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Country	**Organisation**	**Reference**	**Comment**	**EFSA Panel Response**
Austria	Ministry of Health, Family and Youth Austria	D, 02 Information on the sequences actually inserted or deleted	With regard to the assessment of all detectable inserts the notifier presents Southern Blot data as well as results of PCR experiments. These data were included to characterise the transgenic inserts in GM maize 1507. However most of the presented Southern Blot data are of inferior technical quality (specifically Fig. 8-10, technical dossier 57-59) and therefore not adequate to unambiguously support the conclusions drawn by the notifier. Generally, the blots do not show discrete hybridisation signals that could be easily distinguished. Instead single fragments originating e.g. from using the cry1F probe to detect PmeI-cut plasmid PHP8999 as positive control do not resolve into discrete bands (at about 6,2 kB) but smear over a molecular weight range of approximately 2 to 6,5 kb (see e.g. Fig. 9, page 58). Such data are not conclusive and have to be rejected. The experiments furthermore are not accompanied by a demonstration of their sensitivity. Therefore it cannot be assessed what is the minimal size of transgenic insertions, which would be detected by the experiments. In comparison the experiments to demonstrate that the nptII gene as well as other plasmid backbone elements are absent from GM maize 1507 are of better technical quality and furthermore incorporate a dilution series of the positive control to demonstrate the sensitivity of detection. Incompleteness of the molecular characterisation is evident specifically concerning location and size of the additional copy of cry1F in the GM maize 1507 genome. In the present notification the notifier stated that such an additional fragment was detected, but concluded that the Southern Blot experiments described in the technical dossier, p. 15 were not designed to allow for a further characterisation of this additional cry1F copy. The results submitted in the chapter dealing with absence of vector backbone sequences (technical dossier p. 20) might lead to different conclusions and is not referred to in the above mentioned discussion of inserted cry1F sequences. For the additional data described in p 20 (see Fig. 20 – 24) the notifier did not describe the	New molecular data were received from the applicant, including Southern analysis with different probe/enzyme combinations and these,support the initial conclusion.

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			origin of the control line used. The notifier is thus requested to clarify whether a line with the HiII-background was used as for the other submitted data. It is unclear whether this additional copy of the cry1F gene in GM maize 1507 contains a fragment of the ubiquitin promoter region. The notifier submitted data from PCR-experiments demonstrating that certain regions of 5´and 3´flanking sequences (Regions 1-3, Region 15; technical dossier p. 18, Fig. 16 – 17) can be found also in non-modified maize and are therefore native to the maize genome. However the notifier failed to present a detailed characterisation of the locus of insertion in non-modified maize and to compare the structure of this loci in GM maize 1507 and non-modified maize. Therefore the notifier is requested to submit a complete dataset for characterisation of all detectable transgenic inserts based on experiments with an optimised design and with the results presented in a quality which is adequate for an assessment. The notifier shall further present a concise discussion of all presented evidence addressing specific characterisation issues, like characterisation of the additional cry1F copy. Additionally, the notifier shall present data to clarify the sensitivity of the experiments. Concerning the chromosomal locations of the transgenic elements present in GM maize 1507 no adequate evidence was presented or referenced in the notification. The notifier concluded that the characterised transgenic insertion is integrated into the maize genome of GM maize 1507, but did not submit information on chromosomal location. The notifier is requested to submit meaningful information to substantiate the conclusions and clarify the chromosomal location of the insert.	

