names, lay and scientific terminology, common typos, translation issues); (2) adapt the search to the size of the retrieved publications (and thus not combine search sets when one of the search sets already yields only a small number of publications).
Austria	Fed.Ministry_ Labour/Soc.A/ Health	2.3.2. Updated bioinformatics	AUT Comment_02	An update of insert DNA sequencing of GM maize MON88017xMON810 should be provided in order to reduce any uncertainties with respect to the identification of similarities to toxic proteins and/or microbial sequences.	The applicant did not submit new sequence information and no additional studies were included in the dossier. The GMO Panel performed the assessment under the assumption that the sequences of events MON88017 and MON810 are identical to the originally assessed sequences of the single events.

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				From the presented information, it is not clear whether new sequencing information from GM maize MON88017xMON810 currently on the market or the sequence retrieved from the initial application has been used for updated bioinformatic analyses. We are of the opinion that using up-to-date sequence information from the varieties currently on the market for sequence comparison studies was the intention of the legislator when the request for renewal was implemented in the GMO legislation. We have to reiterate that even the EFSA Guidance for renewal applications itself states, “Amongst those studies, data on the sequence of the event(s) for renewal, derived from seed lines containing this event(s) and giving rise to varieties imported to the EU close to the time of the renewal application, should be included” (EFSA 2015). [EFSA, 2015. Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. EFSA Journal 13(6): 4129.]	

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Austria	Fed.Ministry_ Labour/Soc.A/ Health	2.3.2. Updated bioinformatics	AUT Comment_03	FROM CBI: Technical Report MSL0029193 ([redacted]) BLASTN analysis of the insert sequence against microbial sequences stored in the NCBI database was performed using the megablast algorithm. Homology search was performed according the parameters recommended by EFSA. The NCBI Microbes database used was from January 2018 and, thus, is now more than 2 years of age and could be more up-to-date. The applicant reported that the tested bacterial database contained 5469 complete bacterial genome sequences. It is doubtful that this small number can provide meaningful results concerning the potential for horizontal gene transfers and homologous recombination between incoming transgenic DNA and indigenous bacteria in natural environments. Considering the fact that it was estimated that for instance 1 g of soil may contain 10,000 (Torsvik et al. 2002) to more than 10 million different bacterial species (Gans et al. 2005) this bioinformatic approach covered only a negligible fraction of bacterial genomes which may serve as potential recombination partners in natural environments. Moreover, genomes even of the same bacterial species show substantial sequence variability, are highly dynamic and	Following an EFSA request, the applicant submitted an updated bioinformatic analysis for HGT analysis using up-to-date databases (additional information Clock1, 26/02/2020). The analysis was performed according to EFSA guideline (EFSA, 2017). The GMO Panel concluded that given the results of this analysis and that the recombinant DNA in maize MON 88017 x MON 810 does not confer selective advantages to microorganisms, the GMO Panel identified no safety concern linked to an unlikely but theoretically possible HGT.

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				appear to be in a constant genetic flux (compare for instance the propensity of microbes to form different strains or to acquire or loose pathogenicity islands), which is clearly not sufficiently reflected in the present microbial databases of GenBank (Schmidt and Hensel 2004; Myers et al. 2006). At the present stage the relevance of the drawn conclusions for estimating a potential risk derived from horizontal gene transfer events by homology searches against currently available microbial sequence data collections are probably highly questionable but certainly affected by a high degree of uncertainty. This shortcoming is to be documented during the risk assessment process to facilitate an informed decision-making process for the involved risk managers (EFSA Scientific Committee 2016). [EFSA Scientific Committee, 2016. Guidance on uncertainty in EFSA scientific assessment. Draft. EFSA Journal. https://www.efsa.europa.eu/sites/default/files/consultation/150618.pdf (last access: 7.8.2017). Gans J, Wolinsky M, Dunbar J, 2005. Computational improvements reveal great bacterial diversity and high metal toxicity in	

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				soil. Science 309(5739): 1387-1390. Myers GS, Rasko DA, Cheung JK, Ravel J, Seshadri R, DeBoy RT, Ren Q, Varga J, Awad MM, Brinkac LM, Daugherty SC, Haft DH, Dodson RJ, Madupu R, Nelson WC, Rosovitz MJ, Sullivan SA, Khouri H, Dimitrov GI, Watkins KL, Mulligan S, Benton J, Radune D, Fisher DJ, Atkins HS, Hiscox T, Jost BH, Billington SJ, Songer JG, McClane BA, Titball RW, Rood JI, Melville SB, Paulsen IT, 2006. Skewed genomic variability in strains of the toxigenic bacterial pathogen, Clostridium perfringens. Genome Res 16(8): 1031-1040. Schmidt H, Hensel M, 2004. Pathogenicity Islands in Bacterial Pathogenesis. Clin Microbiol Rev 17(1): 14-56. Torsvik V, Ovreas L, Thingstad TF, 2002. Prokaryotic Diversity--Magnitude, Dynamics, and Controlling Factors. Science 296(5570): 1064-1066.]	
Austria	Fed.Ministry_ Labour/Soc.A/ Health	2.3.2. Updated bioinformatics	AUT Comment_0 4	FROM CBI: Technical report RAR-2018-0496 ([redacted]) Page 5: The applicant is stating, “Consequently, the likelihood of a HR mediated gene transfer from MON88017 to archaea, bacteria, plasmids, or bacteriophage viruses is very low if not impossible.” Homologous	

