Application EFSA-GMO-RX-Bt11 Comments and opinios submitted by Member States during the three-month consultation period				Annex G
Country	**Organisation**	**Reference**	**Comment**	**EFSA Comments**
Comments from National Competent Authorities under Directive 2001/18/EC				
Austria	Ministry of Health, Family and Youth	D, 02 Information on the sequences actually inserted or deleted	With regard to the assessment of all detectable inserts the notifier concluded that single copies of the Cry1Ab, pat and ColE1 transgenic elements, as well as 2 copies of the 35S promoter are present in GM maize Bt11 based on results of an analysis by Southern Blot (technical dossier p.19f). Additionally the notifier concluded that the amp-gene is absent in GM maize Bt11 (The Amp-gene is a part of the plasmid from which the transformation cassette to construct GM maize Bt11 was derived). However the different experiments which analyse the presence of certain elements were conducted with lines of Bt11, which have different breeding histories and thus a different genetic background (see Appendix 1.2 Fig. 3 to Fig. 5, p.17-19). Additionally the design of experiments to assess the presence of individual genetic components is different and sometimes not suitable to deliver fully conclusive results (e.g. analysis of presence of ColE1 element, Appendix 1.2 Fig. 15, p.29). Furthermore experimental data are missing in the submitted document, which are crucial to assess the conclusion, that vector backbone sequences, specifically the amp-gene, are absent from GM maize Bt11 (Appendix 1.1, p. 8). Therefore the notifier is requested to submit a complete dataset for characterisation of all detectable transgenic inserts based on experiments with an optimised design using sample material from a single representative line of Bt11. The information on the transgene insert in GM maize Bt11 (Appendix 1.5) indicates that 8 changes to the sequence previously reported for Bt11 were identified: 4 changes located in the intervening sequences within the Bt11 insert, 2 changes in the maize genomic sequences flanking the insert and 2 changes located in the 2 copies of the NOS terminator sequence present in the insert. The notifier is requested to indicate whether these changes have any impact on the characteristics of GM maize Bt11. An independent assessment by the Belgian authorities in 2003 (Moens, 2003) indicated uncertainties for the molecular characterisation of GM maize Bt11 (concerning rearrangements involving parts of the 35S-promoter sequences and the number of inserts present in Bt11). The notifier is requested to indicate whether new information on GM maize Bt11 addresses in full the questions in the mentioned report and to submit relevant data to assess the identified uncertainties. Moens, W. (2003). Report on the molecular characterisation of the genetic map of event Bt11.	With regard to the selection of lines for molecular characterisation the applicant has shown, both on this and on previous occasions, the stability of the trait and the insert over several generations using Southern blots. This includes stability in hybrids with stacked events which include Bt11. (EFSA 2005). There is no evidence that the structure of the insert has changes from the original application. The absence of *amp* gene sequences has been demonstrated using appropriate restriction enzymes and probe combinations and positive maize controls know to carry the *amp* gene. The Southern data are considered sufficient for safety assessment and no elements of the insert cause any safety concern. The nucleotide sequence of the entire Bt11 insert in sweet corn was determined which enabled a direct comparison to the previously reported sequence (from field corn). A total of eight nucleotide changes were identified when the Bt11 insert sequence was compared to the previously reported Bt11 sequence. The applicant attributed this discrepancy to sequencing errors in the original datasets. The GMO Panel supports this assessment which is validated by an updated sequence analysis of both the insert and the original plasmid used for transformation. Bioinformatic analysis of the insert and flanking regions (including an updated analysis in 2008) does not indicate any safety concern with regard to the position of the insert in the maize genome. Southern analysis of progenies from a backcrossing programme indicated stability of the inserted DNA. Molecular approaches were used to confirm Mendelian inheritance.

			http://www.biosafety.be/gmcropff/EN/TP/MGC_reports/Report_Bt11.pdf Concerning the chromosomal locations of the transgenic elements present in GM maize Bt11 no adequate evidence is presented or referenced in the notification. Contrary to the statement by the notifier in the technical dossier (see tech. dossier p.21) appendix 2 does not contain specific data, which demonstrate a Mendelian inheritance pattern of the inserted traits. The notifier is requested to submit meaningful information to substantiate the conclusions.	
Austria	Ministry of Health, Family and Youth	D, 03 Information on the expression of the insert	The notifier has not presented any new data on expression of GM maize Bt11. The present notification again refers to previously submitted data, which are of low quality (see following comments) and thus have to be considered inadequate for a proper assessment. Data on expression of Cry1Ab and Pat were established in different field trials conducted at one location each in the USA in 1996 and 2002, respectively. For all studies submitted detailed information on agricultural management and environmental conditions is missing. Specifically information is missing, whether the cultivated plants were treated with Glufosinate or not. Accordingly no comparison between treated and untreated GM maize Bt11 is presented. Since GM maize Bt11 has been commercially used outside the EU and was investigated in field-trials in several EU member state countries in recent years, data should be available on expression patterns under relevant different environmental conditions. The notifier has failed to present any of these data. The submitted data on the other hand were established in trials with different sampling protocols, analysed by different laboratories, and data presented in different formats. Data were furthermore not adequately analysed and do not permit comparisons between different growing seasons and locations. Thus they are insufficient for an adequate assessment. We therefore request submission of data from the notifier assessing the differences in expression between different varieties, years and locations according to current guidance and standards.	The applicant has provided a summary table showing the range of protein expression levels over more than one year. The data do not indicate any safety concern.

Austria	Ministry of Health, Family and Youth	D, 03 Information on the expression of the insert	Expression of potential fusion proteins The notfier is requested to address the issue, since no specific information is submitted within the notification or referenced in the notification. The notifier shall specifically address the questions regarding characterisation of potential fusion proteins as contained in a report published by Belgian authorities in 2003 (Moens, 2003). The notifier is further requested to not only assess any potential fusion proteins at the junction sequences of the insert in GM maize Bt11 and bordering genomic sequences, but also include in the assessment the sequences derived from the vector backbone which are bordering and separating the functional transgenic expression cassettes for Cry1Ab and pat in GM maize Bt11. An analysis of potential fusion proteins encoded by internal insert sequences should be presented, like in the notification submitted for GM maize GA21 by the present notifier. Moens, W. (2003). Report on the molecular characterisation of the genetic map of event Bt11. http://www.biosafety.be/gmcropff/EN/TP/MGC_reports/Report_Bt11.pdf	Updated bioinformatics data were provided in 2008. No novel open reading frames (ORFs) were identified that spanned either the 5' or the 3' junctions between the Bt11 insert and *Zea mays* genomic sequences. No fusion proteins are therefore expected. In addition, the results of the compositional and phenotypic analyses did not reveal unintended differences between Bt11 maize and non-GM maize. Furthermore, animal testing data from short term feeding studies, did not show any adverse effects and confirmed the equivalence of Bt11 maize when compared to non-GM maize.

