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Austria	Ministry of Health, Family and Youth	General comments	The results of the studies carried out on the GM hybrids Bt11 and GA21 are used to argue that the combination of these two GM lines by conventional breeding should not result in any changes in the new stacked event. This approach is based on the assumption that the insertion of gene-cassettes, a combination of transgenic DNA fragments, has either no effect on the host plant genome or a predictable effect in the case of stacking. This cannot be regarded as appropriate. According to recent guidance possible interactions of trait combinations in stacked events need to be assessed by the notifier (EFSA, 2007b). EFSA (2007). Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events. The EFSA Journal 512: 1-5.	Molecular characterisation of maize Bt11xGA21 indicated that the integrity of the single maize events was retained. Published opinions on the safety of the inserts in the single maize events (EFSA, 2005, 2007b, 2009) did not raise any safety concerns. There are no data from any component of maize Bt11xGA21 risk assessment to indicate any adverse effects as a result of combining the single maize events by traditional crosses.
Austria	Ministry of Health, Family and Youth	General comments	Detection method As long as no official (guidance) document on the interpretation of detection results of the described method for stacked events are available, no approval for placing on the market of this product should be given.	Outside the remit of the EFSA GMO Panel.
Austria	Ministry of Health, Family and Youth	D, 02 Information on the sequences actually inserted or deleted	Information on the sequences actually inserted (D.2) The molecular description provided by the notifier for the transgene insert derived from GM Maize GA21 shows that there are several copies of the restriction fragment used for construction of GA21. These fragments are contained as a contiguous stretch of transgenic DNA in GM maize Bt11xGA21. The insert comprises 3 full-length copies of the fragment; two copies with a base pair substitution in the NOS-terminator region. Apart from these full-length copies 3 other copies with specific individual deletions are present. The molecular modification present in GM maize Bt11xGA21 additionally comprise of an identified disruption of a genomic maize gene, the creation of several new putative open reading frames at the border regions (2 ORFs at the 5´border) and 2 other putative ORFs 3´ of the insert but in close proximity to the inserted promoter. The reasoning provided by the notifier to	Bioinformatic analysis of the single maize events Bt11 and GA21 has not indicated the potential for producing novel toxins or allergens. With respect to disruption of maize open reading frames (ORFs), there are no indications of any adverse effects in either Bt11 or GA21. Flanking sequence analysis of Bt11 revealed homology with a maize 180 bp knob-associated tandem repeat. The insertion of the *Not*I fragment in the maize genome does not disrupt any maize endogenous ORF. Sequencing also confirmed the absence of vector backbone fragments, including partial amp coding sequences. An updated bioinformatic analysis (2008) has confirmed the original data provided by the applicant and no safety concerns are raised.

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			conclude that these molecular alterations have no unintended negative effects is not consistently based on experimental evidence. Furthermore the bioinformatics analysis of putative new ORFs at the GA21 insertion locus to assess homologies to known allergens and toxins was utilizing sequence databases as of 2005. Since data from direct tests are not provided it remains unclear whether these alterations of the GA21 derived sequences have any subtle phenotypic effect in GM maize Bt11xGA21. The notifier thus is requested to indicate that his conclusions with regard to effects of the modifications derived from GM maize GA21 are still valid in light of the current knowledge on toxins and allergen sequences. The information on the transgene insert derived from GM maize Bt11 (according to application EFSA-GMO-RX-Bt11, Appendix 1) indicates that there were 8 changes to the sequence inserted in Bt11: 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 Bt11xGA21. 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 S35-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 concerning uncertainties 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. http://www.biosafety.be/gmcropff/EN/TP/MGC_reports/Report_Bt11.pdf	A total of eight nucleotide differences 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 EFSA GMO Panel supports this assessment which is validated by an updated sequence analysis of both the insert and the original plasmid used for transformation.

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Austria	Ministry of Health, Family and Youth	D, 03 Information on the expression of the insert	Information on the expression of the insert (D.3) Samples for analysis of the expression of the transgenic proteins contained in GM maize Bt11xGA21 were taken from a single location and thus are not fully representative of conditions occurring at commercial cultivation at locations in different environments. Furthermore it is not indicated whether Glyphosate or Glufosinate herbicides were used to treat the plants from which samples were taken for analysis. Therefore no comparison of expression levels in untreated and treated plants is included in the dossier (see technical dossier p. 25). The dossier does not contain any data itself, but refers to Appendix 2 for data and details. Results indicate that cry1Ab levels in roots of GM maize Bt11xGA21 at anthesis were significantly higher than levels in GM maize Bt11, and that levels of mepsps were significantly lower in kernels of GM maize Bt11xGA21 at seed maturity stage than in GM maize GA21. These differences were not further investigated. The notifier concludes that these differences were rather small and not found consistently throughout the growing season. In our opinion this reasoning is not convincing since the differences are significant anyhow and in one case only a single timepoint (kernels at seed maturity) was considered. We request that the notifier submits further data to support his conclusions as well as data to assess expression in GM plants treated with non-selective herbicides (Glyphosate, Glufosinate).	The "Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events" (EFSA, 2007a) states in section 3.A.ii. that "stability of protein expression and phenotype should be assessed on materials representative of those designed for commercial production, i.e. which will enter the environment and the food/feed chain", and does not specify the number of sites or seasons required for protein expression studies. The EFSA GMO Panel has provided positive opinions on the safety of the single maize events (EFSA, 2005, 2007b, 2009) and there is no indication that protein expression in maize Bt11xGA21 is appreciably different from that in the single maize events. The EFSA GMO Panel does not consider the levels of the newly expressed proteins in maize Bt11xGA21 to be a safety concern.

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Austria	Ministry of Health, Family and Youth	D, 03 Information on the expression of the insert	Expression of potential fusion proteins (D.3.c) The notifier is requested to indicate whether his conclusions concerning the Bt11 derived inserts address in full 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 indicate whether his assessment of potential fusion proteins is restricted to an analysis of the junction sequences for the insert derived from Bt11 or whether the assessment includes the sequences derived from the vector backbone which are present in the Bt11 insert in GM maize Bt11xGA21. In case only the junctions of insert and bordering maize genomic sequences have been assessed the notifier is requested to submit additional information on potential fusion proteins encoded by insert sequences, like for the insert derived from GM maize GA21. 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	Bioinformatic analysis of the single maize events Bt11 and GA21 has not indicated the potential for producing novel toxins or allergens. With respect to disruption of maize ORFs, there are no indications of any adverse effects in either Bt11 or GA21. Flanking sequence analysis of Bt11 revealed homology with a maize 180 bp knob-associated tandem repeat. The insertion of the *Not*1 fragment in the maize genome does not disrupt any maize endogenous ORF. Sequencing also confirmed the absence of vector backbone fragments, including partial amp coding sequences. An updated bioinformatic analysis (2008) has confirmed the original data provided by the applicant and no safety concerns are raised.

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Austria	Ministry of Health, Family and Youth	D, 04 Information on how the GM plant differs from the recipient plant in: …	Information on how the GM plant differs from the recipient plant in: reproduction, dissemination and survivability (D.4) The notifier notes that there is no reason to anticipate changes in reproduction, dissemination and survivability due to the modifications present in GM maize Bt11xGA21. This conclusion is based on observations of the parental events and a study on the agronomic performance of GM maize Bt11xGA21 (technical dossier p. 27, see Appendix 3). This is not satisfying for the following reasons: The study is designed to analyse grain yield and agronomic performance of pairs of early- and mid-maturity GM varieties and corresponding non-transgenic near isogenic varieties at 4 and 5 US locations in the year 2005, respectively. Data for 23 parameters were submitted, but only 7 parameters, which are mostly concerning grain yield, were statistically analysed. Most of the parameters 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 treatment with the non selective herbicides Glyphosate and Glufosinate. The notifier is requested to submit additional data to adequately assess any potential differences regarding reproduction, dissemination and survivability of GM maize Bt11xGA21, 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. According to recent guidance by EFSA (2007), the assessment shall include the parental events in the trial design. The notifier is therefore requested to submit adequate data which includes results for the mentioned parameters also for the parental events Bt11 and GA21, from which GM maize Bt11xGA21 was derived. This is important because the review of the assessment of GM	The herbicide tolerance traits can only be regarded as providing a potential agronomic advantage for the GM maize plant where and when glufosinate-ammonium- and/or glyphosate-based herbicides are applied. Similarly, insect resistance against certain lepidopteran pests provides a potential agronomic advantage in cultivation under infestation of target pests. However, survival of maize outside cultivation in Europe is mainly limited by a combination of low competitiveness, absence of a dormancy phase, and susceptibility to plant pathogens and cold climate conditions. Since these general characteristics are unchanged in maize Bt11xGA21, herbicide tolerance and insect resistance are not likely to provide a selective advantage outside cultivation in Europe. Therefore, it is considered very unlikely that plants or volunteers of maize Bt11xGA21 or its progeny will differ from conventional maize varieties in their ability to survive until subsequent seasons or to establish feral populations under European environmental conditions. Applicant's field trials have shown that there are no indications of an altered fitness of the single maize events Bt11 and GA21 as compared to conventionally bred hybrids with similar genetic background. In addition to the field trials carried out with the single maize events Bt11 and GA21 (EFSA, 2005, 2007b, 2009), a series of field trials with maize Bt11xGA21 were conducted across nine US corn belt locations in 2005. Information on phenotypic and agronomic characteristics was provided to assess the agronomic performance of maize Bt11xGA21 in comparison with non-GM maize. These field trial data showed enhanced biomass production when glufosinate-ammonium- and/or