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				recombination as defined by the stringent conditions by EFSA (EFSA 2017) is indeed assumed to be a rare event. However, under selection pressure this rare event is rapidly fixed in the exposed bacterial populations (Townsend et al. 2012; Nielsen et al. 2014). We would like to indicate that extremely rare transformation frequencies are not predictive to exclude long term adverse events (Pettersen et al. 2005). We would like to ask the EFSA GMO Panel to take this into consideration. We acknowledge that the applicant has located the MON88017 T-DNA insert on chromosome 4. Page 6: The applicant maintains, "Each of the parsed protein sequences displayed an extreme compositional bias towards proline and/or glycine; therefore, these alignments do not reflect conserved structure or function indicating that its potential for inducing an allergenic response is highly unlikely." An appropriate reference in support of this conclusion is missing. Please provide the missing information. Query sequence preparation, page 8: The source for the query sequence is not clearly described. Please provide a clear indication for the source of the query sequence. The indicated reference (Vest and	Following an EFSA request, the applicant submitted an updated bioinformatic analysis for HGT analysis using up-to-date databases (additional information Clock1, 26/02/2020). The analysis was performed according to EFSA guideline (EFSA, 2017). The GMP Panel takes Austria's comment into consideration. The applicant submitted an updated bioinformatic analysis for events MON810 and MON88017 using up-to-date databases (additional information Clock1, 26/02/2020). The updated bioinformatic analysis did not identify new evidence in the renewal application EFSA-GMO-RX-017 for new hazards or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017 × MON810 (EFSA GMO Panel, 2009). Upon EFSA request, the applicant clarified the source of the sequences used in the bioinformatic analysis for both events MON810 and MON88017. The applicant also clarified that the sequences of these

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				Silvanovich, 2016) is not available in the submitted reference package. Sequence database searches, page 9: The indicated literature reference (EFSA 2015) is outdated. The alignment studies should have been performed according to EFSA (2017). Significance of the alignments, page 11: The applicant is indicating a conservative threshold which "is consistent with the information reviewed and summarised by (EFSA 2009) where relative rates of HR for DNA segments of varying lengths were reported." We are of the opinion that the applied restrictions and thresholds for identifying a valid recombination potential are much too stringent to identify biologically relevant homologous recombination events. Homology directed illegitimate recombination (HDIR) requires a single homologous anchor sequence of approx. 150-180 bp and a short region of microhomology of ca. 3 10 bp of incomplete sequence identity at the opposite end of the incoming DNA strand to mediate the insertion of foreign completely non-homologous to the recipient genome (de Vries and Wackernagel 2002; Prudhomme et al. 2002). These are substantially more relaxed conditions as presented by the	events are identical to the sequences of the originally assessed single events (additional information Clock2, 29/05/2020). Following an EFSA request, the applicant submitted an updated bioinformatic analysis for HGT analysis using up-to-date databases (additional information Clock1, 26/02/2020). The analysis was performed according to EFSA guideline (EFSA, 2017).

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				applicant (2 x 95% sequence identity of 200 bp). By applying the stringent requirements for successful horizontal gene transfers as performed by the applicant, only high frequency transfers of genes or gene fragments between plant and bacterial DNA would be accessible. The applied bioinformatic strategy is thus prone to deliver false negative results due to obvious insensitivity. The applicant indicates, "As no alignment (Appendix 1) met the threshold criteria it is unlikely the query sequence from MON 88017 supports HR with any sequence from ARC_2018 database." Please clarify if the bacterial epsps sequence was plant-codon optimised. According to the initial technical dossier from 2008, the native C4 epsps sequence was used, thus at least alignment with the gene from Agrobacterium tumefaciens should have been reported if the chosen alignment strategy is valid. We would like to ask the EFSA GMO Panel to clarify the situation. [de Vries J, Wackernagel W, 2002. Integration of foreign DNA during natural transformation of Acinetobacter sp. by homology-facilitated illegitimate recombination. Proc Natl Acad Sci U S A	The GMO Panel takes note of the comment. The applicant submitted an updated bioinformatic analysis for HGT using up-to-date databases (additional information Clock1, 26/02/2020). The analysis was performed according to EFSA guideline (EFSA, 2017). CP4 EPSPS sequence was codon optimized for expression in plant. The bioinformatic

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				99(4): 2094-2099. EFSA, 2017. Explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms. EFSA Supporting Publications 12(12): EN-1273. Nielsen KM, Bohn T, Townsend JP, 2014. Detecting rare gene transfer events in bacterial populations. Front Microbiol 4: 415. Pettersen AK, Bohn T, Primicerio R, Shorten PR, Soboleva TK, Nielsen KM, 2005. Modeling suggests frequency estimates are not informative for predicting the long-term effect of horizontal gene transfer in bacteria. Environ Biosafety Res 4(4): 223-233. Prudhomme M, Libante V, Claverys JP, 2002. Homologous recombination at the border: insertion-deletions and the trapping of foreign DNA in Streptococcus pneumoniae. Proc Natl Acad Sci U S A 99(4): 2100-2105. Townsend JP, Bohn T, Nielsen KM, 2012. Assessing the probability of detection of horizontal gene transfer events in bacterial populations. Front Microbiol 3: 27.]	analysis using an updated bacterial database (BCT_2019) identified one alignment to the EPSPS sequence in MON88017 (Appendix 2, study REG-2019-0179). However, the alignment was not significant according to EFSA requirements (EFSA, 2017) due to the codon optimization and the absence of a paired or higher order alignments.

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Belgium	Biosafety Advisory Council	3. Overall assessment	MON 88017 x MON 810	We neither have comments, nor requests for additional information	The GMO Panel thanks for the comment.
Germany	BfN	1. General comments	Comment 1 / Federal Agency for Nature Conservation (BfN)	The Federal Agency for Nature Conservation (BfN) considers that the environmental risk assessment of MON88017 x MON810 needs to include the following new (later than 2009) scientific information: i) fate of Bt toxins in the environment after livestock has been fed with Bt maize; ii) occurrence of teosinte as a wild relative of maize in Europe. Consequently, further information should be presented before the application can be renewed. We want to point out that there is no toxicological study with plant material of maize MON88017 x MON810 and that effects of mixed residues of Cry3Bb1, glyphosate and Cry1Ab are not tested. The rat study conducted with the single event MON88017 does not assure the absence of other GM material in the basal diet (LabDiet 5002) which could enhance background effects and hide significant effects of the test material MON88017. Therefore the toxicological assessment is not complete. In addition, the monitoring plan based on consent given by Commission Decision 2010/429/EU and the monitoring reports (2011 to 2018) have many deficiencies and are neither in line with Directive 2001/18/EC	The GMO Panel took note of these comments. The information/datasets provided by the applicant for the renewal of authorisation of maize MON 88017 × MON 810 are in line with the requirements outlined in the EFSA guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003 (EFSA, 2015). The assessment of potential effects of mixed residues of herbicides are not in the remit of the EFSA GMO Panel. No new information which might change previous assessment were reported. In the context of the assessment of several applications for the renewal authorisation of genetically modified (GM) plants for food and feed uses, import and processing, the environmental risk