Austria	Ministry of Health, Family and Youth	D, 04 Information on how the GM plant differs from the recipient plant in: …	The data submitted by the notifier in Appendix 4 are insufficient to conclusively assess the effect of the modification with regard to reproduction, dissemination and survivability. Only one of the two submitted studies contains quantitative data, which were analysed statistically. However the parameters investigated in these trials in the year 1994 were chosen to evaluate agronomic performance rather than differences in reproduction, dissemination and survivability and are thus of limited significance to the assessment. Furthermore the notifier did not indicate whether the trial included any treatment with Glufosinate. The only other reference supplied by the notifier (general link to all Part-B notifications and reports) is not specific for GM maize Bt11 and is furthermore not addressing adequate material, e.g. individual studies with report specific data, which are conclusive with regard to the issues in question. Specifically to assess survivability the notifier refers to results from field trials conducted in several EU member states between 1994 and 2006. However, no data are provided on the results of these field trials. Instead it is referred to the JRC webpage and to the Summary notification reports of Part B trials in the EU. As these reports do not contain any data on the results of the part B trials but present a "summary" this is not considered satisfactory. The notifier should present the data collected during these field trials including a sound statistical analysis in order to substantiate the drawn conclusions. The notifier is thus requested to submit additional data to adequately assess any potential differences regarding reproduction, dissemination and survivability of GM maize Bt11, including relevant parameters addressing tolerance to differences in environmental conditions, changes in competitiveness, seed viability and susceptibility to pests. These data should be statistically analysed and also assessed with regard to variations between locations.	The scope of application RX-Bt11 maize is for food and feed uses, import and processing maize Bt11and all derived products and does not include cultivation. Considering the intended uses of maize Bt11, excluding cultivation purposes, the environmental risk assessment is concerned with indirect exposure through manure and faeces from the gastrointestinal tracts of mainly animals fed on the GM maize and with accidental release into the environment of GM seeds for food or feed uses, import and processing. Accidental release is considered in the scientific opinion. See also section 3.3 of the scientific opinion Moreover, in 2005, the GMO Panel has assessed a full set of environmental data for the notification C/F/96/05.10). The GMO Panel has issued a positive scientific opinion on all uses of maize Bt11, including scope cultivation, and stated "*no unintended environmental effects due to the establishment and spread are anticipated*".

Austria	Ministry of Health, Family and Youth	D, 05 Genetic stability of the insert and phenotypic stability of the GM plant	For the demonstration of genetic stability results from different Southern Blot experiments were submitted by the notifier (see Appendix 1.1 and 2). Plants from different generations of Bt11 breeding pedigrees were analysed with different approaches employed in individual experiments (Southern Blots of individual plants of BC3 and BC6 generations of H8540 pedigree Appendix 1.1, as well as pooled samples of 10 plants of BC1, BC3 and BC5 generations of NP912xNPII2316 pedigree, Appendix 2). The design of these experiments however would only identify major rearrangements of the Bt11 insert and indicate high frequency instabilities. Furthermore the segregation data which are referred to with regard to BC3 and BC6 assessments were not submitted in the technical dossier or the Appendixes referred to by the notifier. The final reports to trials according to Part B releases also do not contain specific data to assess phenotypic stability. The notifier is thus requested to submit adequate data to demonstrate phenotypic stability of GM maize Bt11. Furthermore the notifier shall submit additional information regarding the power of the analysis by Southern Blot conducted to assess genetic stability and submit data demonstrating genetic stability on a detailed level (compared with the data contained in the notification).	The applicant has provided appropriate molecular data which confirms a Mendelian inheritance pattern. There are no data which would indicate any instability of the Bt11 event and its associated phenotype.

Austria	Ministry of Health, Family and Youth	D, 07.03 Selection of compounds for analysis	The notifier states that in the French trials high N contents are attributed to the high N supply in the greenhouse where the plants were raised. Since protein content and amino acid composition as well as other compounds deriving from the N metabolism are influenced by fertilisation this over-fertilization could overlay all potential differences caused by the GM. It has to be mentioned that in comparative trials good agricultual practices should be used. Thus no final conclusions can be drawn. In the US trials the grain quality evaluation is limited to density, weight, size, protein, oil, starch and fiber. Significant differences in the protein contents were found, the two GM hybrids displaying lower contents in the northern regions. This was attributed to incomplete backcrossing, making it evident that compositional differences do occur when creating hybrids. In a second trial in the USA significant differences were found in fatty acids (palmitic and stearic acid) and amino acids (cystine and arginine). These differences were explained by the fact that the comparator was near-isogenic, not identical, and thus variations occur and are not of relevance to the GM variant. It is therefore highly recommended, that the choice of comparator is done with more care, otherwise all results are meaningless. Likewise all observed differences were seen as natural variations, not caused by GM. But in all field trials various hybrids were used for the comparisons, thus no systematic information on potential differences in composition is provided and EU trials are difficult to compare with USA and Canada trials. Even different analytical methods were used making it even more difficult to compare the tests. Additionally for a comprehensive risk assessment a broader spektrum of analytical parameters for the comparative assessment such as vitamins, minerals or anti-nutrients to be assessed, is highly recommended.	The Panel did not identify any new information regarding the comparative analysis that could change its previous conclusion.

Austria	Ministry of Health, Family and Youth	D, 07.04 Agronomic traits	For the agronomic assessment data are provided from one growing season in the USA/Canada (1994) and 1 growing season in France (1995). This is not considered to be sufficient for a representative testing of agricultural environments. Several representative regions must be selected in order to confirm that the agronomic performance of the GMO does not differ from the non-GM control. The data presented for the USA/Canada 1994 trials must be considered inadequate for a complete evaluation, as information on the varieties assessed and their relationship (GMO and control line), use of the herbicides, pesticides and the applied fertilizer regime is missing. Furthermore information is missing on environmental conditions during trials. A complete breeding history of the maize varieties analysed in the trials should be provided as well as a complete description of the agricultural management applied in each location. In particular, as this GMO is tolerant to Glufosinate, a herbicide-treated and a herbicide untreated variant must be included and potential differences assessed, which are due to the different treatments. The parameter "intactness rating" should be specified, and the method for its evaluation indicated. Apart from the incomplete presentation of materials and methods used in the USA field trials in 1994, only a summary of results is contained in the submitted study. No raw data are presented or data on a per location basis. The data presented for the 1995 France trial are insufficient for an assessment of agronomic behaviour of GM maize Bt11. No information is contained on the location of the sites, the methods applied to assess the indicated parameters, the agronomic management conditions (herbicide, pesticide, fertilizer regime), the environmental conditions, the field trial design (plot size, replication etc.) and the breeding history of the GM and non-GM varieties used. Due to the insufficient data provided by the notifier no conclusions can be made on the agronomic behaviour and characteristics of the GM maize Bt11 as well as related phenotypic characteristics such as reproduction, dissemination and survivability.	The Panel did not identify any new information regarding the comparative analysis that could change its previous conclusion.