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Austria	Ministry of Health, Family and Youth	D, 03 Information on the expression of the insert	The notifier has not presented any new data on expression of GM maize 1507. The present notification again refers to previously submitted data, for which the following shortcomings are identified: - Although data on expression of transgenes were derived from different field trials at different locations only one replicate of samples was assessed for the European locations, and the effect of the Glufosinate treatment was not systematically evaluated, since Glufosinate-treated and non-treated plants were not consistently evaluated at all locations. - No assessment of expression of cry1F and pat in different genetic backgrounds is possible due to missing information on the origin of tested GM maize 1507 hybrids. We therefore request submission of data from the notifier from recent trials in the EU assessing the differences in expression between different varieties, years and locations and systematically assessing the effect of the Glufosinate-treatment on expression of transgenes.	Some of the comments pertain to data which were addressed by the Panel in its previous opinions. Concerning this renewal application, an update on the expression levels of Cry1F and PAT in grains was requested to the applicant. New data were submitted, coming from field experiments in 2008 in USA. The new data do not indicate any 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 The notification contains a discussion of the expression of potential fusion proteins including an analysis whether any variants related to Cry1F or PAT proteins are expressed in GM maize. For the characterisation of potential fusion proteins not related to the inserted transgenes, the notifier submitted data of Northern Blot analysis and RT-PCR analysis to assess the potential expression of fusion proteins identified at the 5´ part of the transgenic insertion (ORF3, spanning regions 4-7b) and 3´ of the inserted functional cry1F copy (ORF4, spanning sequences derived from ORF 25 terminator to the 35S promoter element of the pat transgene), see technical dossier p.21ff. A weak expression in certain GM maize 1507 samples was detected for ORF4, however dismissed to be of relevance by the notifier due to the reasoning that the detected mRNA is probably contained on a read through transcript produced from the Ubiquitin-Promoter -cry1F cassette and would therefore most probably not be translated from the polycistronic mRNA. To assess the toxic and allergenic potential of any translated products the protein sequences of ORF 3 and 4 were further subjected to sequence homology comparisons. With regard to the conclusions drawn concerning expression of potential fusion proteins the notifier is requested to describe whether recommendations from the guidance by FAO/WHO (2001) were followed and whether the results from comparisons reported in the year 2002 are still valid based on the current knowledge on toxins and allergens reflected in present versions of the respective databases.	In the evaluation of the renewal application, updated bioinformatics analysis included the identification of all putative peptides resulting from the insertion (at all new junctions created by the insertion) and homology search with toxins, allergens, and bioactive peptides from recent releases of databanks. No safety issue was identified by this analysis, which was considered sufficient by the GMO Panel.

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Austria	Ministry of Health, Family and Youth	D, 05 Genetic stability of the insert and phenotypic stability of the GM plant	For the demonstration of genetic and phenotypic stability results from segregation experiments for BC2F1 and F1 (BC3F1) generations assessing the inheritance of the herbicide tolerance trait were submitted. These data demonstrate the Mendelian pattern of inheritance and the phenotypic stability with regard to this trait. However, the genetic stability (assessed by Southern Blot analysis) was only tested for the generations T1S1 and BC4F1 and for less individual GM plants than used in the above mentioned tests. The notifier is thus requested to submit a detailed analysis of an adequate number of individual plants for the stability of the inserted modifications, allowing to assess the frequency of changes to inserted transgenes as well a flanking sequences in GM maize 1507. The notifier is therefore requested to address the previously mentioned concerns and submit further data and an adequate analysis of these data relevant to address the concerns.	The new dataset provided by the applicant after a request by the GMO Panel included Southern results and ELISA measurements of protein expression in grains, obtained from genotypes resulting from multiple backcrosses, selfings and crosses with elite lines. These results indicated stability and integrity of the insert, as well as sufficient stability of the protein levels in grains.