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			maize GA21 showed that necessary data were missing to adequately assess differences in reproduction, dissemination and survivability, as well as a possible change of the ability of the GM maize GA21 for transfer of genetic material. EFSA (2007). Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events. The EFSA Journal 512: 1-5.	glyphosate-based herbicides are applied and/or under infestation of target pests, but do not show changes in plant characteristics that indicate altered fitness and invasiveness of maize Bt11xGA21 plants. In addition to the data presented by the applicant, the EFSA GMO Panel is not aware of any scientific report of increased spread and establishment of maize Bt11xGA21 and any change in survival capacity, including over-wintering. Since maize Bt11xGA21 has no altered survival, multiplication or dissemination characteristics except when glufosinate-ammonium- and/or glyphosate-based herbicides are applied and/or under infestation of target pests, the EFSA GMO Panel is of the opinion that the likelihood of unintended environmental effects as a consequence of spread of genes from this GM maize event will not differ from that of maize Bt11 and GA21 or that of conventional maize varieties.
Austria	Ministry of Health, Family and Youth	D, 05 Genetic stability of the insert and phenotypic stability of the GM plant	Genetic stability of the insert and phenotypic stability of the GM plant (D.5) The notifier concludes that the inserts are stably integrated from the molecular characterisation of GM maize Bt11xGA21 by Southern Blot (technical dossier p. 27). The conclusion is based on an analysis a pooled sample of 10 individual plants of GM maize Bt11xGA21 without indication of their pedigree. The few analysed samples were derived from a single greenhouse cultivation experiment. It thus is not possible to assess whether more than one generation of GM maize Bt11xGA21 has been investigated. As further data only results established for the parental events (Bt11 and GA21) are referenced by the notifier. We request that further data on genetic as well as phenotypic stability of GM maize Bt11xGA21 should be submitted by the notifier to support his conclusions.	The applicant has provided pedigree information for the single maize events Bt11 and GA21 used in the comparative molecular analysis of maize Bt11xGA21. Appropriate non-GM maize parental controls were used in the analysis of both the single maize events and the stacked maize event. The single maize events are stable and the data presented on the stacked maize event do not indicate a stability issue.

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Austria	Ministry of Health, Family and Youth	D, 07.01 Comparative assessment	Although the field trials with GM maize Bt11xGA21 were conducted in the USA 1995 as mentioned above, the compositional analyses were done with a different GM stacked event: Bt11 x MIR604 x GA21, grown in 2006, referring to the aforementioned EFSA Guidance Document 2007b. This can not be regarded as approriate. For an adequate assessment of GM maize Bt11xGA21 submission of data established for GM maize Bt11xGA21 is superior and recommended. Significantly lower contents of protein and accordingly amino acids in the GM corn indicate differences in the N uptake and utilisation. No data are available to assess whether the same amount of N was available in the test fields. Furthermore no cultivation details were given; neither pesticide residues nor mycotoxins were mentioned. These uncertainties impede the evaluation of conclusions by the notifier. We request that the notifier submits additional information to address the mentioned issues.	On request of the EFSA GMO Panel, the applicant has provided a compositional analysis of grain and forage obtained from the double stacked maize event Bt11xGA21, which was based on field trials carried out at six locations in the US in 2005. The EFSA GMO Panel has evaluated this analysis and concluded that maize Bt11xGA21 is compositionally equivalent to the non-GM maize counterpart with comparable genetic background and conventional maize with the exception of the newly expressed proteins (see sections 4.1.3 and 4.2 of the scientific opinion).
Austria	Ministry of Health, Family and Youth	D, 07.02 Field trials	Agricultural performance Late root lodging was not recorded at all locations (App. 3 Agronomic Assessment). There was no late root lodging at Janesville and Seward in both maize lines. But on the sites, where late root lodging occurred, considerably more incidents were noted in the GM maize (Alleman: 5 vs 0; Bloomington: 20 vs 10; Wapella: 35 vs 25; Mackinaw: 5 vs 0), indicating less resistance to suboptimal conditions. Therefore additional data are considered as necessary for the assessment.	Although several parameters were not analysed at all locations in the field trials for the comparative analysis the EFSA GMO Panel is of the opinion that the total data provided are sufficient to allow for the conclusion that the phenotypic characteristics and agronomic performance of maize Bt11xGA21 are comparable to those of its non-GM maize counterpart except for the introduced traits (see section 4.1.4 of the scientific opinion).

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Austria	Ministry of Health, Family and Youth	D, 07.08 Toxicology	As mentioned above by the notifier and EFSA, the stacking of event is presumed to have no further effects on the host plant and as a consequence it is argued that the risk assessment of the GM parental lines can be adopted for the stack. This may disregard potential adverse effects due to synergistic or additive interactions of traits. This assumption is used to explain why only a broiler feeding study and detailed assessment of subchronic toxicity of GM maize Bt11xGA21 has been conducted. This cannot be regarded as state of the art. Whole feed conversion studies 42 days Broiler feeding study The feed was prepared from stored grain and pelleted. According to the analyses of the line Bt11 x MIR604 x GA21 (harvest 2006) the contents of Cry1Ab and mEPSPS in the grain were 0,69-0,92 µg/g fw and 3,69–4, 71 µg/g fw respectively. The grain of this feed from 2005 showed mean values of 1,0 and 3,50 µg/g fw for Cry1Ab and mEPSPS respectively. In the diet were contents between 0,24 and 0,40 µg/g fw for Cry1Ab and between 0,63 and 0,77 µg/g fw for mEPSPS. The diets made from various maize grain sources were not identical concerning amino acid content, but an attempt was made to balance the diets with vermiculite and sand. The compositional analyses also showed lower protein and accordingly lower amino acid contents (see above). The levels of the mycotoxins aflatoxin, fumonisin, T2 toxin and deoxynivalenol did not differ between the test and control hybrids, but there was more zearalenone in the GM variant (110 vs 123 ppm). Concentration of pesticide residues were not indicated. Considering the facts, that toxicological endpoints were not assessed in the submitted study, that the diets were not identical and males showed a less than optimal feed conversion ratio the conclusion, that "….the data from this study show an absence of obviously deleterious effects associated with the consumption of diets prepared with transgenic stacked Bt11 x GA21 positive maize grain when compared to consumption of diets made from control	Regarding potential interactions between the single maize events, the EFSA GMO Panel has considered that two traits conferring tolerance to different herbicides targeting amino acid metabolism are present in maize Bt11xGA21. The EFSA GMO Panel noted that the comparative compositional analysis, including determination of the levels of amino acids and crude protein, did not reveal relevant differences between maize Bt11xGA21 and the non-GM maize counterpart (see section 4.1.3 of the scientific opinion). In addition, the molecular characterization undertaken on maize Bt11xGA21 identified no altered stability of the events when these were brought together by crossing, and expression analysis of the proteins Cry1Ab, PAT and mEPSPS revealed no relevant change in protein expression levels that could raise concerns for human and animal health (see section 3.2). Considering all the data available for maize Bt11xGA21 and the newly expressed proteins, the EFSA GMO Panel is of the opinion that interactions between the single maize events that might impact on the food and feed safety of maize Bt11xGA21 are unlikely. Since maize Bt11xGA21 was considered compositionally, phenotypically and agronomically equivalent to the non-GM maize counterpart, except for the introduced traits (see sections 4.1.3, 4.1.4 and 4.2 of the scientific opinion), no further animal safety or nutritional studies are required in accordance with the "Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed" (EFSA, 2006a). For the evaluation of the nutritional study using broiler chickens it is referred to the scientific opinion (see section 5.1.6).