Austria	Ministry of Health, Family and Youth	D, 07.08 Toxicology	The safety of Cry1A(b) is based on the argument of the notifier of three decades of safe use of microbial sprays such as Dipel with CRY proteins as active ingredients. But a distinctive feature of B.t. is the presence of a protein crystal composed of protoxin and only under the appropriate alkaline conditions and in the presence of proteolytic enzymes, the protoxin is activated to endotoxin(s). In GM maize variants the endotoxin is expressed in its active form by the truncated, plant-adapted version of the Cry1A(b) gene. All toxicity studies have been carried out with the active trypsin-resistant fragment of the E. coli expressed Cry1A(b) protein. The microbially produced- and the plant-expressed trypsin-resistant fragment of the protein were purified and trypsinized. These fragments were tested and found equivalent and thus the microbially produced protein was used for safety assessments. Such studies provide only limited evidence for safety of the GMO. Acute toxicity in mice In the Techn. Dossier, Part 1, page 34 it is stated, that "the Cry1Ab expressed in Bt11 maize is 33 amino acid residues shorter than the one expressed in the Bt176 maize, used at the study discussed above (the acute oral tox. study with mice). " Thus the safety of Bt11 is based on the study done with the truncated version of the Cry1Ab as present in Bt176 with the argument, that the active fragments represent the same toxins. It is regarded as essential that this test is repeated with the truncated version present in Bt11.	Comments rather pertain to the previous application. As already mentioned no new information has been made available to the Panel, e.g. from the extensive review of the published literature on Bt11 but also on other insect resistance GM maize that express similar Bt protein, that could prompt the Panel to change its previous opinion. The panel notes that in the present application for renewal, bioinformatic studies have been updated and performed with the Cry1Ab truncated protein which is actually expressed in Bt11 maize.
Austria	Ministry of Health, Family and Youth	D, 07.08 Toxicology	Whole feed conversion studies in broilers A feeding study with broilers was performed (Brake, J., Faust, M.A., Stein, J, (2003): Evaluation of Transgenic Bt11 Hybrid Corn in Broiler Chickens. Dep. of Poultry Science, North Carolina State Univ. and Syngenta). The feed was given as pellets. The contents of Cry1Ab was measured in the grain at levels of 0,80 µg/g fw, but was not measured in the diets. Bt11 was also used to feed laying hens. The administration of the treated diet and egg collection took 14 days. The grain was stored during the winter months. The diet was given as meal. The Cry1Ab contents at the start of the study was 0,38 µg/g fw in the grain and 0,24 µg/g fw in the diet on day 0. It is difficult to draw any conclusions from these experiments since there is no available information on the decline of transproteins during the process of pelleting. Cry1Ab might be heat sensitive. But it is known, that during storage the contents decline. The test grain should therefore be used after harvest. Furthermore tests on the effect of pelleting should be supplied. A few more feeding tests with farm animals were conducted with Bt11: A 14 days feeding study with 12 lactating cows was conducted to determine whether milk produced by lactating dairy cows contained Cry1Ab or PAT proteins when cows are fed fresh whole-plant Bt11 corn. It is stated that … "daily harvest of corn	Comments rather pertain to the previous application. As already mentioned no new information has been made available to the Panel, e.g. from the extensive review of the published literature on Bt11 but also on other insect resistance GM maize that express similar Bt protein, that could prompt the Panel to change its previous opinion.

			plants was necessary to ensure that the feed fed to cows contained the highest levels possible of the transgenic proteins, and that the opportunity for degradation of these proteins in feedstuffs was minimized." This approach is very recommendable, but the Cry1Ab contents in the Bt plant material were 635,7 ng/g fw (0,6357 ìg/g fw) and only 27,1 ng/g fw (0,0271 ìg/g fw) in the prepared feed. This is about the lowest concentration level ever encountered in GM feeding studies and should be questionned. Folmer et al. (2002) conducted 3 feeding experiments with Bt11: • with 12 lactating cows for 21 days, fed with 40% test corn silage and 28% rolled corn grain • with 67 steer calves a 70 days corn residue grazing experiment and • with 128 calves a 101 days feeding test with 90% corn silage. The Cry1Ab contents of the GM hybrids used in these experiments were: • Fresh pre-ensiled Bt plant material from 2 test hybrids: 4923,5 ng/g dw and 8508,8 ng/g dw • Silage after 4 resp. 9 days unquantifiable amounts • Stalks of grazing experiment: after harvest 935,9 ng/g dw and after 3 months 590,2 ng/g dw No adverse effects of the Bt corn were detected (Folmer, J.D., Grant, R.J., Milton, C.T., Beck, J. (2002): Utilization of Bt corn residues by grazing beef steers and Bt corn silage and grain by growing beef cattle and lactating cows. Dep. of Animal Science, Univ. of Nebraska and Syngenta). The longest experiment with the most animals (128 calves for 101 d) does not show that Bt11 resp. Cry1Ab had no adverse effect, since ensiling reduces the transprotein content to unquantifiable amounts. The lactating cows were only 12 and fed for a short period and again 40% was corn silage. All aforementioned feeding studies could not be classified as studies on toxicology. Though, the conclusions on general health were made by the notifier: "Administration identified no risk for mammalian safety by feeding…" which is not justified as this study is not a toxicity study. Similar statements were made for the other studies which could not be classified as toxicity studies. Therefore they can not support the safety of the product. Whole feed toxicity studies Bt11 is approved for human consumption but still no long term toxicity studies (neither a 90 day feeding study nor multi-generation studies) were conducted not taking into account the general principles of Regulation (EC) 178/2002 laid down in Art. 14 (4).	

Austria	Ministry of Health, Family and Youth	D, 10 Potential changes in the interactions of the GM plant with the biotic…	No new data were presented in the ERA specifically for maize Bt11 for - the evaluation of selective advantage or disadvantage of Bt11 maize - the assessment of potential for gene transfer of Bt11 maize - the assessment of the interaction between Bt11 maize and target organisms - the assessment of the interaction between Bt11 maize and non-target organisms, in particular Lepidoptera native to Europe and water organisms - the assessment of effects of Bt11 maize on biogeochemical processes including data on the persistence of the Cry1Ab toxin in soil and water/water sediments With respect to the exposure of Bt11 maize to the environment the notifier identifies faeces of animals fed with Bt11 as the main exposure route. However, no detailed discussion on this subject is provided. As Cry1Ab toxin fragments are present in the gastrointestinal tract and faeces of livestock (Cowdhury et al. 2003, Einspanier et al. 2004), potential effects on soil organisms cannot be excluded. This exposure pathway should thus be considered in more depth. The notifier has further identified accidental introduction of Bt11 maize into the environment as an exposure pathway of Bt11 maize to non-target organisms. The notifer, however, assumes that survival of grain would be very unlikely. However, as the agronomic evaluation of Bt11 maize and thus the evaluation of the survivability of this maize as compared to non-GM maize is insufficient, this statement requires further backing by experimental data. In fact, germination and the occurrence of volunteers has not been comparatively assessed neither in this nor in earlier notifications (e.g. C/F/96/05-10) thus the notifiers assumptions are not based on any evidence. Chowdhury E. H., Kuribara, H., Hino A., Sultana P., Mikami O., Shimada N., Guruge K.S., Saito M. & Y. Nakajima (2003). Detection of corn intrinsic and recombinant DNA fragments and Cry1Ab protein in the gastrointestinal contents of pigs fed genetically modified corn Bt11. J. Anim. Sci. 2003. 81:2546–2551 Einspanier, R., Lutz B., Rief St., Berezina, O., Zverlov V., Schwarz W. & J. Mayer (2004). Tracing residual recombinant feed molecules during digestion and rumen bacterial diversity in cattle fed transgene maize. Eur. Food Res. Technol. 218 (3) 269-273.	The scope of application RX-Bt11 maize is for food and feed uses, import and processing of maize Bt11 and all derived products and does not include cultivation. Considering the intended uses of maize Bt11, excluding cultivation purposes, the environmental risk assessment is concerned with indirect exposure through manure and faeces from the gastrointestinal tracts of mainly animals fed on the GM maize and with accidental release into the environment of GM seeds for food or feed uses, import and processing. Accidental release is considered in the scientific opinion. See also section 3.3 of the scientific opinion Most of the CRY proteins would be degraded by enzymatic activity in the gastrointestinal tract and only very low amounts of CRY protein would remain intact to pass out in faeces. These data conformed to data from studies of related CRY proteins (Lutz et al., 2005, 2006) and references therein which indicate that the majority of CRY proteins are degraded in the gastrointestinal tract. In conclusion, exposure of soil and water environments to CRY toxins of maize Bt11 from disposal of animal wastes or accidental spillage of maize kernels is likely to be very low and localized. Thus exposure of potentially sensitive non-target organisms to the CRY1Ab protein is likely to be very low and of no biological relevance.