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Country	**Organisation**	**Reference**	**Comment**	**EFSA Panel Response**
Austria	Ministry of Health, Family and Youth	D, 07.01 Comparative assessment	The field trials in Chile comprised only one year. Table 11 only shows the climate data of the growing year without reference to rainfall and temperature averages of past data collections. The analytical results are presented as means of the cultivation sites only. Significant differences between the test hybrids e.g. some fatty acids, total tocopherols are not discussed. It is pointed out that all values were found to be within the published range for maize. If analytical results are interpreted in that way, the cultivation of a near-isogenic comparator seems redundant, which can not be regarded as state of the art. Pesticide residues are not even mentioned. The field trials in Italy and France were also conducted for one year only. Again it is stated, that "the conclusions in the report are primarily derived from a comparison of nutrient levels in the test line to levels in the literature". This approach can not be regarded as suitable to detect potential GM effects. Furthermore in cases, where levels were slightly above the literature ranges (e.g. threonine, isoleucine in 1507) these minor increases are not considered to be nutritionally significant. First of all no "dramatic" differences can be expected in the main components of harvested crops anyway, since these compounds are essential for plants to grow. Therefore small but consistent differences have to be considered as important indicators of potential effects, even if the nutritional quality would not be implicated. Only mean values are given in the tables. Significant differences have been detected concerning more protein and less carbohydrates in the sprayed 1507 as compared to the near isogenic line, indicating changes in the two main metabolic cycles of the plant (N and C metabolism). Pesticide residues are not even mentioned. Both data sets are an insufficient proof to exclude a possible effect of the GM with regard to the compositional equivalence, thus excluding unexpected effects in other years or regions.	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinions. The Panel did not identify any new information regarding the comparative assessment that could change its previous conclusion.

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Country	**Organisation**	**Reference**	**Comment**	**EFSA Panel Response**
Austria	Ministry of Health, Family and Youth	D, 07.08 Toxicology	Acute toxicity in mice Microbial proteins (PAT, CRY1F) were used for the oral toxicity tests. Tests with proteins originating from microbial expression system provide limited information about the plant expressed protein. Furthermore a repeated dose 28-day oral toxicity study is preferable to the acute oral toxicity study. Whole feed toxicity study (MacKenzie et al. 2007). A 90 day rat feeding study with five different diets, two containing the GM maize 1507 (33% and 11%), one with near isogenic maize and two with commercial hybrid maize was conducted. Twelve Cr1:CD (SD) IGS BR rats per sex and group were in the study design as proposed by the relevant OECD test guide line. The results showed significantly higher feed consumption in males of the high-dose group. Furthermore haematology analyses revealed lower mean red cell count, hemoglobin and number of eosinophils only in females of the high-dose group. The clinical chemistry evaluation showed a lower level of alkaline phosphatase in males of the high dose group. Additionally the kidney weight was lower in these male rats. Mean body weight gain in male and female rats fed diets containing 33% 1507 was higher on most test days than that of rats fed the control diet, but mean body weight gains were similar over individual test day intervals. Such transient effects should not be underrated, since they do not mean that the test substance is safe in the long run. Aberrant feeding behaviour only found on a daily or weekly basis thus not presenting a consistent trend, could be triggered by an aversion to or preference of the new feed or any numbers of physiological short-term needs of the animals. Short-term feeding tests with adult animals are not sufficient to prove safety beyond doubt. Feed effects are more likely to become apparent in times of high performance, e.g. reproduction. Therefore more generation tests should be conducted, especially when transient significant differences are discovered even in a 90day study with rodents.	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinions. The Panel did not identify any new information regarding the toxicology assessment that could change its previous conclusion.

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Austria	Ministry of Health, Family and Youth	D, 07.08 Toxicology	Whole feed conversion study with broiler (Zeph 2000) In addition, a poultry feeding study was conducted over a 42-day period with diets containing grain from 1507 maize. For comparison, diets containing grain from non-GM maize with comparable genetic background and from three types of commercial maize were also fed to the chickens. It is not clear, whether the study was performed under GLP practice. P.2 of 24 shows a GLP declaration but p.3 of 24 says "Non-GLP Study". Studies for applications should follow GLP practise. This has to be clarified. Further more only male broilers were used. Therefore the conclusions are relevant for males only. There is a need for female broilers as they are also used in poultry production. The assessment of body weight was only done on day 0 and 42. Transient changes in body weight are lost by this approach. There are no analyses on feed hygiene, pesticide residues and proof of the presence of the genetic modification in the diets (only amount of Cry 1F in "test substance" but this does not explicitly refer to the diet). The whole study is poorly described. No signs of mortality were shown but there was no statement about animal health. No data are available about the investigation of the overall health status or any moribund animals. Therefore it is highly recommended to repeat this study with a state of the art test-design.	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinions. The Panel did not identify any new information regarding the toxicology assessment that could change its previous conclusion.