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				and the corresponding guidelines nor with EFSA guidance on the post-market environmental monitoring (PMEM) of genetically modified plants (EFSA 2011). Therefore, the applicant is asked to complete the monitoring reports and to revise and to detail the monitoring plan (see 2.2 and 4. for details). An improved monitoring plan and completed monitoring reports have to be provided before consent for renewal may be given (EFSA 2015). References: EFSA (2011) Scientific opinion. Guidance on the Post-Market Environmental monitoring (PMEM) of genetically modified plants. The EFSA Journal, 9(8): 2316, 40 pp. EFSA (2015) Guidance for renewal applications of genetically modified food and feed authorised under regulation (EC) No 1829/2003. The EFSA Journal 13(6):4129 1-8.	assessment (ERA) working group of the GMO Panel has been analysing the contents of the annual post market environmental monitoring (PMEM) reports as well as the relevance of their underlying monitoring methodology. The PMEM plans proposed by applicants consist of general surveillance of imported GM plant material. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. Although the final adoption of PMEM plans fall outside the remit of EFSA, the GMO Panel considers that further discussion with applicants and risk managers is needed on the practical implementation of the PMEM for GM plants for import and processing (e.g. actual data gathered on exposure and/or adverse effects as implemented in existing monitoring systems).
Germany	BfN	2.2. Post-market monitoring and post-market environmental monitoring reports	Comment 2 / Federal Agency for Nature Conservation (BfN)	The monitoring reports of MON88017 x MON810 maize for the authorisation period have fundamental shortcomings. They do not provide any sound data that could support the conclusion that there have been no adverse health or environmental effects associated with the import and use of the GMO. The monitoring reports fail to address these important topics. Completed and detailed monitoring reports are needed to be able to draw conclusions	In the context of the assessment of several applications for the renewal authorisation of genetically modified (GM) plants for food and feed uses, import and processing, the environmental risk assessment (ERA) working group of the GMO Panel has been analysing the contents of the annual post market environmental monitoring (PMEM) reports as well as the relevance of their underlying monitoring methodology. The PMEM plans proposed by applicants consist of general surveillance of imported GM plant material. This general surveillance is

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				based on monitoring data. Accidental release of viable seeds of MON88017 x MON810 maize may pose risks on the receiving environment. Addressing loss and spillage of MON88017 x MON810 maize during transport, storage and handling therefore must be a crucial element of the PMEM. According to EFSA (2011) also the efficacy of management measures applied has to be monitored.	coordinated by EuropaBio and implemented by selected operators (federations involved in import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. Although the final adoption of PMEM plans fall outside the remit of EFSA, the GMO Panel considers that further discussion with applicants and risk managers is needed on the practical implementation of the PMEM for GM plants for import and processing (e.g. actual data gathered on exposure and/or adverse effects as implemented in existing monitoring systems).

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Germany	BfN	2.3.1. Systematic search and evaluation of literature	Comment 3 / Federal Agency for Nature Conservation (BfN)	Since the original application of MON88017 x MON810 maize new literature concerning persistence and invasiveness including plant to plant gene flow as well as potential interaction with NTOs have been published and should be considered in its renewal application. The applicant's literature research found only some of the literature mentioned below, but did not consider it, because the studies were not conducted with MON88017 x MON810. In our opinion this reasoning is premature and not always applicable: some studies investigated more general aspects of GM maize interaction with the environment and Bøhn et al. (2010) investigated effects of MON810 which are also relevant for MON88017 x MON810 (see also below). Persistence and invasiveness including plant-to-plant gene flow Teosinte has been reported to occur in Spain and France (EFSA 2016). As Spain is considered one of the four main import countries for maize (see monitoring reports) gene flow from GM maize to teosinte and vice versa must be considered in the risk assessment and monitoring (see also Pascher 2016). The potential for gene flow between teosinte and cultivated maize is high,	The applicant submitted two systematic literature searches covering the period from January 2009 till September 2020. Both searches were performed in accordance with the recommendations on literature search outlined in EFSA (2010, 2017). The GMO Panel assessed the applicant's literature searches on maize MON 88017 × MON 810 and the newly expressed proteins Cry3Bb1, Cry1Ab, and CP4 EPSPS. The assessment included the eligibility/inclusion criteria selected by the applicant to establish the relevance of the retrieved publications. For the selection of eligibility/inclusion criteria, the applicant took into account the scope of EFSA-GMO-RX-017, that is, renewal authorisation for all uses as any other maize but excluding the cultivation of maize MON 88017 × MON 810. EFSA considered that the overall quality of the performed literature searches was acceptable. However, the GMO Panel considered that future searches could be fine-tuned. The GMO Panel therefore recommended the applicant for future searches to: (1) ensure that enough search term variation is used (covering possible synonyms, related terms, acronyms, spelling variants, old and new terminology, brand and generic names, lay and scientific terminology, common typos, translation issues); (2) adapt the search to the size of the retrieved publications (and thus not combine search sets when one of the search sets already yields only a small number of publications). As no potential adverse environmental effects were identified in the environmental risk assessment (ERA)