Austria	Ministry of Health, Family and Youth	D, 12.02 Case-specific GM plant monitoring	Case-Specific Monitoring On the basis of the outcome of the ERA the notifier does not propose any case-specific monitoring. However, as mentioned above, the ERA is not considered satisfactory with respect to data and evidence provided that Bt11 maize is safe for the environment. Thus a full conclusion on the environmental risks can only be done after an updated ERA has been provided by the notifier. The notifier states that maize Bt11 can accidentally be introduced into the environment. The notifier states that the import of unprocessed maize as a whole grain is exceptional. This statement should be supported by data, e.g. data from import statistics of maize in the EU. Thus, in order to cover the risk of accidental spillage or unintended release into the environment of GM maize Bt11 a case-specific monitoring plan should be proposed. This comprises the monitoring along transportation routes, ports and harbours, processing plants etc. The notifier has missed to establish surveillance or management systems which are suitable to monitor and detect possible unintended environmental exposure by accidental spillage or release of Bt11 maize as well as other routes of exposure such as waste materials from processing or use or faeces for livestock. Although the notifier proposes that grain handlers, processors and importers shall report on potential adverse effects including grain loss, this will only cover substantial amounts that are economically relevant rather than small amounts that however might be of environmental relevance. An active monitoring of not only substantial but also small size grain losses at diverse locations including an analysis of potential areas of concern and exposure pathways should be performed. In this context the role of existing environmental networks has to be emphasised which should be included in the monitoring of accidental spillage and release of GM maize Bt11.	The GMO Panel is of the opinion that the general approaches and measures of the monitoring plan proposed by the applicant are in line with the EFSA opinion on post-market environmental monitoring (EFSA, 2006b) as well as with the intended uses of Bt11 maize since the environmental risk assessment does not cover cultivation and identified no potential adverse environmental effects. No specific environmental impact of this GM maize was indicated by the environmental risk assessment and thus no case-specific monitoring is required.

Austria	Ministry of Health, Family and Youth	D, 12.03 General Surveillance of the impact of the GM plant	The notifier proposes to report indirect and delayed effects at the stage of re-evaluation or at the end of the consent. It has to emphasized that indirect and delayed effects have to be reported immediately by the notifier upon occurrence. In conclusion the proposed monitoring plan seems short of addressing relevant questions for the general surveillance of human and animal health as well as the monitoring of accidental spillage of GM maize Bt11. The notifier is thus required to update the General Surveillance plan with the following information: • Information on how potential environmental effects will be covered in the GS plan. • Information if and how existing networks or established monitoring systems collecting ecological or environmental parameters in different member states will be integrated into the GS plan. • Information on the evaluation if the data collected by these existing networks are suitable to detect potential adverse effects of GM maize MON810 cultivation. • Information on the agreement of external networks to provide relevant data to the notifier. • Information on existing networks for monitoring effects on human/animal health to be used in the GS plan.	The GMO Panel requested additional information to the applicant in relation to frequency of reporting within the General Surveillance Plan. The GMO Panel noticed that the reference to MON810 cultivation is out of context for the present application. The GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance. See section 3.3 of the scientific opinion: *The scope of the monitoring plan provided by the applicant is in line with the intended uses of maize Bt11 since this does not include cultivation* See section 5.2 of the PMEM opinion (EFSA, 2006b): *Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. Thus detailed local arrangements will be developed by the applicant after the application has been accepted (…).* See section 11.4.2 of the GMO Panel Guidance Document (EFSA, 2006a): *Knowing the limitations of existing monitoring systems, it is important for the applicant to describe the processes and criteria that will be used for selecting and evaluating existing monitoring systems for supplying data related to the unanticipated adverse effects of GM plants in the general surveillance*.

Austria	Ministry of Health, Family and Youth	D, 12.03 General Surveillance of the impact of the GM plant	General Surveillance The notifier considers the following main elements of the GS plan: • Participation of selected, existing networks: The notifier should give an overview of the national organisations to be involved in each individual EU member state and not only the associations at EU level. It must be clear before placing on the market of GM maize Bt11, which existing networks will be involved and to which degree they will be involved. • The GS will be influenced by the availability, extent and composition of existing networks in EU member state: the notifier should give an overview of the networks to be used in each EU member state. It must be clear before placing on the market of GM maize Bt11, which existing networks will be involved. As the notifier states that the availability of the existing networks indifferent EU countries will have a direct influence on the surveillance information, it has to be clarified beforehand in which EU countries no networks are available or accessible. The notifier should then elaborate an alternative approach for these countries. • The selection of networks to be involved is based on importers and grain handlers of maize. As this maize is mainly used for food / feed products for the surveillance of unanticipated effects on human and animal health respective medical or veterinary networks are to be involved. The notifier did not include any medical or veterinary association. Additionally, environmental institutions should be involved to cover potential unexpected effects derived from accidental spillage of GM maize Bt11 (see CSM). • The notifier shall document the commitment of the organisations which will be part of the monitoring network to actively take part in the monitoring and to assist the notifier in the monitoring. The notifier shall furthermore describe responsibilities of members to the monitoring network and specify his own responsibilities for collecting and analysing information in detail. • The methodology of the proposed GS is only based on passively collecting information. A more active approach of GS, including specific activities for monitoring accidental spillage, should also be employed by the notifier (see CSM). • Different intensity of surveillance activities in different EU Member States depending on import and processing: if this approach is chosen the notifier should indicate how it will be ensured that import volumes of GM maize Bt11 into each EU member state will be reported separately. This should also take into consideration volumes of GM maize Bt11 in shipments containing mixtures of GM maize. GS should not take place in representative areas only, but specifically consider the above mentioned import volumes. The notifier refers to a study investigating import and movement of maize in the EU (LMC International Ltd. 2005), for the justification to focus the GS plan on Spain and Portugal. This study is not attached to the notification and should be made available to Competent Authorities by the notifier. It is unclear why only the notifier intends to focus on Spain and Portugal as the import volumes	The GMO Panel requested additional information to the applicant in relation to frequency of reporting within the General Surveillance Plan. The GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance. See section 3.3 of the scientific opinion: *The scope of the monitoring plan provided by the applicant is in line with the intended uses of maize Bt11 since this does not include cultivation.* See section 5.2 of the PMEM opinion (EFSA, 2006b): *Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. Thus detailed local arrangements will be developed by the applicant after the application has been accepted (…).* See section 11.4.2 of the GMO Panel Guidance Document (EFSA, 2006a): *Knowing the limitations of existing monitoring systems, it is important for the applicant to describe the processes and criteria that will be used for selecting and evaluating existing monitoring systems for supplying data related to the unanticipated adverse effects of GM plants in the general surveillance*.

			of several other countries are in the same range (Italy, Netherlands, Sweden) according to Appendix 16. In Appendix 16 the notifier refers specifically to import volumes of Bt11 sweet maize which should thus be provided. In addition, as Bt11 sweet maize has been authorized for placing on the market as food since 2004 and as feed since 1998 (http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=1). Thus the notifier should be able to report on the respective import volumes of Bt11 maize into the EU in general and individual EU member states specifically.	
Austria	Ministry of Health, Family and Youth	General comments	General Remarks - with regard to the data presented on agronomic traits and substantial equivalence, mostly only scanned documents are presented which can not be regarded as user-friendly - the notifier submitted no new data for several important aspects of the ERA, as well as for other assessment issues (as compared to a previous notification according to Directive 90/220/EEC) - the notifier frequently refers to the ERA of the notification C/F/96/05-10, in particular its positive opinion by the EFSA This practice cannot be regarded as satisfactory. EFSA (2006) clearly states that "any new information, experience and data that have been collected during the authorisation period shall be taken into account". As Bt11 maize has been tested in several EU member states in part B trials, to which the notifier also referred in the ERA. Data on the environmental safety of this product generated by the notifier should be presented in a renewal application. Thus, the assessment of environmental effects including the assessment of expression of transgenes and the agronomic evaluation of GM maize Bt11 provided by the notifier cannot be regarded as sufficient and needs to be updated accordingly. EFSA (2006). Guidance document of the Scientific Panel on Genetically Modified Organisms for renewal of existing GMO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003. The EFSA Journal 435, 1-4	The GMO Panel considers the information presented in the application sufficient and did not requested the detailed part B field trials conducted in Europe during the authorization period. Application EFSA-GMO-RX-Bt11 is assessed according to the scope of the application. The scope of the application is for food and feed uses, import and processing and excludes cultivation purposes. Therefore, there was no requirement for scientific information on possible environmental effects associated with the cultivation of maize Bt11.
Belgium	Belgian Biosafety Advisory Council	D, 07.03 Selection of compounds for analysis	Information on nutrients and anti-nutrients is less comprehensive in comparison to other recent maize dossiers. Anti-nutrients and secondary plant metabolites are only partly covered.	Comments rather pertain to the previous application. As already mentioned no new information has been made available to the Panel, e.g. from the extensive review of the published literature on Bt11 but also on other insect resistance GM maize that express similar Bt protein, that could prompt the Panel to change its previous opinion.