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			(nontransgenic) maize grain" is not convincing. Additional data adequately addressing toxicolocical effects should be submitted by the notifier.	
Austria	Ministry of Health, Family and Youth	D, 07.08 Toxicology	Whole feed toxicity studies It is generally argued, that no special comparisons or even a 90 day rodent study is necessary with the stacked event, if no adverse effects are found for the parental lines. Apart from the fact, that in stacked events unpredictable changes could occur and they should be treated like any new event, there no 90 day feeding study was submitted for Bt11. Only for GA21 a 90 day feeding study with laboratory rats was performed. The observed significant differences (body weight, feed utilisation, organ weights, clinical pathology) were regarded as not treatment-related, since they were of small magnitude as well as inconsistent between sexes and treatment groups. But small consistent differences as well as sex-related differences could indicate chronic effects of the diet. To deepen the understanding of such inconsistencies multi-generation studies are necessary. In any case it is highly recommended that a 90 day toxicologigal study with rodents is performed, specifically since no such study has been carried out for Bt11 for notifications which have been completely assessed - and the one for GA21 showed significant differences.	With regard to the evaluation of the single maize events GA21 (including an assessment of the 90-day feeding study using diets containing grains from this maize) and Bt11, it is referred to the respective scientific opinions of the EFSA GMO Panel (EFSA, 2005, 2007b, 2009). Regarding maize Bt11xGA21, the comparative analysis showed that maize Bt11xGA21 was compositionally, phenotypically and agronomically equivalent to the non-GM maize counterpart, except for the introduced traits. In addition, the EFSA GMO Panel found no indication that crossing of maize Bt11 and GA21 results in an interaction between the single events, which causes compositional or agronomic changes (see sections 4.1.3, 4.1.4 and 4.2 of the scientific opinion). Therefore, in accordance with the "Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed" (EFSA, 2006a), further animal safety studies with the whole food/feed derived from maize Bt11xGA21 are not required.

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Austria	Ministry of Health, Family and Youth	D, 07.08 Toxicology	Other feeding tests with farm animals were conducted with GM maize Bt11: A 14 day 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 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! 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 highest amount of 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. Only 12 lactating cows were fed for a short period and 40% of feed consisted of maize silage. This test design can not be regarded as appropriate	With regard to the evaluation of the single maize event Bt11 including the assessment of relevant animal feeding studies, it is referred to the previous scientific opinions of the EFSA GMO Panel (EFSA, 2005, 2009).

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			for a toxicological risk assessment.	
Austria	Ministry of Health, Family and Youth	D, 07.08 Toxicology	Whole feed conversion studies with the parental GM maize lines GA21 and Bt11 also showed no detectable influence of the GM test corn. In the broiler feeding study with the parental line GA21 the diets were not identical like in the aforementioned study with the stacked event (protein and amino acid contents), but here no differences in feed conversion ratio were discovered. The mEPSPS concentrations in the GA21 grain were 3.96 ± 0.21 ìg/g fw (sprayed) and 4.15 ± 0.14 ìg/g fw (unsprayed). The diets contained from 1.22 ± 0.05 to 1.25 ± 0.10 ìg/g fw, which was more than in the broiler study with the stacked event. Thus the differences in the feed conversion ratios in the stacked event broiler feeding test could possibly be attributed to the presence of the Cry1Ab toxin – therefore clarification is needed. A feeding study with broilers was also performed with the second parental line GM maize Bt11 (Brake et al. 2003 - Brake, J., Faust, M.A., Stein, J, (2003): Evaluation of Transgenic Bt11 Hybrid Corn in Broiler Chickens. Dep. of Poultry Science, North Carolina State	For the evaluation of the single maize events Bt11 and GA21 including animal feeding studies using diets containing materials derived from these events, it is referred to the respective scientific opinions of the EFSA GMO Panel (EFSA, 2005, 2007b, 2009). On the basis of the available data, the EFSA GMO Panel found no indications that the Cry1Ab protein present in maize Bt11 is toxic to mammals. The evaluation of the broiler feeding study using diets containing grains from the stacked maize event Bt11xGA21 can be found in the scientific opinion (see section 5.1.6).

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			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. As compared to the broiler study with the stacked event the Cry1Ab content of the grain was lower (see above: 1.00 ìg/g fw), but the concentration in the starter diet was the same (0.24 ìg/g fw). 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 the effect of feed preparation (pelleting) on test material should be assessed.	
Austria	Ministry of Health, Family and Youth	D, 08 Post-market monitoring of GM food/feed	According to Art. 5 (3) k) of EU-Regulation 1829/2003 a post-market monitoring-plan should be added to the dossier.	The EFSA GMO Panel concluded in its evaluation that no data have emerged to indicate that maize Bt11xGA21 is any less safe than its non-GM maize counterpart and the parental GM maize lines. In addition, maize Bt11 xGA21 was, from a nutritional point of view, considered equivalent to conventional maize. Therefore, in line with the "Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed" (EFSA, 2006a), post-market monitoring of the food/feed derived from maize Bt11xGA21 is not necessary (see section 5.1.7 of the scientific opinion).

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Austria	Ministry of Health, Family and Youth	D, 10 Potential changes in the interactions of the GM plant with the biotic…	Potential changes in the interactions of the GM plant with the biotic environment The assessment by the notifier of any changes in the interactions of the GM plant with the biotic environment, specifically of interactions with non-target organisms, is based on the argument that effects are highly unlikely because the scope of the application does not include cultivation in the EU. This however disregards other routes of exposure of the environment to products derived from GM maize Bt11xGA21 and of constituents of GM maize Bt11xGA21, like cry1Ab toxin. Particularly exposure resulting from processing, feed use and spillage of the GM maize Bt11xGA21 are not adequately addressed. Therefore we request that the notifier includes an assessment of any effects resulting from these routes of exposure with specific regard to release of waste materials or sewage from use of GM maize Bt11xGA21 into the environment and the effects of these exposure on non-target organisms, specifically effects on water dwelling organisms and food webs in aquatic environments. These group of organisms was not considered adequately in preceding risk assessments of GM plants expressing cry1Ab toxins, but is known to be affected by Bt toxins (Rosi-Marshall et al. 2007). Rosi-Marshall EJ, Tank LJ, Royer TV, Whiles MR, Evans-White M, Chambers C, Griffiths NA, Pokelsek J, Stephen ML (2007). Toxins in transgenic crop byproducts may affect headwater stream eco-systems. Proceedings of the National Academy of Science USA, 104, 16204-16208.	The scope of the application includes food and feed uses, import and processing of maize Bt11xGA21 and excludes cultivation. Considering the intended uses of maize Bt11xGA21, the environmental risk assessment is concerned with indirect exposure mainly through manure and faeces from gastrointestinal tracts of animals fed maize Bt11xGA21 and with the accidental release into the environment of maize Bt11xGA21 grains during transportation and processing. There are no indications of increased likelihood of establishment or survival of feral maize plants in case of accidental release into the environment of viable maize Bt11xGA21 grains during transportation and processing for food and feed uses. Taking into account the scope of the application, both the rare occurrence of maize plants and low levels of GM maize plants and Cry1Ab exposure through other routes indicate that the risk to target and non-target organisms is considered negligible.