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				especially for *Zea mays* ssp. parviglumis, for which hybridization rates of 50% and more have been reported (Chavez et al. 2012). Chavez et al. concluded that biosafety regulators in regions where teosinte occurs should not only consider outcrossing from maize to teosinte but also the possibility of teosinte acting as a genetic bridge back to maize. Teosinte is difficult to control and is considered an agricultural pest which needs management. Teosinte flowers earlier and longer than maize and pollen of both species can spread over long distances. The kernels can remain for long periods in the seed bank. Recent evidence confirms the occurrence of hybrids between maize and teosinte in Europe and the existence of a new teosinte subspecies in Europe (Tritikova et al. 2017). For applications with scope of import of maize seed, the PMEM should collect data on the occurrence of teosinte and GM-maize. References: Chavez, N. B., Flores, J. J., Martin, J., Ellstrand, N. C., Guadagnuolo, R., Heredia, S., & Welles, S. R. (2012). Maize x teosinte hybrid cobs do not prevent crop gene introgression. Economic botany, 66(2), 132-137.	of maize MON 88017 × MON 810 (EFSA, 2009), case-specific monitoring was not considered necessary by the GMO Panel. Moreover, in its scientific opinion on application EFSA-GMO-RX-017, the GMO Panel concluded that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment on maize MON 88017 × MON 810. Given that environmental exposure of non-target organisms to spilled GM seeds or occasional feral GM maize plants arising from spilled GM seeds is limited, and because most proteins are degraded before entering the environment through faecal material of animals fed GM maize, potential interactions of the GM plant with non-target organisms are not considered a relevant issue by the GMO Panel.

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				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. 13 pp. Pascher, K. (2016). Spread of volunteer and feral maize plants in Central Europe: Recent data from Austria. Environmental Sciences Europe, 28 (1), 30. Trtikova, M., Lohn, A., Binimelis, R., Chapela, I., Oehen, B., Zemp, N., Widmer, A. & Hilbeck, A. (2017). Teosinte in Europe - Searching for the Origin of a Novel Weed. Scientific Reports, 7 (1), 1560. Fate of Bt proteins in the environment and interaction of Bt proteins with NTOs Import and processing of Bt maize are usually considered to have less environmental impact than cultivation. However, as BfN pointed out in other Bt maize applications, exposure of the environment to Bt toxins should be considered in the ERA. For Bt proteins, in principle, the exposure route from feed, via manure into the environment has been demonstrated (e.g. Gruber et al. 2011; Gürtler et al. 2010, Paul	

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				et al. 2010). To our understanding present studies are not sufficient to conclude that exposure of the environment and thus effects on non-target organisms will be negligible. Instead, further experiments are necessary to conclude on the exposure and subsequent effects and risks for non-target organisms from the exposure to Bt proteins via manure or sewage. Campos et al. (2018) demonstrate that dung beetles can be considered to relevant non-target organisms in this respect. The applicant did not consider the retrieved study of Bøhn et al. (2010), because it did not use the maize hybrid MON 88017 × MON 810. Bøhn et al. tested the food/feed quality of a variety of MON810 maize expressing Cry1Ab Bt-toxin over the life-cycle of the model organism Daphnia magna and found that survival, fecundity and population growth rate data generally disfavoured the GM variety as feed for D. magna compared to the unmodified near isogenic maize line. Since MON88017 x MON810 contains MON810 as single event and both express Cry1Ab, we consider these results relevant for present application. References: Bøhn, Thomas; Traavik, T.; Primicerio, R. (2010) Demographic responses of Daphnia magna fed transgenic Bt-maize. In:	

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				Ecotoxicology 19 (2), S. 419–430. Campos, R.C., Holderbaum, D.F., Nodari, R.O., Hernandez, M.I.M. (2018) Indirect exposure to Bt maize through pig faeces causes behavioural changes in dung beetles. J. Appl. Entomol.,vol. 57, 117. Gruber,H., Paul,V., Guertler,P., Spiekers, H., Tichopad, A., Meyer, H. H. D. & Müller, M. (2011) Fate of Cry1Ab Protein in Agricultural Systems under Slurry Management of Cows Fed Genetically Modified Maize (Zea mays L.) MON810: A Quantitative Assessment. Journal of Agricultural & Food Chemistry 59 (13), 7135–7144. Gürtler, S.P., Paul, V., Steinke, K., Wiedemann, S., Preißinger, W., Albrecht, C., Spiekers, H., Schwarz, F. J. & Meyer, H. H. D. (2010) Long-term feeding of genetically modified corn (MON810) - Fate of cry1Ab DNA and recombinant protein during the metabolism of the dairy cow. Livestock Science 131, 250-259. Paul,V., Guertler,P., Wiedemann,S., and Meyer.H.H. (2010) Degradation of Cry1Ab protein from genetically modified maize (MON810) in relation to total dietary feed proteins in dairy cow digestion. Transgenic Res. 19: 4.	

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Germany	BfN	2.3.2. Updated bioinformatics	Comment 4 / Federal Agency for Nature Conservation (BfN)	The EFSA guidances for renewal applications (2015 and 2019) are valid under the assumption that the event(s) has remained identical in regard to its sequence to the original events. The applicant has not provided any data in favor of this hypothesis. Without re-sequencing of current transgenic lines containing the events MON88017 and MON810 this renewal application cannot be considered complete and updated bioinformatic analysis should take into consideration potential differences identified by re-sequencing. From CBI RAR-2018-0495 ([redacted]): the gene "putative purine permease 11" (PUP11) (LOC100502445) is located in very close proximity to the insertion site of the transgene in the event MON 88017, i.e. in the promoter region of the gene. This opens the possibility that the insertion of the transgene influences its expression. Due to the proximity of the transgene to PUP11, transgenic regulatory elements might additionally influence the expression patterns of the endogenous maize gene (Weigel et al. 2000). Conclusive studies about gene function of purine permease 11 are lacking from the literature. The applicant has provided additional information on different purine permease genes in maize	Upon EFSA request, the applicant clarified the source of the sequences used in the bioinformatic analysis for both events MON810 and MON88017. The applicant also clarified that the sequences of these events are identical to the sequences of the originally assessed single events (additional information Clock2, 29/05/2020). The GMO Panel has assessed the updated bioinformatic data submitted by the applicant in the frame of renewal application EFSA-GMO-RX-017 (additional information Clock1, 26/02/2020). The updated information on maize endogenous gene interruption for event MON88017 submitted in the frame of application EFSA-GMO-RX-017 confirmed previous assessment indicating that there is no evidence for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON88017 (EFSA, 2009; EFSA GMO Panel, 2020). EFSA (European Food Safety Authority), 2009. Scientific Opinion of the Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-CZ-2005-27) for the placing on the market of the insect-resistant and herbicide-tolerant