Belgium	Belgian Biosafety Advisory Council	D, 07.08 Toxicology	Comment 1 A range of 12 - 154 μg/g dry weight of Cry1Ab protein is measured in Bt11 maize. In dossier (Bt11 x GA21) no values exceeding 36 mg/kg are shown. Is the 154 μg/g value correct? Degradation of the Cry1Ab protein in simulated intestinal fluid. Not mentioned. Has this test been performed? If not, why wasn't this done? Degradation of the PAT protein in simulated intestinal fluid. Not mentioned. Has this test been performed? If not, why wasn't this done? Comment 2: D.7.8.4 Testing of the whole GM food/feed In the study with laying hens 60 instead of 10 animals per treatment would have provided the right power in the statistical analysis, based on the reported standard deviation and differences between mean values. In the study of the lactating dairy cows the number of animals per treatment are sufficient for testing the somatic cell account, but not for testing milk production.	The Panel did not identify any new information regarding the assessment of the food/feed safety, e.g. in the review of the literature published up to 2008, that could change its previous conclusion .
Belgium	Belgian Biosafety Advisory Council	D, 07.09 Allergenicity	With the current knowledge, Cry1Ab and PAT are unlikely to be allergenic. However, the allergen databases that have been used to construct the company internal allergen database for sequence comparisons should be updated (as the major ones dates back from 2001). The applicant did not assess the allergenicity of the whole GM plant. Conversely to what is stated in the application, maize allergy has been documented, although it is not recognized as a major allergy concern. Some maize allergens have already been described in the literature (Pastorello et al. 2003; Pasini et al. 2002, Weichel et al. 2006). Due to the introduction of the new traits as described in the application, over-expression of endogenous proteins, among them possibly the maize allergens, may occur. Therefore, it is relevant to analyze whether the expression levels of known maize allergens is increased in genetically modified Bt11 maize grains or to analyze whether the overall allergenicity of the modified maize has increased, compared to a natural counterpart. Patient IgE binding to maize grain extract or titration of known major allergens of maize should be carried out. Since allergy is an individual trait, follow up has to be continued. Pasini et al. Allergy 2002; 57:98-106 Pastorello et al. J Allergy Clin Immunol 2003; 112:775-83 Weichel et al. Allergy 2006;61:128-35	Regarding the assessment of allergenicity of the newly expressed proteins, the Panel notes that new bioinformatic studies have been performed using updated databases as recommended by the Belgian Biosafety Advisory Council (see Appendix 19 of the dossier). Regarding the allergenicity of the whole plant, given the fact that maize is not a most common food allergen, the Panel considers unlikely that the genetic modification could induce changes in the pattern of expression of maize endogenous allergenic proteins that would raise safety concerns.

Belgium	Belgian Biosafety Advisory Council	D, 10.01 Persistence and invasiveness	It is very unlikely that spillage will occur within agricultural land. Should this occur, there are, anno 2008, no indications that the transgene would have a selective advantage in current Belgian agricultural practices. The germination and persistence of spilled kernels along transport ways is not very probable. Should spilled kernels germinate and flower occasionally, pollen transfer remains possible. So, according to the precautionary principle, it is recommended to monitor transport routes in order to guarantee traceability. On top of this, measures to be taken in case of accidental spillage are needed as is information regarding the packing and other means of confinement during transportation and storage. And of course, should transgenic plants survive, they can not be killed by the herbicides they are made resistant for, so the quote of the applicant "…could be easily controlled by any of the current agronomic measures….." is not true.	See section 3.3 of the scientific opinion "*The GMO Panel advises that appropriate management systems should be in place to restrict seeds of maize Bt11 entering cultivation as the latter requires specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003*"
Belgium	Belgian Biosafety Advisory Council	D, 12.01 General	As already mentioned in D.10.1 it is recommended to record all transport routes in order to guarantee traceability. So we support the recommendation of ACRE (2006) that provision of detailed arrangements for general surveillance post-market monitoring plans for the import and processing of grain from GM maize should be made a condition of any consent. Monitoring and reporting on the possible establishment of feral populations should be a point of particular attention in the report to be delivered annually to the Commission. More details on the organisation and implementation of the monitoring are necessary.	See section 3.3 of the scientific opinion "*The GMO Panel advises that appropriate management systems should be in place to restrict seeds of maize Bt11 entering cultivation as the latter requires specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003*" However, the GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance. See section 5.2 of the PMEM opinion (EFSA, 2006b): *Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. Thus detailed local arrangements will be developed by the applicant after the application has been accepted (…).*

Belgium	Belgian Biosafety Advisory Council	D, 12.03 General Surveillance of the impact of the GM plant	The essential elements of the surveillance plan for Bt11 maize appear vague. For example (Technical dossier p. 55, but see also Appendix 10.3): "i. The best possible chance of detecting an unanticipated adverse effect would be ensured by having an adequate number of people, with relevant experience, involved in the surveillance process" "ii. In order to allow detection of the broadest possible scope of unanticipated adverse effects it is proposed that general surveillance is performed by selected, existing networks…" Representative organisations have been identified among the importers, grains handlers and processors. However, the initiative and responsibility lie exclusively on these organisations, as illustrated by the "Suggested questions to be asked as part of the General Surveillance Plan" (Appendix 10.3, p. 11), e.g.: "Have you informed your member associations who represent importing, merchanting and handling companies to ask their own member companies to monitor…?". If (one of) these components of the monitoring network fail to do their share of the work, the whole monitoring network is at risk. Therefore a strong and solid monitoring plan is necessary.	The GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance.
Denmark	Danish Environmental Protection Agency	D, 12.03 General Surveillance of the impact of the GM plant	Annex VII: NERI suggests that possible adverse consequences to non-target organisms such as rare species of butterflies should be monitored in and near to the cultivated fields. The applied methods should primarily depend on quantitative field data on occurrence of Lepidopteran non-target organisms and less on farmer questionnaires and resistance management.	Application EFSA-GMO-RX-Bt11 is assessed according to the scope of the application. The scope of the application is for food and feed uses, import and processing and excludes cultivation purposes. Therefore, there was no requirement for scientific information on possible environmental effects associated with the cultivation of maize Bt11.
Finland	Board for Gene Technology	General comments	The Board for Gene Technology wants to emphasize that high quality of general surveillance plan should be taken into consideration when the plan is adopted in a specific country. The general surveillance plan should indicate that the monitoring will be carried out in an active manner.	The GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance. See section 5.2 of the PMEM opinion (EFSA, 2006b): *Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. Thus detailed local arrangements will be*