Application EFSA-GMO-UK-2007-49 (Bt11 x GA21 Maize) **Comments and opinions submitted by Member States during the three-months consultation period**				**ANNEX G**
Country	**Organisation**	**Reference**	**Comment**	**EFSA GMO Panel response**
Comments from National Competent Authorities under Directive 2001/18/EC				
Austria	Ministry of Health, Family and Youth	D, 12.02 Case-specific GM plant monitoring	Case-Specific Monitoring The notifier states that maize Bt11xGA21 can accidentally be introduced into the environment. Thus, in order to cover the risk of accidental spillage or unintended release into the environment of GM maize Bt11xGA21 a case-specific monitoring plan should be proposed. This comprises the monitoring along transportation routes, ports and harbours, processing plants etc. However, 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 Bt11xGA21 maize. Although the notifier proposes that grain handlers and importers 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 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 maize Bt11xGA21 (see below).	The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on post-market environment monitoring (PMEM) (EFSA, 2006a,b) following a broad consultation with stakeholder, 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 (…).* See section 6.1.3 of the scientific opinion.
Austria	Ministry of Health, Family and Youth	D, 12.03 General Surveillance of the impact of the GM plant	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 Bt11xGA21 which existing networks 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 (see above). It must be clear before placing on the market of GM maize Bt11xGA21 which existing networks will be involved. - The selection of networks to be involved is based on importers and	The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion. The EFSA GMO Panel concluded in its evaluation that no data have emerged to indicate that maize Bt11xGA21 is any

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Comments from National Competent Authorities under Directive 2001/18/EC				
			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 Bt11xGA21 (see CSM). - The methodology of the proposed GS is only based on passively collecting information. A more active approach of GS, including specific actions for monitoring accidental spillage, should also be employed by the notifier (see CSM). - Different intensity of surveillance activities in different EU MS 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 Bt11xGA21 into each EU member state will be reported separately. This should also take into consideration volumes of Bt11xGA21 in mixtures of GM maize. GS should not take place in representative areas only, but be proportional to 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. 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 Bt11xGA21.	less safe than its non-GM maize counterpart and the parental GM maize lines. In addition, maize Bt11xGA21 was, from a nutritional point of view, considered equivalent to conventional maize. Therefore, in line with the "Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed" (EFSA, 2006a), post-market monitoring of the food/feed derived from maize Bt11xGA21 is not necessary (see section 5.1.7 of the scientific opinion).

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Country	**Organisation**	**Reference**	**Comment**	**EFSA GMO Panel response**
Comments from National Competent Authorities under Directive 2001/18/EC				
Belgium	Belgian Biosafety Advisory Council	C. Information relating to the genetic modification	Table 1: - The accession number indicated for the "Maize intervening intron sequence 6 from the maize adh1 gene (Entrez Accession Number X04090)" is incorrect. X04090 refers to a human catalase gene.	The applicant has confirmed that correct accession number is actually X04049. The report has been corrected.
Belgium	Belgian Biosafety Advisory Council	D, 07.01 Comparative assessment	Of the 56 analytes measured in grain, statistically significant differences were noted for levels of total dietary fiber (TDF) and fat, vitamin E (α-tocopherol), and linoleic fatty acid. The average values of all analytes measured for both the Bt11 x GA21 (measured in Bt11 x MIR604 x GA21) grain and the nontransgenic grain were within the ranges reported in the literature.	On request of the EFSA GMO Panel, the applicant has provided a compositional analysis of grain and forage obtained from the double stacked maize event Bt11xGA21, which was based on field trials carried out at six locations in the US in 2005. The EFSA GMO Panel has evaluated this analysis and concluded that maize Bt11xGA21 is compositionally equivalent to the non-GM maize counterpart with comparable genetic background and conventional maize with the exception of the newly expressed proteins (see sections 4.1.3 and 4.2 of the scientific opinion).
Belgium	Belgian Biosafety Advisory Council	D, 07.03 Selection of compounds for analysis	For the majority of analytes no statistical differences were found. In a few cases, like total dietary fibre, vit E en linoleic acid a statistically significant difference was found. The values were however within the range of literature data.	See previous comment.
Belgium	Belgian Biosafety Advisory Council	D, 07.04 Agronomic traits	The Bt11 x GA21 maize was tested in the USA during the 2005 growing season. The results of these trials suggest that there is no statistically significant difference in grain yield or agronomic performance between the Bt11 x GA21 maize hybrids and the corresponding near-isogenic hybrids. These results are based on only 1 year of trials, excluding the potential year effect.	The comparative agronomic analysis showed that the phenotypic characteristics and agronomic performance of maize Bt11xGA21 was comparable to those of its non-GM maize counterpart (see section 4.1.4 of the scientific opinion). In addition, the comparative compositional analysis did not reveal any statistically significant differences for constituents for which a food safety concern could be foreseen. Therefore, the EFSA GMO Panel accepted that none of the field trials was replicated in a second year (see 4.1.3 of the scientific opinion).

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Comments from National Competent Authorities under Directive 2001/18/EC				
Belgium	Belgian Biosafety Advisory Council	D, 07.08 Toxicology	Mean concentrations of mEPSPS protein are comparable in both GA21 maize and Bt11 x GA21 maize. Comparing mean concentrations of Cry1 Ab and PAT proteins, results from Bt11 are comparable with Bt11 x GA21. In dossier RX-Bt11 a range of 12 - 154 μg/g dry weight is mentioned for Cry1 Ab. 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 isn't it performed? Degradation of the PAT protein in simulated intestinal fluid: Not mentioned. Has this test been performed? If not, why isn't it performed?	With regard to the evaluation of the single maize event Bt11 including the newly expressed proteins Cry1Ab and PAT, it is referred to the previous opinions of the EFSA GMO Panel (EFSA, 2005, 2009).
Belgium	Belgian Biosafety Advisory Council	D, 07.09 Allergenicity	Assessment of the allergenicity of the whole GM plant or crop. The applicant did not assess the allergenicity of the whole GM plant. Conversely to what is stated by the applicant, maize allergy has been described, though it is not recognized as a major allergen source. 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 three new traits described in the application, over-expression of endogenous proteins, among them the maize allergens, might occur. Therefore, it appears as relevant to analyze whether the expression levels of known maize allergens is increased in genetically modified Bt11 x GA21 maize grains. Patient IgE binding to maize grain extract or titration of known major allergens of maize should be carried out. 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	Allergenicity of the whole crop could be increased as an unintended effect of the random insertion of the transgene in the genome of the recipient, for example, through qualitative or quantitative modifications of the expression of the endogenous proteins. However, given that no biologically relevant agronomic and compositional changes were identified previously in maize Bt11 and GA21 and in the stacked maize event Bt11xGA21, with the exception of the introduced traits, no increased allergenicity is anticipated for maize Bt11xGA21. Moreover, maize is not considered a common allergenic food.

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Comments from National Competent Authorities under Directive 2001/18/EC				
Belgium	Belgian Biosafety Advisory Council	D, 10.01 Persistence and invasiveness	The germination and persistence of spilled kernels along transport ways is not probable. Hence invasiveness is not very probable neither. According to the precautionary principle, it is recommended to monitor transport routes in order to guarantee traceability. 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 using any of the current agronomic measures…." is not true.	Traceability and risk management fall outside the remit of the EFSA GMO Panel. The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.
Belgium	Belgian Biosafety Advisory Council	D, 10.02 Selective advantage or disadvantage	It is very unlikely that spillage will occur within agriculture land. Should this occur, there are, anno 2008, no indications that the transgene would have a selective advantage in current Belgian agricultural practices. Nevertheless, according to the precautionary principle, it is recommended to monitor transport routes in order to guarantee tracability.	Traceability falls outside the remit of the EFSA GMO Panel. The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.
Belgium	Belgian Biosafety Advisory Council	D, 10.03 Potential for gene transfer	The germination of spilled kernels along transport ways is not very probable (and hence the occurrence of flowering transgenic maize along the transport ways is very unlikely too). Therefore, gene transfer via pollen is not very likely neither. Nevertheless, according to the precautionary principle, it is recommended to monitor transport routes in order to guarantee traceability and clear prescriptions about packaging during transport and storage are needed.	Traceability and labelling fall outside the remit of the EFSA GMO Panel. The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.

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Comments from National Competent Authorities under Directive 2001/18/EC				
Belgium	Belgian Biosafety Advisory Council	D, 12.01 General	As already mentionned in D.10.1, D.10.2 and D.10.3, it is recommended to record all transport routes in order to guarantee tracability. 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, as indeed foreseen in Appendix 8 of the application at hand, should therefore be a point of particular interest in the report to be delivered annually to the Commission. More details on the organisation and implementation of that monitoring would be useful.	Traceability falls outside the remit of the EFSA GMO Panel. The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.
Belgium	Belgian Biosafety Advisory Council	D, 12.03 General Surveillance of the impact of the GM plant	The application (p 49) states that "Syngenta is committed to informing grain traders and maize processors with details on the safety of Bt11 x GA21 maize". This sentence makes one to presume that the monitoring will be overviewed by these traders and processors. A better and clear monitoring plan on package labelling and traceability is needed.	Traceability falls outside the remit of the EFSA GMO Panel. The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.
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 EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.