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				indicating that they might have redundant functions (EFSA 2019). Nonetheless without further information (e.g. studies on expression of LOC100502445 in MON 88017; functional analysis of PUP11) risk assessment of the putative disruption of an endogenous gene remains inconclusive. References: EFSA (2015) Guidance for renewal applications of genetically modified food and feed authorised under regulation (EC) No 1829/2003 The EFSA Journal 13(6):4129 1-8. EFSA (2019) Administrative guidance on the submission of applications for renewal of authorisation of genetically modified food and feed under Articles 11 and 23 of Regulation (EC) No 1829/2003 2019 EFSA (2019). Application EFSA-GMO-RX-014 according to Regulation (EC) No 1829/2003. Responses to EFSA GMO Panel question of 29 July 2019. Ref. EW/SM/TR/rb – OC-2019–21718949 Weigel, Detlef; Ahn, Ji Hoon; Blázquez, Miguel A.; Borevitz, Justin O.; Christensen, Sioux K.; Fankhauser, Christian et al. (2000) Activation Tagging in Arabidopsis. In: Plant Physiol. 122 (4), S. 1003–1014. From CBI RAR-2018-0214 [redacted]): The gene coding for "putative HECT E3 ubiquitin ligase" (ZmUPL3) is truncated by insertion of the	genetically modified maize MON 88017, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2009; 7(5):1075, 28 pp. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2020. Scientific Opinion on the assessment of genetically modified maize MON 88017 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-014). EFSA Journal 2020;18(3):6008, 10 pp.

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				MON810 construct, its remnants are located in the 3' region of the transgene (Rosati et al 2008). Ozeki et al. (2005) is cited to support the view that the ZmUPL3 protein has no biological relevance. Ozeki et al. report that they did not find matches for a ZmUPL3 homologue from Oryza sativa in EST sequence data. However, the database search is based on entries of 2005. Li et al. (2019) found that the HECT E3 ubiquitin ligase gene family is differentially expressed in maize tissues and expression patterns indicate that some of the genes may have non-redundant functions in abiotic stress response. Therefore, without further information on the expression of ZmUPL3 in maize, risk assessment of the putative disruption of an endogenous gene in MON88017 x MON810 is incomplete. References: Li, Y.; Zhai, L.; Fan, J.; Ren, J.; Gong, W.; Wang, X.; Huang, J. (2019) Genome-wide identification, phylogenetic and expression analysis of the maize HECT E3 ubiquitin ligase genes. In: Genetica 147 (5-6), S. 391–400. Ozeki, Y. (2005) Study for ensuring the safety of genetically modified food - Study for the safety for stacked products. Report for study by Grant-in-Aid for Scientific Research by	The applicant submitted an updated bioinformatic analysis to identify maize endogenous gene interruption using up-to-date databases (additional information Clock1, 26/02/2020). EFSA requested additional information on the interruption of putative HECT E3 ubiquitin ligase for event MON810 taking into account new information on the expression of HECT E3 ubiquitin ligase genes provide in Li et al. (2019). The applicant clarified that the gene identified in the analysis for MON810 (LOC103626504 on chromosome 5) was not identified in the search included in Li et al. (2019) publication. This emphasized the fact that the maize endogenous gene potentially interrupted which was identified in MON810 bioinformatic analysis is categorized as "putative" with no known functional role in maize. The GMO Panel concludes that there is no new evidence in the renewal application EFSA-GMO-RX-017 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017 × MON810 (EFSA GMO Panel, 2009). EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2009. Scientific Opinion of the Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-CZ-2006-33) for the placing on the market of the insect-resistant and glyphosate-tolerant genetically modified maize MON 88017 x MON 810, for food and feed uses, import and

Country	Organization	Reference	Topic	Comment	GMO Panel responses
				Ministry of Health, Labor and Welfare 5:157-162. Rosati, A.; Bogani, P.; Santarlasci, A. (2008) Characterisation of 3´transgene site and derived mRNAs in MON810 YieldGard maize. In: Plant Mol Biol. DOI: 10.1007/s11103-008-9315-7	processing under Regulation (EC) No 1829/2003 from Monsanto The EFSA Journal (2009) 1192, 1-27.
Germany	BfN	3. Overall assessment	Comment 5 / Federal Agency for Nature Conservation (BfN)	Interplay between environmental risk assessment and monitoring The information necessary to conclude on the ERA is still partly missing. Thus, the safety of MON88017 x MON810 maize cannot be fully assessed. Depending on those results the conclusions concerning case-specific monitoring may need to be revised.	The information/datasets provided by the applicant for the renewal of authorisation of maize MON 88017 × MON 810 are in line with the requirements outlined in the EFSA guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003 (EFSA, 2015). There was no evidence in the renewal application EFSA-GMO-RX-017 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017 × MON 810. Therefore, case-specific monitoring was not considered necessary by the GMO Panel.
Germany	BfN	4. Monitoring plan and proposal for improving the conditions of the original authorisation	Comment 6 / Federal Agency for Nature Conservation (BfN)	General Monitoring the environmental effects of MON88017 x MON810 maize should serve as an early warning system: The data which will be collected should be relevant to and suitable for a “rapid assessment and implementation of measures to reduce any consequences to the environment” (Council Decision 2002/811/EC). To achieve this aim a meaningful monitoring plan in line with the scope of use of the GMO has to be provided.	In the context of the assessment of several applications for the renewal authorisation of genetically modified (GM) plants for food and feed uses, import and processing, the environmental risk assessment (ERA) working group of the GMO Panel has been analysing the contents of the annual post market environmental monitoring (PMEM) reports as well as the relevance of their underlying monitoring methodology. The PMEM plans proposed by applicants consist of general surveillance of imported GM plant material. This general surveillance is