				developed by the applicant after the application has been accepted (…).
France	MEIE - DGCCRF	General comments	Malgré une présentation confuse des données dans le dossier technique, l'Agence Française de Sécurité Sanitaire des Aliments considère que : Ø la structure moléculaire des maïs portant l'événement de transformation Bt11 est caractérisée Ø l'analyse de composition chimique conduite sur plusieurs études ne met pas en évidence de différence significative et démontre l'équivalence en substance des variétés de maïs Bt11 par rapport aux variétés de maïs témoin et conventionnelles, Ø bien qu'il n'y ait pas d'étude de toxicité sub-chronique de 90 jours chez le rongeur à partir d'une variété de maïs portant l'événement Bt11, l'historique de consommation de ces variétés de maïs depuis 12 ans, la connaissance acquise sur les protéines apportées par la modification génétique et les études sur animaux cibles disponibles dans la littérature scientifique, conduisent à considérer que la consommation humaine et animale de variétés de maïs portant l'événement Bt11 ne présentent pas de risques, Ø les études d'équivalence nutritionnelle réalisée chez les animaux cibles (poule pondeuse, poulet, vache laitière et bouvillon) ne mettent pas en évidence de différences nutritionnelles entre les maïs Bt11 et les maïs témoins. En conséquence, l'Agence Française de Sécurité Sanitaire des Aliments estime, qu'au regard des données présentées dans le dossier les variétés de maïs portant l'événement de transformation Bt11 et leurs produits dérivés présentent le même niveau de sécurité sanitaire que les variétés de maïs conventionnelles et leurs produits dérivés. Cette transmission ne préjuge en rien de la position finale des autorités françaises sur cet OGM.	The Panel is in agreement with the conclusions of AFSSA and MEIE – DGCCRF.
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	A, 07 Where appropriate, the conditions for placing on the market the food(s) or…	The import documents should indicate that Bt11 has not been approved for cultivation by the EC. Appropriate measures have to be taken during transport, storage, and processing to avoid unintended release into the environment.	The labeling requirement is outside the remit of the GMO Panel. See section 3.3 of the scientific opinion "*The GMO Panel advises that appropriate management systems should be in place to restrict seeds of maize Bt11 entering cultivation as the latter requires specific approval under Directive 2001/18/EC or Regulation (EC)*

				No 1829/2003".
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 03 Information on the expression of the insert	Updated information on the Cry1Ab protein expression has been presented for different plant tissues obtained from a single location in one growing period in the US field. Considering the long time-span of commercial application of Bt11, the presented data sets are rather scarce. The applicant should be requested to provide a review on available expression data on event Bt11 single and in stacked events. The applicant is requested to provide updated information on the levels of expression of the PAT protein or give a justifiable reason for not providing this information.	The applicant has provided a summary table showing the range of protein expression levels over more than one year. The data do not indicate any safety concern.
Germany	Federal Agency for Nature Conservation (BfN)	D, 03 Information on the expression of the insert	Additional comments of the Federal Agency for Nature Conservation (BfN): The notifier is requested to provide additional data on the expression of Cry1Ab and PAT in Bt11 maize. Data should cover the different geographical regions where Bt11 maize has been cultivated commercially. Data should be analysed statistically to test for any changes in expression due to time, environmental factors or seed varieties.	The applicant has provided a summary table showing the range of protein expression levels over more than one year. The data do not indicate any safety concern.
Germany	Federal Agency for Nature Conservation (BfN)	D, 07.01 Comparative assessment	Comments of the Federal Agency for Nature Conservation (BfN): The applicant failed to provide data to showing that the composition of Bt11 maize has been stable over the first period of authorization. The applicant is requested to provide such data. Moreover, information on the compositional analyses (Appendix 3) has not been presented according to good scientific practice. In summary the submitted information does not allow to draw the conclusion that Bt11 maize is equivalent to other maize. It is obvious that the presented information has been copied from one or several other documents. The applicant is requested to provide exact information from which studies the information presented in Appendix 3 has been copied. The studies presented are ambiguous with regard to several factors such as the origin of plant material, year of sampling, pooling of data, or statistics. Study summaries should only be used when the full study has also been made available via EFSA-net.	The Panel did not identify any new information regarding the compositional analysis that could change its previous conclusion.

Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.04 Agronomic traits	The data provided by the applicant are not sufficient to show that Bt11 maize is phenotypically equivalent to conventional isogenic maize lines. Data on the mentioned field trials in Spain, France, Italy and Portugal are not presented. Appendix 4 contains only a draft summary on results obtained in the United States and a visual comparison of Bt11 to its non-modified isogenic hybrid in France. The applicant is requested to either provide detailed data on the mentioned field trials or provide and discuss other data that support the conclusion of phenotypic equivalence of Bt11 to its non-modified isogenic counterpart. Information on the equivalence of stacked hybrids containing Bt11 as provided in the applications EFSA/GMO/UK/2007/49 and EFSA/GMO/UK/2007/50 might be used in this context.	The scope of application RX-Bt11 maize is for food and feed uses, import and processing Bt11 maize and all derived products and does not include cultivation. Considering the intended uses of maize Bt11, excluding cultivation purposes, the environmental risk assessment is concerned with indirect exposure through manure and faeces from the gastrointestinal tracts of mainly animals fed on the GM maize and with accidental release into the environment of GM seeds for food or feed uses, import and processing. Accidental release is considered in the scientific opinion. See also section 3.3 of the scientific opinion Moreover, in 2005, the GMO Panel has assessed a full set of environmental data for the notification C/F/96/05.10). The GMO Panel has issued a positive scientific opinion on all uses of maize Bt11, including scope cultivation, and stated "*no unintended environmental effects due to the establishment and spread are anticipated*".
Germany	Federal Agency for Nature Conservation (BfN)	D, 07.04 Agronomic traits	Additional comments of the Federal Agency for Nature Conservation (BfN): The applicant failed to provide any new or meaningful old data to show that Bt11 maize is phenotypically and ecologically equivalent to other maize. Information given in Appendix 4 must be considered as incomplete. It is obvious that the presented information has been copied from one or several other documents. The applicant is requested to provide exact information from which studies the information presented was copied. The information given in Appendix 4 is ambiguous with regard to several factors such as the origin of plant material, year of sampling, pooling of data, or statistics. Study summaries should only be used when the full study has also been made available via EFSA-net. The applicant is requested to amend Appendix 4 in a way that allows regulatory bodies to fully evaluate the information and to meet the criteria of good scientific practice. In addition the applicant is requested to provide new data to assess the phenotypic and agronomic stability over the last period of authorization.	The Panel did not identify any new information that could change its previous conclusion. Moreover, in 2005, the GMO Panel has assessed a full set of environmental data for the notification C/F/96/05.10). The GMO Panel has issued a positive scientific opinion on all uses of maize Bt11, including scope cultivation, and stated "*no unintended environmental effects due to the establishment and spread are anticipated*".