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Comments from National Competent Authorities under Directive 2001/18/EC				
France	MEIE - DGCCRF	General comments	L'Agence Française de Sécurité Sanitaire des Aliments émet les conclusions suivantes : · Les études menées pour montrer l'équivalence de composition ont été réalisées sur le triple transformant Bt11xMIR604xGA21 et sont considérées comme extrapolables au maïs Bt11xGA21 en conformité avec les lignes directrices de l'AESA. Etant donné qu'il n'y a aucun lien de fonction connue entre les protéines apportées par chacune des transformations génétiques, l'AFSSA prend en compte ces résultats d'autant plus que l'équivalence de composition chimique entre Bt11xGA21 et son témoin est confirmée dans l'étude d'alimentarité réalisée chez le poulet. · Bien qu'il n'y ait pas d'étude de toxicité subchronique de 90 jours chez le rongeur à partir du maïs portant l'événement de transformation Bt11, qui au moment de son évaluation n'était pas requise, l'historique de consommation de ce 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 à comité de lecture conduisent à considérer que le maïs portant l'événement Bt11xGA21 ne présente pas d'effets délétères liés à sa consommation. En conséquence, l'Agence Française de Sécurité Sanitaire des Aliments considère que les maïs Bt11xGA21 portant les deux événements de transformation Bt11 et GA21 et leurs produits dérivés sont équivalents en substance avec leurs témoins non transgéniques et présentent le même niveau de sécurité sanitaire que les maïs conventionnels et leurs produits dérivés. Cet avis ne préjuge pas des observations qui pourraient être formulées lors de l'évaluation du dossier de renouvellement d'autorisation des maïs portant l'événement Bt11.	The FF WG agrees with the conclusion of the French competent authority on the substantial equivalence of maize Bt11xGA21, as compared with its conventional counterpart.

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Comments from National Competent Authorities under Directive 2001/18/EC				
France	MEIE - DGCCRF	D, 07.01 Comparative assessment	(7) Informations relatives aux effets toxiques, allergiques, et autres effets délétères pour la santé humaine et animale (7.1-3) Extrait avis AFSSA : L'analyse de composition chimique a été réalisée sur un triple hybride Bt11xMIR604xGA21 issue du croisement conventionnel de trois lignées de maïs génétiquement modifié et comportant en plus des événements Bt11 et GA21, objet de la demande d'autorisation, l'événement MIR604. Ce choix est en accord avec les lignes directrices de l'AESA (1) concernant l'évaluation des doubles transformants issus du croisement conventionnel de lignées transgéniques. En effet, l'AESA permet l'évaluation sur un multi-transformant contenant un plus grand nombre d'événements dans la mesure où chacun d'eux est contenu dans le multi-transformant utilisé pour l'évaluation. MIR 604 est génétiquement modifié par introduction d'un gène codant une protéine Cry3A, toxique pour les coléoptéres du genre Diabrotica et d'un gène marqueur codant une phosphomannose-isomérase. Le maïs portant cet événement a été évalué par l'AFSSA en 2005 et a reçu un avis favorable à sa mise sur le marché pour l'importation et l'utilisation en alimentation humaine et animale de grains et de ses produits dérivés (avis du 2 décembre 2005). Par conséquent, l'AFSSA considère que l'analyse de composition chimique sur le triple hybride est acceptable d'autant plus que les caractères apportés par chacune des modifications génétiques n'interagissent pas ou ne concernent pas les mêmes mécanismes d'action. Cette analyse a été réalisée à partir d'échantillons du maïs Bt11xMIR604xGA21 et témoins non transformés ont été cultivés conjointement sur 6 sites (3 répétitions par site) aux États-Unis en 2006 ; l'analyse de composition fourragère porte sur les éléments suivants : humidité, protéines, lipides, glucides, cendres, fibres solubles dans les détergents acides et neutres (ADF,NDF), calcium, phosphore ; l'analyse de composition pour le grain porte sur les éléments suivants : humidité, protéines, lipides, glucides, cendres,	The FF WG agrees with the conclusion of the French competent authority on the substantial equivalence of maize Bt11xGA21, as compared with its conventional counterpart.

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			fibres totales, fibres solubles dans les détergents acides et neutres (TDF, ADF, NDF), amidon, 10 minéraux, 7 vitamines, 18 acides aminés, 5 acides gras, 7 métabolites secondaires et facteurs antinutritionnels (acide férulique, acide para-coumarique, inositol, acide phytique, inhibiteur trypsique, furfural, raffinose). Une analyse statistique de type ANOVA des paires transgéniques-non transgéniques a été appliquée pour les 6 sites et que les résultats de cette analyse ne montrent pas de différences significatives pour la composition fourragère mais montrent un effet génotype pour certains paramètres du grain (protéines, zinc et calcium, vitamine B1, acides-aminés). Cependant, les teneurs mesurées restent dans la limite des fourchettes des tables de composition établies pour le maïs grain au niveau international (ILSI, 2006 ou OCDE (2)) et les teneurs en composés majeurs du grain en particulier les acides aminés indispensables ne diffèrent pas. En conséquence, l'ensemble des données présentées conduit à conclure à une équivalence en substance entre le maïs hybride Bt11xGA21 et son témoin. (1)Guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified plants containing stacked events, adopted on 16 may 2007. (2) ILSI 2006 International life sciences institute crop composition database, v3.0. OCDE 2002 consensus document on compositional considerations for new varieties of maize (zea mays) : Key food and feed nutrients, anti-nutrients and secondary plant metabolites » series on the safety of novel foods and feeds, N°6.	

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Comments from National Competent Authorities under Directive 2001/18/EC				
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	A. General information	The German CA is of the opinion that the data provided with the application do not suffice to complete the evaluation of dossier EFSA-GMO-UK-2007-49. Further information is required to conclude on the risk assessment of Bt11 x GA21. 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 EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.
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 x GA21 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.	Risk management issues fall outside the remit of the EFSA GMO Panel.
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.01 Comparative assessment	According to the EFSA Guidance Document for the risk assessment of GM plants, it is advisable that experiments with herbicide tolerant crops "include both blocks of genetically modified plants exposed to the intended herbicide and blocks not exposed to the herbicide". In the study report on the compositional analyses (Appendix 4), data are given from glyphosate and glufosinate treated Bt11 x MIR604 x GA21 plants only. The applicant is asked to include compositional data from Bt11 x MIR 604x GA21 maize treated and not treated with glyphosate and glufosinate.	On request of the EFSA GMO Panel the applicant has provided a compositional analysis of grain and forage obtained from the double stacked maize event Bt11xGA21, which was based on field trials carried out at six locations in the US in 2005. The EFSA GMO Panel has evaluated this analysis and concluded that maize Bt11xGA21 is compositionally equivalent to the non-GM maize counterpart with comparable genetic background and conventional maize with the exception of the newly expressed proteins (see sections 4.1.3 and 4.2 of the scientific opinion). The EFSA GMO Panel considered the fact that treatment of the single maize events Bt11 and GA21 with the corresponding target herbicides did not affect their agronomic / compositional characteristics compared to plants not treated with these herbicides. Therefore, the EFSA GMO Panel accepted the design of the field trials although maize Bt11xGA21 untreated with the target

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				herbicides was not included in the studies.
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 08 Post-market monitoring of GM food/feed	Since the risk assessment of maize GA21 x Bt11 cannot be finalised on the basis of the data provided, it is not feasible to decide on the necessity of measures for post-market monitoring of GM food/feed.	The EFSA GMO Panel concluded in its evaluation that no data have emerged to indicate that maize Bt11xGA21 is any less safe than its non-GM maize counterpart and the parental GM maize lines. In addition, maize Bt11xGA21 was, from a nutritional point of view, considered equivalent to conventional maize. Therefore, in line with the "Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed" (EFSA, 2006a), post-market monitoring of the food/feed derived from maize Bt11xGA21 is not necessary (see section 5.1.7 of the scientific opinion).
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	The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.