Country	Organization	Reference	Topic	Comment	GMO Panel responses
				The plan has to meet the following scientifically recognised minimum standards: - A fully specified list of monitoring parameters has to be provided. - An operating schedule giving full details of points in time is requested. - The methods of data analysis including the statistical methods have to be elaborated. - The baseline status of the receiving environment has to be characterised. - The applicant is requested to indicate how the monitoring plan is adapted to various local conditions. - The time-period of monitoring needs to be sufficient to detect delayed, long-term or cumulative adverse effects and check of requirements of certain monitoring parameter. Furthermore, the monitoring should be run primarily in regions, where the GMO will be trans-ported, stored, packaged, processed or used. Since traders may commingle the GMO with other commercial GM maize imported, pro-cessed or used for food/feed, the applicant is requested to explain how the monitoring will be designed to distinguish between potential adverse effects caused by the GMO and those caused by other GM maize.	coordinated by EuropaBio and implemented by selected operators (federations involved in import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. Although the final adoption of PMEM plans fall outside the remit of EFSA, the GMO Panel considers that further discussion with applicants and risk managers is needed on the practical implementation of the PMEM for GM plants for import and processing (e.g. actual data gathered on exposure and/or adverse effects as implemented in existing monitoring systems).

Country	Organization	Reference	Topic	Comment	GMO Panel responses
				Case-specific monitoring BfN is of the opinion that a case-specific monitoring addressing loss and spillage during transport, storage and handling in the environment is necessary. The case-specific monitoring has to focus on pathways where MON88017 x MON810 maize or material containing the GMO get into the environment, which occurs during transport, processing or use of the GMO as food and feed. The applicant is requested to provide an appropriate case-specific monitoring plan, comprising the following elements at least: i) spillage or loss of the GMO during transport, storage, packaging, processing and use (food and feed); ii) potential spread and persistence of the GMO, if spillage or loss of viable grains of the GMO occurs; iii) If spread and persistence of the Cry-Proteins occur, further observations of impacts on organisms, food chains, and habitats are required. iv) exposure of the Cry proteins to the environment e.g. via sewage water, waste material or by-products which occurs during processing or use of the GMO material as food/feed; v) The GMO may enter the environment together with other approved GM maize	As no potential adverse environmental effects were identified in the environmental risk assessment (ERA) of maize MON 88017 × MON 810 (EFSA, 2009), case-specific monitoring was not considered necessary by the GMO Panel. Moreover, in its scientific opinion on application EFSA-GMO-RX-017, the GMO Panel concluded that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment on maize MON 88017 × MON 810.

Country	Organization	Reference	Topic	Comment	GMO Panel responses
				lines con-taining different Bt proteins. Therefore, a special focus should be on combined effects. vi) occurrence of teosinte species in regions affected by transport, storage, packaging, pro-cessing and use (feed and food) and subsequently potential outcrossing of the transgenes. For these parameters, the use of the following methods is recommended (https://www.vdi.eu/engineering/vdi-standards/): • VDI-Standard 4330 Part 10 “Floristic mapping of genetically modified plants, their crossing partners and their hybrid offspring”. • VDI-Standard 4330 Part 5 “Guideline for the collection and preparation of plant samples for molecular biological analysis”. The BfN is of the opinion that risk management measures like the control of adventitious maize plants and clean up measures to control viable plant material during transport, storage, packaging or processing should be confirmed as mandatory. The efficacy of the implemented risk management measures should be monitored during case-specific monitoring (EFSA 2011). General surveillance for unanticipated adverse effects	

Country	Organization	Reference	Topic	Comment	GMO Panel responses
				The general surveillance plan needs further specification concerning the monitoring methodology to be applied (parameters, methods, locations etc.). The general surveillance plan has to focus on possible pathways how MON88017 x MON810 maize can enter the broader environment and how unforeseen adverse effects on human health and the environment can be linked to the dispersal and use of the GMO. The applicant has to provide an appropriate general surveillance plan comprising the monitoring of spillage or losses of the GMO during transport, storage, packaging, processing and use as well as potential spread and persistence. A special focus should be on possible combined effects together with other approved GM maize. The general surveillance plan provided is predominantly based on collaboration with third parties. Therefore, the monitoring expertise of external people involved in the monitoring activities and detailed information about participating networks (e.g. name, EU country, responsible authority, availability, scope of monitoring, composition of the network) have to be specified. Binding agreements/contracts with third parties (external people and existing networks) are requested which	

Country	Organization	Reference	Topic	Comment	GMO Panel responses
				clearly determine what data are provided and how these data are made available. The professional qualification of involved people and the involvement of other operators further down the food chain should be specified. This information is so far not given in the monitoring reports and not yet part of the monitoring plan. Reporting the results of the monitoring The applicant is required to report on the monitoring methodology applied (parameters, methods, locations, involved stakeholders etc.) and on the results of the monitoring. All raw data have to be made available. Moreover, the monitoring reports should also deliver detailed information on i) actual volumes of MON88017 x MON810 maize imported into the EU (separated information from conventional maize), ii) the ports and silos where shipments of the GMO were unloaded, iii) the processing plants where the GMO was transferred to, iv) the amount of the GMO used on farms for feed, and v) transport routes of the GMO. References: EFSA (2011) Scientific opinion. Guidance on the Post-Market Environmental monitoring (PMEM) of genetically modified plants. The EFSA Journal, 9(8): 2316, 32-34.	

Country	Organization	Reference	Topic	Comment	GMO Panel responses
Germany	BVL (German CA)	1. General comments	Comment 1 / Federal Office of Consumer Protection and Food Safety (German CA)	Application EFSA-GMO-RX-017 requests for renewal of the authorization for foods and food ingredients as well as feed containing, consisting of, or produced from the genetically modified maize MON 88017 x MON 810 and products other than food and feed containing or consisting of correspondent genetically modified plants for the same uses as any other maize with the exception of cultivation, authorized under Regulation (EC) No 1829/2003 (Commission Decision 2010/429/EU). The Federal Office of Consumer Protection and Food Safety (BVL) as German CA is of the opinion that the data provided with application EFSA-GMO-RX-017 and the experience gained during the commercial use of maize MON 88017 x MON 810 give no indication towards safety concerns and support the conclusion of the original risk assessment that maize MON 88017 x MON 810 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses. Nevertheless, some points of the dossier have room for improvement. In this regard, the applicant should be asked to provide documents supporting the application in a more structured way in the future. Besides, the monitoring plan needs further elaboration.	The GMO Panel thanks BVL and takes note of the comment.