Germany	Federal Agency for Nature Conservation (BfN)	D, 09 Mechanism of interaction between the GM plant and target organisms (if…	Comments of the Federal Agency for Nature Conservation (BfN): Taking into account the scope of the application the main exposure route of non-target organisms with the Bt protein or Bt-protein fragments will be via faeces from domestic animals fed with Bt-maize. Only few experiments have addressed the question whether and to what extend bio-active Bt-fragments are released into the environment as a result of animal feed containing Bt maize. Experiments carried out in Germany (Einspanier et al. 2004) indicate that Cry1Ab will not be completely degraded in the bovine gastro-intestinal tract and that immunoactive Bt-protein can be detected in low quantities in faeces. The applicant is asked to provide a respective exposure analysis and to provide additional data to clarify whether soil organisms, especially insects associated with dung, can be affected by Bt-containing faeces.	The scope of application RX-Bt11 maize is for food and feed uses, import and processing of maize Bt11 and all derived products and does not include cultivation. Considering the intended uses of maize Bt11, excluding cultivation purposes, the environmental risk assessment is concerned with indirect exposure through manure and faeces from the gastrointestinal tracts of mainly animals fed on the GM maize and with accidental release into the environment of GM seeds for food or feed uses, import and processing. Accidental release is considered in the scientific opinion. See also section 3.3 of the scientific opinion Most of the CRY proteins would be degraded by enzymatic activity in the gastrointestinal tract and only very low amounts of CRY protein would remain intact to pass out in faeces. These data conformed to data from studies of related CRY proteins (Lutz et al., 2005, 2006) and references therein which indicate that the majority of CRY proteins are degraded in the gastrointestinal tract. In conclusion, exposure of soil and water environments to CRY toxins of maize Bt11 from disposal of animal wastes or accidental spillage of maize kernels is likely to be very low and localized. Thus exposure of potentially sensitive non-target organisms to the CRY1Ab protein is likely to be very low and of no biological relevance.
Germany	Federal Agency for Nature Conservation (BfN)	D, 12.01 General	Interplay between environmental risk assessment and monitoring Comments of the Federal Agency for Nature Conservation (BfN): The information necessary to conclude on the e.r.a. is partly missing. Thus, the safety of the Bt11 maize cannot be fully assessed. Depending on those results the conclusions concerning case-specific post-market monitoring may need to be revised.	No specific environmental impact of this GM maize was indicated by the environmental risk assessment and thus no case-specific monitoring is required.

Germany	Federal Agency for Nature Conservation (BfN)	D, 12.01 General	Comments of the Federal Agency for Nature Conservation (BfN): The scope of this application is for import, processing, and all uses for food and feed. The applicant provides an environmental monitoring plan, which only covers adverse effects that might occur during handling and processing but fails to address other areas such as effects from loss and spillage and effects mediated via new proteins in animal faeces. The monitoring should serve as an early warning system. It 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). The monitoring plan fails to meet this goal but only presents a general idea about how the monitoring might be carried out. Thus, the monitoring plan does not meet the objectives defined in Annex VII of Directive 2001/18/EC and the supplementing guidance notes (2002/811/EC). The monitoring plan therefore requires further specification and amendment before a consent can be given.	See section 5.3 of the scientific opinion: *The scope of the monitoring plan provided by the applicant is in line with the intended uses of maize Bt11 since this does not include cultivation".*
Germany	Federal Agency for Nature Conservation (BfN)	D, 12.02 Case-specific GM plant monitoring	Comments of the Federal Agency for Nature Conservation (BfN): The data provided with the application are not sufficient to complete the e.r.a. Incidental spillage of Bt11 maize can occur during transport, storage, package, processing, and use. Furthermore, the exposure of the environment to Bt11 maize and its proteins Cry1Ab and PAT during or after the production process and during animal consumption is given. Therefore, case-specific monitoring has to focus on pathways, where Bt11 maize enters the environment. Based on the currently available data, the case-specific monitoring plan has to comprise the following elements: • exposure of the environment to Bt11 maize kernels e.g. via spillage during transport, storage, packaging, processing, and use, • spread, persistence, and accumulation of Bt11 maize and its proteins Cry1Ab and PAT, if spillage or loss during transport, storage, packaging, processing, and use occurs, • exposure of the environment to the proteins Cry1Ab and PAT e.g. via sewage water, waste material or by-products which occur during processing. If spread, persistence and accumulation of Bt11 maize and its proteins Cry1Ab and PAT in the receiving environment occur e.g. via loss and spillage of Bt11 maize or via sewage water, waste material or by-products containing Bt11 maize, further observations of possible impacts on organ-isms, food chains and habitats are required.	See section 5.3 of the scientific opinion: *The scope of the monitoring plan provided by the applicant is in line with the intended uses of maize Bt11 since this does not include cultivation".*

Germany	Federal Agency for Nature Conservation (BfN)	D, 12.03 General Surveillance of the impact of the GM plant	Additional comments of the Federal Agency for Nature Conservation (BfN): The provided general surveillance plan is very unspecific and does not meet the objectives defined in Annex VII of Directive 2001/18/EC and Council Decision 2002/811/EC. A revised plan is required that considers the following issues: • The general surveillance plan has to focus on possible pathways how Bt11 maize and its proteins Cry1Ab and PAT can get into the environment and how unforeseen adverse effects on human and animal health and the environment can be linked to the consumption and dispersal of the GMO. • The applicants' approach is to collect and coordinate information on adverse effects from the company's and external networks/associations involved in the production process. The applicant intends to ask general questions concerning the information collection methodology as part of the General Surveillance plan. This is insufficient. It is the applicants' task to define appropriate parameters and methodologies to detect potential adverse effects. Harmonized methods are a prerequisite to fully analyse the collected data. It is proposed that monitoring data will be collected by existing networks (COCERAL, FEDIOL). The monitoring activities and detailed information about these networks, however, remain unclear and thus have to be specified as well as how the monitoring data are made available. • It is suggested by the applicant that the operators further down the food chain should not to be involved in the process of monitoring. We do not agree since also processed material may be a cause of adverse effects. • A specified list of monitoring parameters has to be defined. The applicant is requested to present for each parameter a detailed statement of the parameter definition, the observation methods (collection and analysis of samples with references), the frequencies of observations (time and number of visits to collect data) and the monitoring locations including number and size. Furthermore an operating schedule giving full details of points in time is requested. • The concept of sampling needs to be elaborated. Particularly, it must be explained how the required representativeness of the collected data in space and time shall be achieved. The se-lection of other countries than Spain and Portugal may be reasonable if Bt11 maize is processed elsewhere. • The data analyses, including the statistical methods, have to be elaborated in detail.	See section 3.3 of the scientific opinion "*The GMO Panel advises that appropriate management systems should be in place to restrict seeds of maize Bt11 entering cultivation as the latter requires specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003*" However, the GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance. See section 5.2 of the PMEM opinion (EFSA, 2006b): *Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. Thus detailed local arrangements will be developed by the applicant after the application has been accepted (…).*

Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 12.03 General Surveillance of the impact of the GM plant	The general surveillance plan is basically acceptable, but needs some modifications. As part of the "active surveillance", it is planned to inform traders and processors as well as to gather information from different communication networks. It is requested that the applicant specifies in detail, how and which information will be pro-actively queried and gathered. The use of questionnaires could be an appropriate measure to survey this information. In addition, it might be useful to integrate existing national networks on food and feed surveillance. 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. Furthermore, the applicant should specify monitoring activities in the field of human and animal health. Therefore, it should be described in more detail how animal and human health surveillance is integrated in the monitoring plan. The methodology of data analysis shall be explained transparently. A report on GS activities on an annual basis is sufficient. However, the monitoring reports should not only contain general information from participating networks. This general information should also be analysed by the consent holder in detail.	See section 5.2 of the PMEM opinion (EFSA, 2006b): *Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. Thus detailed local arrangements will be developed by the applicant after the application has been accepted (…).*
Germany	Federal Agency for Nature Conservation (BfN)	D, 12.06 Reporting the results of monitoring	Comments of the Federal Agency for Nature Conservation (BfN): The applicant is required to report on the results of the monitoring including all issues of case-specific monitoring and general surveillance on an annual basis. Raw data have to be made avail-able if requested.	The GMO Panel requested additional information to the applicant in relation to frequency of reporting (indirect and delayed effects) within the General Surveillance Plan.