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Country	**Organisation**	**Reference**	**Comment**	**EFSA GMO Panel response**
Comments from National Competent Authorities under Directive 2001/18/EC				
			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.	
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 considers that further information is required before the risk assessment of EFSA/GMO/UK/2007/49 can be finalised (see specific comments). Information (data and data analyses) provided on expression of the inserts, agronomic traits and composition is insufficient, and conclusions of substantial equivalence of Bt11 x GA21 maize and conventional maize based on this information are premature. Although application EFSA/GMO/UK/2007/49 does not include the cultivation of Bt11 x GA21 maize in the European Union, possible ecological consequences arising from accidental spillage or other forms of introduction of the transgene products in the environment should be considered more thoroughly. The applicant's proposal for an environmental monitoring plan does not meet the objectives defined in Annex VII of Directive 2001/18/EC and the supplementing guidance notes (Council Decision 2002/811/EC). With regard to references in application EFSA/GMO/UK/2007/49 to applications for the authorisation of Bt11 and GA21 in the European Union, we refer to statements of the German Competent Authorities including comments of the Federal Agency for Nature Conservation on these applications.	The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.

Application EFSA-GMO-UK-2007-49 (Bt11 x GA21 Maize) **Comments and opinions submitted by Member States during the three-months consultation period**				**ANNEX G**
Country	**Organisation**	**Reference**	**Comment**	**EFSA GMO Panel response**
Comments from National Competent Authorities under Directive 2001/18/EC				
Germany	Federal Agency for Nature Conservation (BfN)	D, 03 Information on the expression of the insert	Comments of the Federal Agency for Nature Conservation (BfN): According to the EFSA Guidance Document for the risk assessment of stacked transformation events (EFSA 2007), expression, among others, should be a focus of risk assessment to address interactions between the stacked events. Therefore, with regard to a final assessment of the expression of the inserts in Bt11 x GA21 maize, a more robust and reliable data basis is required, including a higher number of replications per site and sufficient statistics (based on such an extended data set). Since protein expression in plants can be affected by climatic conditions, soil fertility, agricultural practice or unknown gene-environment interactions, data from a single season give a rough estimate of expression levels only. A more robust and reliable data basis should, therefore, include data from at least three field seasons at the same location (with six locations representing different environmental conditions) to integrate possible differences in expression values triggered by differences in ecological conditions.	The "Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events" (EFSA, 2007a) states in section 3.A.ii. that "stability of protein expression and phenotype should be assessed on materials representative of those designed for commercial production, i.e. which will enter the environment and the food/feed chain", and does not specify the number of sites or seasons required for protein expression studies. The EFSA GMO Panel has provided positive opinions on the safety of the single maize events (EFSA, 2005, 2007b, 2009) and there is no indication that protein expression in maize Bt11xGA21 is appreciably different from that in the single maize events. The EFSA GMO Panel does not consider the levels of the newly expressed proteins in maize Bt11xGA21 to be a safety concern.
Germany	Federal Agency for Nature Conservation (BfN)	D, 04 Information on how the GM plant differs from the recipient plant in: …	Comments of the Federal Agency for Nature Conservation (BfN): Experiments must be conducted according to the case-by-case principle for ERA, even though the applicant does not see a reason to anticipate that the stacked event differs in reproduction, dissemination, and survivability. Although the agronomic characteristics in application EFSA/GMO/UK/2007/49 (Appendix 3) do not indicate a potential for differences in reproduction, dissemination and survivability of Bt11 x GA21 maize, the selected parameters themselves cannot sufficiently indicate such changes. Moreover, the data set is based on a field design which is – because of the small plot size – not comparable to common agricultural practice. With regard to a final assessment, further	After having requested additional information from the applicant, the EFSA GMO Panel considered the studies and the derived spectrum of data for the comparative agronomic (and compositional) assessment as sufficient (see section 4.1.2). The comparative agronomic analysis showed that the phenotypic characteristics and agronomic performance of maize Bt11xGA21 was comparable to those of its non-GM maize counterpart (see sections 4.1.2 and 4.1.4 of the scientific opinion).

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Comments from National Competent Authorities under Directive 2001/18/EC				
			information on reproduction, dissemination, and survivability is required, because the information provided is not considered sufficient to support the conclusion of a substantial equivalence of Bt11 x GA21 maize and conventional maize, which is the basis of further conclusions in application EFSA/GMO/UK/2007/49. The applicant should be asked to provide a robust and reliable data basis for reproduction, dissemination and survivability to assess potential interactions between the events. Field studies with ecology-based parameters such as frost tolerance, seed dormancy, or competitiveness of Bt11 x GA21 maize tested under field conditions should be included in the application. Relevant data should be collected to account for a minimum of three growing seasons and six locations representing different environmental conditions. The environmental conditions should be documented and provided with the application to assess their possible effects on the considered parameters. A summarising statistical analysis should address the between-site variation of the data. According to the EFSA Guidance Document for the risk assessment of stacked transformation events (EFSA 2007), appropriate comparators for the GM plant containing stacked events should include parental GM lines and isogenic controls. The applicant is asked to provide a statistical analysis comparing data from Bt11 x GA21 maize with data from Bt11 maize and GA21 maize. To include possible effects of ecological factors in such a comparison, the applicant is asked to provide a study where the parental GM lines Bt11 maize and GA21 maize are included in the study design at the same study sites.	

Application EFSA-GMO-UK-2007-49 (Bt11 x GA21 Maize) **Comments and opinions submitted by Member States during the three-months consultation period**				**ANNEX G**
Country	**Organisation**	**Reference**	**Comment**	**EFSA GMO Panel response**
Comments from National Competent Authorities under Directive 2001/18/EC				
Germany	Federal Agency for Nature Conservation (BfN)	D, 07.01 Comparative assessment	Additional comments of the Federal Agency for Nature Conservation (BfN): No compositional analysis of Bt11 x GA21 maize, but only of the stacked event Bt11 x MIR604 x GA21 (Appendix 4) is included in application EFSA/GMO/UK/2007/49. In this regard, the applicant refers to the EFSA Guidance Document for the risk assessment of stacked transformation events (EFSA 2007), that "as long as each event in the highest number of stacked events has been risk assessed, the risk assessment of the stacked events might also be applicable to GM stacks containing fewer of these events". However, in line with the case-by-case principle of the risk assessment outlined in European regulations, we highly recommend that the applicant should also conduct and submit a sufficient analysis with Bt11 x GA21 maize in order to receive robust data on the actual composition in Bt11 x GA21 maize, which is the subject of application EFSA/GMO/UK/2007/49. With regard to a final assessment, further information is required, because the information provided is not considered sufficient to support the conclusion of a substantial equivalence of Bt11 x GA21 maize and conventional maize, which is the basis of further conclusions in application EFSA/GMO/UK/2007/49. The applicant should be asked to provide a robust and reliable data basis for composition to assess potential interactions between the parental events. Plant material should be sampled during a minimum of three growing seasons and at six locations representing different environmental conditions. The environmental conditions should be documented and provided with the application. A summarising statistical analysis should address the between-site variation of all parameters. According to the EFSA Guidance Document for the risk assessment of stacked transformation events (EFSA 2007), appropriate comparators for the GM plant containing stacked events should include parental GM lines and isogenic lines. The applicant is asked to include the parental GM lines Bt11 maize,	On request of the EFSA GMO Panel, the applicant has provided a compositional analysis of grain and forage obtained from the double stacked maize event Bt11xGA21, which was based on field trials carried out at six locations in the US in 2005. The EFSA GMO Panel has evaluated this analysis and concluded that maize Bt11xGA21 is compositionally equivalent to the non-GM maize counterpart with comparable genetic background and conventional maize with the exception of the newly expressed proteins (see sections 4.1.3 and 4.2 of the scientific opinion).