Country	Organization	Reference	Topic	Comment	GMO Panel responses
Germany	BVL (German CA)	2.2. Post-market monitoring and post-market environmental monitoring reports	Comment 2 / Federal Office of Consumer Protection and Food Safety (German CA)	Case-specific-monitoring No adverse effects were identified according to the risk assessment and based on the monitoring reports provided by the applicant. Hence, a case-specific monitoring is currently not necessary. General surveillance The applicant provided yearly monitoring reports considering general surveillance from 2011 to 2018. The reports did not reveal any adverse effects (See also below: 4. Monitoring plan and proposal for improving the conditions of the original authorization).	The GMO Panel took note of the comment.
Germany	BVL (German CA)	2.3.2. Updated bioinformatics	Comment 3 / Federal Office of Consumer Protection and Food Safety (German CA)	Given that databases are regularly updated, the EFSA Guidance Document for renewal applications states that bioinformatics analyses should be performed not earlier than one year prior to the submission of the renewal application (EFSA, 2015; EFSA, 2019). The present application was submitted in June 2019. In this context, it should be noted that many of the bioinformatic analyses provided are older than one year and therefore do not meet EFSA's formal requirements. Nevertheless, in terms of content, the newly submitted bioinformatic data do not provide any reason to call into question EFSA's previous conclusions on maize MON 88017 x MON	The applicant submitted an updated bioinformatic analysis for events MON810 and MON88017 using up-to-date databases (additional information Clock1, 26/02/2020). The updated bioinformatic analysis did not identify new evidence in the renewal application EFSA-GMO-RX-017 for new hazards or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017 × MON810 (EFSA GMO Panel, 2009). In this respect, the GMO Panel agrees with the comment from Germany. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2009. Scientific Opinion of the Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-CZ-2006-33) for the placing on

Country	Organization	Reference	Topic	Comment	GMO Panel responses
				810. EFSA (2015). Guidance for renewal applications of genetically modified food and feed authorised under regulation (EC) No 1829/2003 The EFSA Journal 13(6):4129 1-8. EFSA (European Food Safety Authority), 2019. Administrative guidance on the submission of applications for renewal of authorisation of genetically modified food and feed under Articles 11 and 23 of Regulation (EC) No 1829/2003. EFSA supporting publication 2019:EN-1668. 19 pp.	the market of the insect-resistant and glyphosate-tolerant genetically modified maize MON 88017 x MON 810, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto The EFSA Journal (2009) 1192, 1-27.
Germany	BVL (German CA)	4. Monitoring plan and proposal for improving the conditions of the original authorisation	Comment 4 / Federal Office of Consumer Protection and Food Safety (German CA)	The monitoring plan is acceptable but needs further elaboration. Therefore, the applicant is recommended to revise the monitoring plan and present this revised monitoring plan together with a report one year after consent is given to be reassessed. The monitoring plan does not relate the monitoring activities to relevant protection goals. Even more, it is not described which routine observations (including parameters or monitoring characters) are carried out in relation to the protection goals. Only reporting on 'any unanticipated effect' is solely not an appropriate parameter, because it already anticipates an evaluation. This evaluation process should be based on a distinct set of parameters and a scientific	In the context of the assessment of several applications for the renewal authorisation of genetically modified (GM) plants for food and feed uses, import and processing, the environmental risk assessment (ERA) working group of the GMO Panel has been analysing the contents of the annual post market environmental monitoring (PMEM) reports as well as the relevance of their underlying monitoring methodology. The PMEM plans proposed by applicants consist of general surveillance of imported GM plant material. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. Although the final adoption of PMEM plans fall outside the remit of

Country	Organization	Reference	Topic	Comment	GMO Panel responses
				sound data analysis. It is requested that the applicant specifies in detail, how and which information will be pro-actively queried, gathered, and how they will be evaluated. In addition, it might be useful to integrate food and feed surveillance in coordination with the competent authorities. Information about the use of the product in food and feed could deliver supplementary helpful data (of exposure to consumers and animals) for general surveillance. Therefore, the applicant should specify monitoring activities in the field of human and animal health. He should describe in detail how animal and human health surveillance is integrated in the monitoring plan. The strategy of General Surveillance is mainly based on the involvement of importers, traders, silo operators and processors coordinated by EuropaBio. The applicant will inform the selected networks of operators about market release of GM plant products and will remind them to report on 'any unanticipated adverse effect'. He stated that these third parties have to follow legal obligations of food and feed hygiene (HACCP). Nevertheless, the role and interplay of all actors on behalf of recording, analysis and evaluation of monitoring data needs more transparency. The applicant should consider whether other	EFSA, the GMO Panel considers that further discussion with applicants and risk managers is needed on the practical implementation of the PMEM for GM plants for import and processing (e.g. actual data gathered on exposure and/or adverse effects as implemented in existing monitoring systems).

Country	Organization	Reference	Topic	Comment	GMO Panel responses
				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, other sources of information, e.g. peer-reviewed publications or ongoing research, should be taken into account. However, the applicant should describe in detail how he would consider this information within General Surveillance. A report on General Surveillance activities on an annual basis is sufficient. Reporting should refer to the format introduced by the Commission Decision 2009/770/EC. The applicant is requested to state how the monitoring results will be published.	
Latvia	BIOR	2.2. Post-market monitoring and post-market environmental monitoring reports	Comments from Latvia about MON88017 X MON810	PMEM reports show that maize imports to EU countries more than quadrupled between 2010 and 2018 from 3 809 000 tonnes to 17 757 000 tonnes. However, the applicant writes that there has been no significant change in the use of maize in the EU: "since MON 88017 × MON 810 was authorised in the EU, no new hazards or modified exposure have been identified". Experts believe that an analysis of the impact on consumption of such a significant increase in maize imports should be provided. The literature search in PMEM reports	The GMO Panel took note of the comment.