Germany	Federal Agency for Nature Conservation (BfN)	General comments	Additional comments of the Federal Agency for Nature Conservation (BfN): The Federal Agency for Nature Conservation regards the data provided by the applicant as not sufficient to complete the evaluation of application EFSA/GMO/RX/Bt11. In particular the updated information concerning the environmental risk assessment (e.r.a.) and the environmental monitoring plan should be revised. The application should also stronger focus on demonstrating that Bt11 maize is stable and did not change during the last period of authorization. In this respect the applicant should make use of additional data collected during cultivation of Bt11 maize (e.g. the present dossier does not contain updated data on the phenotypic characterization). The literature review (Appendix 15) of the notifier should be amended in order to consider all literature since the original notification in 1998. The current literature compilation of Appendix 15 is restricted to the years 2005 onwards and does not state the databases used for the search. More-over, the applicant is requested to give a meaningful review on the basis of good scientific practice. In the present version the conclusions of the applicant resemble global statements with no indicative reference to the literature compiled. The review should also take into account methodological aspects of the cited literature and should clearly indicate whether the experiments base on event Bt11 or any other GMP. The applicant's proposal for an environmental monitoring plan does not meet the objectives de-fined in Annex VII of Directive 2001/18/EC and the supplementing guidance notes (2002/811/EC).	The GMO Panel requested additional information to the applicant in relation to frequency of reporting within the General Surveillance Plan. Based on its previous scientific opinion adopted in 2005, the GMO Panel considers sufficient the information presented in the application. The applicant provided in Appendix 15 a compilation of scientific literature issued since the last scientific opinion of the GMO Panel. It is correct that the EFSA guidance document on renewal requests a review of scientific publications "since the original authorization". However, in the case where a scientific opinion has been issued by the GMO Panel, the GMO Panel agrees with the submission of scientific review since the date of that scientific opinion (2005). Issues on PMEM are addressed in the comment above.
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	General comments	Considering all available data, the German CA is of the opinion that the use of Bt11 maize according to the scope of the application does not pose any risk for human or animal health or the environment. However, the German CA is of the opinion that the application for the renewal of the authorisation of Bt11 maize does not fully meet the requirements of the Regulation 1829/2003. It is desirable that the applicant adds updated information on the expression of Cry1Ab and PAT and discusses these aspects in more detail. Specification of the plan for general surveillance is requested as the objectives defined in Annex VII of Directive 2001/18/EC and Council Decision 2002/811/EC are not fully met. The applicant should be requested to state the database used for the literature search presented in appendix 15.	Issues on PMEM are addressed in the comments above. The applicant has provided a summary table showing the range of protein expression levels over more than one year. The data do not indicate any safety concern. Comments rather pertain to the previous application. An extensive review of the published literature on Bt11 but also on other insect resistance GM maize that express similar Bt protein was performed by the applicant and extended up to year 2008 by the Panel. As already mentioned no new information has been identified by the Panel regarding the compositional analysis or the toxicity that could prompt it to change its previous opinion. The panel notes that in the present application for renewal, bioinformatics studies have been updated and performed with the Cry 1 Ab truncated protein which is

				actually expressed in Bt11 maize
Italy	Ministero dell'Ambiente e della Tutela del Territorio e del Mare	D, 07.08 Toxicology	The feeding studies on toxicity and allergenicity on poultry and cows were conducted in a very short time; the data provided are only on the detection of Cry1Ab and PAT proteins.	As already mentioned no new information has been made available to the Panel regarding the safety assessment of the newly expressed proteins, e.g. from the extensive review of the published literature on Bt11 but also on other insect resistance GM maize that express similar Bt protein, that could prompt the Panel to change its previous opinion. The panel notes that in the present application for renewal, bioinformatic studies have been updated and performed with the Cry1Ab truncated protein which is actually expressed in Bt11 maize.
Italy	Ministero dell'Ambiente e della Tutela del Territorio e del Mare	D, 12 Environmental Monitoring Plan	General Surveillance Plan The text provides for a theoretical, indefinite and partial, elaboration on principles of post marketing monitoring activities. We have noted that the hypothesis of monitoring plan from the Notifier is based on a general assumption of no-risk for the product.	The GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance. See section 5.2 of the PMEM opinion (EFSA, 2006b): *Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. Thus detailed local arrangements will be developed by the applicant after the application has*

				been accepted (…).
Italy	Ministero dell'Ambiente e della Tutela del Territorio e del Mare	D. Information relating to the GM plant	Molecular characterisation of Bt 11 maize we didn't find details of nucleotide sequences of the insert and the flanking regions. If this is the case, there is a need to get this information as required in point 7 of Annex IV of Directive 2001/18/EC. Southern blot analysis are performed using three different probe (Bt, pat and bla) that covered only partially the vector sequences used for the plant trasformation. To exclude the presence of partial insertions there is a need of new Southern blot analysis using the entire vector as probe.	Sequence information has been provided. Updated bioinformatics data were provided in 2008. No novel open reading frames (ORFs) were identified that spanned either the 5' or the 3' junctions between the Bt11 insert and *Zea mays* genomic sequences. No fusion proteins are therefore expected. Additional Southern analysis with a probe representing the full length of the intended DNA insert (entire restriction fragment of pZO1502) demonstrated a single copy insert in Bt11 maize. The *bla* gene was excised before transformation.
The Netherlands	Ministry of Housing, Spatial Planning and the Environment	D, 03 Information on the expression of the insert | D, 07 Information on any toxic, allergenic or other harmful effects on human or…	The notification lacks an ORF analysis over the junctions of the 5' and 3' end of the insert with the flanking genomic sequences. For a proper risk assessment a complete molecular characterization including such an updated ORF analysis should be provided.	An updated bioinformatic analysis was provided in (2008) on the 5' and 3' flanking regions of Bt11. No new ORFs are present. This confirmed the original data provided by the applicant and no safety concerns are raised.

The Netherlands	Ministry of Agriculture, Nature and Food Quality and Ministry of Health	D, 03 Information on the expression of the insert | D, 07 Information on any toxic, allergenic or other harmful effects on human or…	The applicant has provided an update on the molecular characterization and the bioinformatics-supported comparisons of the introduced transgenic proteins Cry1Ab and PAT with known allergens and toxins. No updated study has been provided, however, for the bioinformatics-supported comparison of hypothetical peptide sequences encoded by the reading frames introduced or created by the insertion of the transgenic DNA in maize containing event Bt11 with allergens and toxins. The EFSA GMO Panel is advised to also consider these issues in its assessment of potential toxicity and allergenicity of Bt11 maize.	Updated bioinformatic analyses (2008) has confirmed the original data provided by the applicant and no safety concerns are raised.
The Netherlands	Ministry of Housing, Spatial Planning and the Environment	D, 12.03 General Surveillance of the impact of the GM plant	A general surveillance plan is supplied. The applicant makes a distinction between reporting direct and indirect effects in the monitoring plan. According to the applicant direct effects will be reported annually and indirect effects only at the stage of re-evaluation or at the end of a given consent. The Dutch CA under the 2001/18/EC is of the opinion that the applicant should report unexpected direct and indirect effects annually.	The GMO Panel requested additional information to the applicant in relation to the General Surveillance Plan.
The Netherlands	Ministry of Housing, Spatial Planning and the Environment	D, 12.03 General Surveillance of the impact of the GM plant	General surveillance will be performed by key networks (like grain traders and maize processors). The permit holder will request these networks to participate and asks them to be informed if any unanticipated adverse effects occur. However, it is unclear how these effects are monitored if these networks do not assist. The permit holder should ascertain that information on adverse effects is obtained even if key networks do not participate.	The GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance. See section 5.2 of the PMEM opinion (EFSA, 2006b): *Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. Thus detailed local arrangements will be developed by the applicant after the application has been accepted (…).*