Country	Organisation	Reference	Comment	EFSA GMO Panel response
Comments from National Competent Authorities under Directive 2001/18/EC				
			MIR604 maize and GA21 maize in the study design at the same study sites.	
Germany	Federal Agency for Nature Conservation (BfN)	D, 07.08 Toxicology	Comments of the Federal Agency for Nature Conservation (BfN): Toxicology of the expression products is addressed by the applicants through references to earlier studies with the proteins Cry1Ab, PAT and mEPSPS provided with the respective applications for authorisation of Bt11 maize and GA21 maize. As application EFSA/GMO/UK/2007/49 is considered to be a stand-alone document, the applicant is asked to add these studies to application EFSA/GMO/UK/2007/49. Studies on combinatory effects of the proteins Cry1Ab, PAT and mEPSPS covering, in particular, concentrations and concentration ratios, which are typical for Bt11 x GA21 maize, are missing and the applicant should be asked to add them to the application. According to the EFSA Guidance Document for the risk assessment of GM plants (EFSA 2004), testing the whole GM food and feed "should include at least a 90-day toxicity study in rodents" in cases where there are "any indications for the potential occurrence of unintended effects, based on the preceding molecular, compositional and phenotypic analysis". Due to insufficient data basis on composition and phenotypic characteristics, the applicant is asked to provide a 90-day feeding study in rats with Bt11 x GA21 maize.	With regard to the evaluation of the single maize events Bt11 and GA21 including the newly expressed proteins Cry1Ab, PAT and mEPSPS, it is referred to the previous opinions of the GMO Panel (EFSA, 2005, 2007b, 2009). No safety concerns concerning these proteins were identified by the EFSA GMO Panel. The applicant has provided new bioinformatics-supported studies, which confirmed the results of the previous studies showing that the amino acid sequences of the proteins did not show homology to known proteins toxic to mammals or allergenic proteins (see sections 5.1.4 and 5.1.5 of the scientific opinion). The EFSA GMO Panel is not aware of any new information that would change the previous conclusions regarding the newly expressed proteins. The comparative analysis showed that maize Bt11xGA21 was compositionally, phenotypically and agronomically equivalent to the non-GM maizecounterpart, except for the introduced traits (see sections 4.1.3, 4.1.4 and 4.2 of the scientific opinion). Considering all the data available for maize Bt11xGA21 and the newly expressed proteins, the EFSA GMO Panel is of the opinion that interactions between the single events that might impact on the food and feed safety of maize Bt11xGA21 are unlikely (see section 5.1.4). Therefore, a 90-day feeding study in rodents is not required in accordance with the "Guidance document of the Scientific

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Comments from National Competent Authorities under Directive 2001/18/EC				
				Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed" (EFSA, 2006a).
Germany	Federal Agency for Nature Conservation (BfN)	D, 08 Post-market monitoring of GM food/feed	Additional comments of the Federal Agency for Nature Conservation (BfN): A post-market monitoring of the use of Bt11 x GA21 maize for food and feed is regarded obligatory and a post-market monitoring plan covering this issue is required	In its evaluation, the EFSA GMO Panel concluded that no data have emerged to indicate that maize Bt11xGA21 is any less safe than its non-GM maize counterpart and the parental GM maize lines. In addition, maize Bt11 xGA21 was, from a nutritional point of view, considered equivalent to conventional maize. Therefore, in line with the "Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed" (EFSA, 2006a), post-market monitoring of the food/feed derived from maize Bt11xGA21 is not necessary.

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Country	**Organisation**	**Reference**	**Comment**	**EFSA GMO Panel response**
Comments from National Competent Authorities under Directive 2001/18/EC				
Germany	Federal Agency for Nature Conservation (BfN)	D, 10 Potential changes in the interactions of the GM plant with the biotic…	Comments of the Federal Agency for Nature Conservation (BfN): Water and soil organisms may be exposed to Bt11 x GA21 maize and their expression products via the release of organic waste material, litter or sewage to the environment, which occurs during processing or through spillage. No data are provided by the applicant about the concentration of the proteins Cry1Ab, PAT and mEPSPS in organic waste material, litter or sewage. The possibility of an accumulation of the mentioned substances in the environment and of subsequent effects on water and soil organisms is not assessed, but should be given more attention. Potential effects of Bt plants on aquatic organisms have so far been neglected. Two recent publications, however, indicate potential risks of Bt toxins or Bt plant material for aquatic invertebrates and associated food webs (Rosi-Marschall et al. 2007, Bøhn et al. 2008). Therefore, the applicant is requested to provide data on this issue and to submit a risk assessment concerning the possible exposure of water and soil organisms to the mentioned substances.	The scope of the application includes food and feed uses, import and processing of maize Bt11xGA21 and excludes cultivation. Considering the intended uses of maize Bt11xGA21, the environmental risk assessment is concerned with indirect exposure mainly through manure and faeces from gastrointestinal tracts of animals fed maize Bt11xGA21 and with the accidental release into the environment of maize Bt11xGA21 grains during transportation and processing. There are no indications of increased likelihood of establishment or survival of feral maize plants in case of accidental release into the environment of viable maize Bt11xGA21 grains during transportation and processing for food and feed uses. Taking into account the scope of the application, both the rare occurrence of maize plants and low levels of GM maize plants and Cry1Ab exposure through other routes indicate that the risk to target and non-target organisms is considered negligible.

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Comments from National Competent Authorities under Directive 2001/18/EC				
Germany	Federal Agency for Nature Conservation (BfN)	D, 12.01 General	Comments of the Federal Agency for Nature Conservation (BfN): As stated by the applicant, the scope of the application of the Bt11 x GA21 maize is for import and processing and all uses for food and feed. The applicant's proposal for an environmental monitoring plan does not fully meet the requirements according to Annex VII of Directive 2001/18/EC and Council Decision 2002/811/EC. Therefore, a plan suitable to meet the objectives is requested. Both parts of the monitoring plan, the case-specific monitoring and the general surveillance have to meet the following requirements: • Provision of a fully specified list of monitoring parameters: 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. • Determination of the baseline status of the receiving environment with respect to the monitoring parameters. • Elaboration of a sampling concept: Particularly, it must be explained how the necessary representativeness of the collected data in space and time is ascertained. The applicant is requested to indicate how the monitoring plan is adapted to different local conditions where appropriate. • Characterisation of reference areas. • In case of monitoring data being collected by external persons or institutions other than the applicant, binding agreements/contracts with third parties are requested which clearly determine what data are provided and how these data are made available. • Elaboration of the methods of data analysis including the statistical methods. The monitoring should be run in regions, where Bt11 x GA21 maize will be transported, processed or used. The time-period of monitoring needs to be sufficient to detect delayed or long-term adverse effects. Therefore, it may be	The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.

Country	Organisation	Reference	Comment	EFSA GMO Panel response
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			necessary to extend the monitoring of certain parameters beyond the period of the consent.	
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 environmental risk assessment. During transport, storage, packaging or processing incidental spillage of Bt11 x GA21 maize can occur. Furthermore, the exposure of the environment to Bt11 x GA21 maize, its Cry1Ab protein, PAT and mEPSPS during or after the production process and during animal consumption is given. Therefore, a case-specific monitoring is necessary and has to focus on pathways, how the Bt11 x GA21 maize can enter 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 x GA21 maize kernels e.g. via spillage during transport, storage, packaging, processing and use, • spread, persistence and accumulation of Bt11 x GA21 maize, its Cry1Ab protein, PAT and mEPSPS if spillage or loss during transport, storage, packaging, processing and use occurs, • exposure of the environment of the Cry1Ab protein, PAT and	The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.

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Comments from National Competent Authorities under Directive 2001/18/EC				
			mEPSPS e.g. via sewage water, waste material or by-products which occur during processing. If spread, persistence and accumulation of Bt11 x GA21 maize, its Cry1Ab protein, PAT and mEPSPS in the receiving environment occur e.g. via spillage, loss or release of Bt11 x GA21 maize or of sewage water, waste material or by-products containing Bt11 x GA21 maize, further observations of possible impacts on organisms, food chains and habitats are required.	
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): According to Directive 2001/18/EC general surveillance is a compulsory part of the monitoring. The objective of general surveillance is to monitor potential cumulative long-term impacts on human health and the environment and to identify the occurrence of adverse effects of the GMO on human health and the environment which were not anticipated in the environmental risk assessment. The general surveillance plan has to focus on possible pathways how Bt11 x GA21 maize can get into the broader environment and how unforeseen adverse effects on human health and the environment can be linked to the dispersal of Bt11 x GA21 maize. The applicant is requested to provide an appropriate monitoring plan to observe the spread, persistence and accumulation of the Cry1Ab protein, PAT and mEPSPS in organisms and the environmental media (soil, air, water).	The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.
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 monitoring results including case-specific monitoring and general surveillance have to be reported on an annual basis. All raw data have to be provided upon request.	Results of the general surveillance will be reported on an annual basis. Moreover, the information supplied by the applicant is in line with this guidance.