Country	Organization	Reference	Topic	Comment	GMO Panel responses
				covered the reporting period from 2011 until May 2018. It was conducted using only two databases: the Web of ScienceTM Core collection database using the Web of ScienceTM platform1 and in the CAB Abstracts® database2 using the EBSCOhost platform. It is advised to conduct similar literature search using Scopus database.	In EFSA (2010, 2017), EFSA advices applicants to search a minimum of at least two multidisciplinary/large databases. This is in agreement with the methodology followed by the applicant in the annual literature searches performed as part of the post-market environmental monitoring reports. EFSA would like to note the applicant also submitted two systematic literature searches covering the period from January 2008 till September 2020, that were performed in accordance with the recommendations on literature search outlined in EFSA (2010, 2017).
Latvia	BIOR	2.3.1. Systematic search and evaluation of literature	Comments from Latvia about MON88017 X MON810 2	As regards to the document titled '2017 FFI Monitoring_Maize' about the Area of the environmental risk assessment: Food/Feed Safety – Toxicology/Animal feeding studies (MON 810). There is an overview of the article of Ibrahim and Okasha (2016) that has pointed out the effect of genetically modified corn on the jejunal mucosa of adult male albino rat. This study indicated that MON 810 negatively affects the histology of the jejunum in rats. The results demonstrated that in the MON 810 group there were a) distortion, shortening, flattening and fusion of some jejunal villi and shedding of the jejunal surface epithelium, associated with a significantly increased crypt proliferation; b) erosion in the villi and denuded mucosal surface; c) congested blood capillaries and focal infiltration with	The GMO Panel took note of the comment.

Country	Organization	Reference	Topic	Comment	GMO Panel responses
				mononuclear cells; d) Significant upregulation of PCNA expression; e) , increase in number of goblet cells; f) a significant increase in both villous height and crypt depth; g) marked ultrastructural changes of some enterocytes with focal loss of the microvillus border. The study (Ibrahim and Okasha, 2016) was not conducted on MON 88017 × MON 810. Even if the the negative finding on the jejunum in rats is only reported using MON 810 that a part of the whole component it shows a potential risk on gastrointestinal tract that may be cause by consumption of genetically modified (GM) plants expressing insecticidal traits. The recommendation to EFSA is to consider to incorporate in the guidance the request to conduct the histological structure studies of the jejunal mucosa of laboratory animals as well as drawing attention to the inflammation markers (such as PCNA-positive immunostained nuclei, goblet cells etc.) using GM crops.	
Netherlands	Dutch GMO Office	1. General comments	Dutch comment on EFSA/GMO/RX/017	The Dutch CA has assessed the renewal dossier with respect to the food and feed safety of MON 88017 x MON 810 maize and has no comments or requests for additional information in relation to the safety of this GM event.	The GMO Panel thanks the Netherlands for the comment.

Country	Organization	Reference	Topic	Comment	GMO Panel responses
Netherlands	Dutch GMO Office	2.3.2. Updated bioinformatics	Dutch comment on EFSA/GMO/RX/017 2	Provided that the sequence of MON 88017 x MON810 at time of renewal remains identical to the original event sequence, the Dutch CA is of the opinion that import and processing of maize MON 88017 x MON 810 poses a negligible risk to the environment in the Netherlands.	The GMO Panel thanks the Netherlands for the comment.
Norway	VKM	1. General comments	Norwegian Scientific Committee for Food and Environment (VKM)	VKM welcomes information on herbicide residue levels and their relevant metabolites in applications for herbicide tolerant GM-plants. Data on glyphosate residue levels, including relevant metabolites, in plant material from the field studies would support the assessment of food, feed, and environmental safety.	The GMO Panel thanks VKM and takes note of the comment.
Spain	Comisión Nacional Bioseguridad	4. Monitoring plan and proposal for improving the conditions of the original authorisation	CNB comment	In this renewal application, the notifier considers that the environmental risk assessment (e.r.a) and monitoring plan do not change in any way the conclusions of the original risk assessment. Since the renewal application does not include authorisation for the cultivation of MON 88017 x MON 810 seed products, therefore, exposure to the environment will be limited to unintended release (accidental spillage) of MON 88017 x MON 810, which could occur via substantial losses during loading/unloading of the viable commodity including MON 88017 x MON 810 destined for processing into animal feed or human food products. It is proposed that exposure	In the context of the assessment of several applications for the renewal authorisation of genetically modified (GM) plants for food and feed uses, import and processing, the environmental risk assessment (ERA) working group of the GMO Panel has been analysing the contents of the annual post market environmental monitoring (PMEM) reports as well as the relevance of their underlying monitoring methodology. The PMEM plans proposed by applicants consist of general surveillance of imported GM plant material. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. Although the

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				can be controlled by clean up measures and the application of current practices used for the control of any adventitious maize plants, such as manual or mechanical removal and the application of herbicides (with the exception of glyphosate based herbicide). As it is already known, since some years ago the presence of compatible species of maize (i.e. teosinte) were detected in some growing areas of maize cultivation in some EU countries. This situation has to be considered into the next monitoring plan and for the risk management actions. In this sense, the e.r.a. and the general surveillance on MON 88017 x MON 810 maize shall be taken this issue into consideration during the new authorization period, the extent of imports of MON 88017 x MON 810, and use thereof in the Member States.	final adoption of PMEM plans fall outside the remit of EFSA, the GMO Panel considers that further discussion with applicants and risk managers is needed on the practical implementation of the PMEM for GM plants for import and processing (e.g. actual data gathered on exposure and/or adverse effects as implemented in existing monitoring systems). As no potential adverse environmental effects were identified in the environmental risk assessment (ERA) of maize MON 88017 × MON 810 (EFSA, 2009), case-specific monitoring was not considered necessary by the GMO Panel. Moreover, in its scientific opinion on application EFSA-GMO-RX-017, the GMO Panel concluded that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment on maize MON 88017 × MON 810.