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Comments from National Competent Authorities under Directive 2001/18/EC				
Greece	Hellenic Food Authority (EFET)	D, 07.01 Comparative assessment | D, 07.02 Field trials | D, 07.03 Selection of compounds for analysis	Data from a comparative assessment with the stacked event Bt11 X GA21, and not only the stacked event Bt11 X MIR604 X GA21, should be provided.	On request of the EFSA GMO Panel, the applicant has provided a compositional analysis of grain and forage obtained from the double stacked maize event Bt11xGA21, which was based on field trials carried out at six locations in the US in 2005. The EFSA GMO Panel has evaluated this analysis and concluded that maize Bt11xGA21 is compositionally equivalent to the non-GM maize counterpart with comparable genetic background and conventional maize with the exception of the newly expressed proteins (see sections 4.1.3 and 4.2 of the scientific opinion).
Greece	Hellenic Food Authority (EFET)	D, 07.08 Toxicology	Despite the fact that a 44-day feeding study in broiler chickens was conducted, an additional 90-day feeding study in rats should be carried out to further complete its safety assessment.	Since the comparative analysis showed that maize Bt11xGA21 was compositionally, phenotypically and agronomically equivalent to the non-GM maize counterpart, except for the introduced traits (see sections 4.1.3, 4.1.4 and 4.2 of the scientific opinion), a 90-day feeding study in rodents is not required in accordance with the "Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed" (EFSA, 2006a).
Italy	Ministero dell'Ambiente e della Tutela del Territorio e del Mare	D, 05 Genetic stability of the insert and phenotypic stability of the GM plant	The stability of the inserted genetic code has been tested for three generations at a phenotypic and a genotypic level. Anyhow it is necessary to check in the time the stability of the inserted genetic code because of the presence of unwanted and highly repeated sequences of the genome of maize and other inserted genetic codes; it is, therefore, required that Southern best analysis come to be periodically executed on the variety in commerce and in the obtained hybrids.	The EFSA GMO Panel guidance document does not require that applicants continue to carry out molecular analysis once a single event or stacked events has/have been approved for placing on the market.
Italy	Ministero dell'Ambiente e della Tutela del Territorio e del Mare	D, 12.01 General	The whole data collected by Syngenta through the network in charge of the general surveillance must be presented to the European Competent Authorities. A particular care should be given to the activities aimed to organize and manage the international data	The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, including national competent authorities. The information supplied by the

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Comments from National Competent Authorities under Directive 2001/18/EC				
				applicant is in line with this guidance. See section 5.2 of the PMEM opinion (EFSA, 2006b) and section 6.1.3 of the scientific opinion.
Norway	Directorate for nature management	General comments	According to the Norwegian Gene Technology Act possible contributions to sustainable development and possible benefits to the society and ethical considerations through the use of a GMO, shall be taken into consideration when evaluating a GMO notification in Norway. We would, in order to facilitate an approval in Norway, like the applicant to elaborate on the effects of Bt11 x Ga21 on these subjects	Outside the remit of the EFSA GMO Panel.
Norway	Directorate for nature management	D, 01 Description of the trait(s) and characteristics which have been introduced…	What changes in agricultural practices will the use of the hybrid lead to, compared to its conventional counterpart? Of special interest are changes in the use of pesticides, both in terms of types and amount, which could result in changes of exposure both to farmers, land workers and to the environment. The Norwegian Competent Authority would therefore like to ask the applicant to provide data on the nature of these changes, and to relate these changes in agricultural practice to benefit to society and contribution to sustainable development.	Outside the remit of the EFSA GMO Panel.
Norway	Directorate for nature management	D, 12.04 Parameters to be used in a monitoring plan	The suggested questions to be asked as part of the General Surveillance Plan serves as a draft, and will be discussed and agreed with the operators and the Commission. We still feel the need to emphasise that it is important for the quality assurance of the surveillance that the member associations and member companies are reminded not only to report in case of adverse effects, but also to report annually if no adverse effects are observed. No reports of adverse effects do not serve as proof that no adverse effects have arisen. The lack of such reports may also be caused by lack of surveillance.	The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.

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Comments from National Competent Authorities under Directive 2001/18/EC				
Norway	Directorate for nature management	D, 12.06 Reporting the results of monitoring	We would like the description of the responsibilities in the network to be more comprehensive. The only description of responsibilities mentioned is the notifier/consent holder's responsibility to inform the Commission of the results of the surveillance. Council decision 2002/811/EC states that responsibilities for each step of the monitoring plan should be clearly assigned in the notification. We do not agree that the notification meets the demands of the Council decision regarding responsibilities, and would like to ask the applicant to present a more comprehensive description of the responsibilities in the general surveillance of Bt 11 x GA 21.	The EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.
Spain	Ministery of the Environment, and Rural and Marine Affairs	D. Information relating to the GM plant	We would appreciate more information in relation to the DNA sequence of the hybrid.	It is not a requirement to sequence the single maize events in stacked GM maize events when these single events have already been risk assessed. Southern analysis of maize Bt11xGA21 indicated the integrity of the single maize events.
The Netherlands	Ministry of Agriculture, Nature and Food Quality and the Ministry of Health	D, 07.01 Comparative assessment	The applicant justifies the choice of the triple stack Bt11 x GA21 x MIR604 as a substitute for Bt11 x GA21 in the compositional analysis by referring to a quote from EFSA's guidance document on stacked varieties. This quote states that the risk assessment for stacked varieties combining a certain number of single events that have already been assessed for their safety would also be valid for stacked events containing a lower number of these single events. However, the study provided by the applicant only pertains to a compositional analysis performed by itself on the triple stack and not to a full risk assessment by EFSA on this stacked event. In this way, the data provided on the comparative assessment are comprehensive neither for Bt11 x GA21, for which agronomic data and a chicken broiler feeding study report have been provided, nor for Bt11 x GA21 x MIR604, for which compositional data have been provided. It would therefore be recommendable that data on the double stack Bt11 x GA21, which is the GMO considered in this application, be supplemented with compositional data in order to	On request of the EFSA GMO Panel, the applicant has provided a compositional analysis of grain and forage obtained from the double stacked maize events Bt11xGA21, which was based on field trials carried out at six locations in the US in 2005. The EFSA GMO Panel has evaluated this analysis and concluded that maize Bt11xGA21 is compositionally equivalent to the non-GM maize counterpart with comparable genetic background and conventional maize with the exception of the newly expressed proteins (see sections 4.1.3 and 4.2 of the scientific opinion).

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			be able to conclude the risk assessment of Bt11 x GA21, because data on composition of the new genetically modified maize are crucial for the risk assessment of food and feed safety. The applicant should give an statement for the choice to provide compositional data of the triple stack in the absence of other data of this triple stack. In addition, the risk assessment of the stacked event is based amongst others on the presumed safety of Bt11. The latter is currently being re-assessed by EFSA under 1829/2003/EC. Therefore, all issues pertaining to Bt11 identified during the assessment for its renewal are valid as well for Bt11 x GA21. However, since no biologically significant differences were observed in the composition of the triple stack, and it is unlikely that biologically significant differences will occur in the double stack Bt11 x GA21 maize in the absence of MIR604, the triple stack study can be used for the present evaluation. It has to be stressed, however, that the usefulness of higher stacks for risk assessment of lower stacks has to be considered case by case.	
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 EFSA GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and scientific opinion on PMEM (EFSA, 2006a,b) following a broad consultation with stakeholder, 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) and section 6.1.3 of the scientific opinion.

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Country	**Organisation**	**Reference**	**Comment**	**EFSA GMO Panel response**
Comments from National Competent Authorities under Directive 2001/18/EC				
The Netherlands	Ministry of Housing, Spatial Planning and the Environment	D, 12.03 General Surveillance of the impact of the GM plant | D, 12.06 Reporting the results of monitoring	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.	Results of the general surveillance will be reported on an annual basis. Moreover, the information supplied by the applicant is in line with this guidance.

List of References

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