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Belgium	Belgian Biosafety Advisory Council	D, 02 Information on the sequences actually inserted or deleted	I do not agree with the statement on p. 19 of part 1 "This fact on the complexity of maize genome would made it very difficult to determine by PCR analysis whether the 5' and 3' flanking genomic sequences are in fact continuous in the untransformed maize". I agree that retrotransposons are a natural source of genetic variation, but the LTR-like sequence located at the 5' border does not seem to be included in a functional mobile genetic element. In addition phenotypic stability and presence of insert were confirmed over several generations, suggesting no remodeling of the insert and neighbouring DNA. It is not clear to me whether the applicant did actually try to determine if the 5' and 3' flanking genomic sequences are continuous in the untransformed maize. This can be done by PCR using primers hybridising in region 1 and 15 (fig. 15). This data would be useful to assess any unforeseen effect linked to gene disruption or modification of the flanking genomic DNA.	The Guidance Document (EFSA, 2006) does not stipulate the reconstruction of the preinsertion site and the information on the flanking sequences do not raise any safety concern.

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Belgium	Belgian Biosafety Advisory Council	D, 07.08 Toxicology	Comment 1 The studies of Kuhn (1998) and Brooks (2007) with mice provide data only from one treatment, so that a comparison with a control group is not possible. The study reported by MacKenzie (2003) has not sufficient statistical power, since 63 animals per treatment are necessary in stead of 12 to find a statistically significant difference, based on the method presented by Berndtson (1991). Comment 2 a) Degradation of the cry1F protein in simulated gastric fluid (Schafer and Korjagin, 2002). Remark: figure 6, panel A (Western blot) is of no use, due to the bad quality. 7e) Degradation of the PAT protein in simulated intestinal fluid (). Test not performed. No data provided. Comment 3 90-day rat feeding study (MacKenzie, 2003): In the document of MacKenzie (2003), only the Cry1F protein is mentionned. What about the PAT protein? Is the gene present in the plant and wasnâ€™t it mentionned by the author because the PAT protein is not detectable in grain, or was there an other reason?	The Brooks (2007) mice study mentioned by the Member State was wrongly quoted since the study provided by the applicant was Brooks (2000). The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the toxicology assessment that could change its previous conclusion.

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Belgium	Belgian Biosafety Advisory Council	D, 07.10 Nutritional assessment of GM food/feed	The study of Zeph (2000) with broilers does not provide information on the variability within treatments, so that the power of the statistical method cannot be calculated. Moreover, overall mortality rate and feed conversion are rather high, while growth rate is rather low.	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the nutritional assessment of GM food/feed that could change its previous conclusion.

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France	MEIE – DGCCRF France	General comments	Le maïs 1507 a été évalué par l'Agence française de sécurité sanitaire des aliments (AFSSA) en 2003 et 2004 au titre de la directive 2001/18/CE et du règlement (CE) n°258/97 pour une utilisation en alimentation animale et humaine. Après examen des données complémentaires fournies par le pétitionnaire, l'AFSSA avait conclu que la consommation de maïs de la lignée TC 1507 présente le même niveau de sécurité sanitaire pour l'homme et l'animal que la consommation de maïs non génétiquement modifié. L'AFSSA considère que les conclusions de l'évaluation effectuée dans le cadre de ces procédures sont transposables à la présente demande de renouvellement. Cette transmission ne préjuge pas de la position finale des autorités françaises sur cet OGM. Maize 1507 was analysed by the French Food Safety Agency (AFSSA) in 2003 and 2004 under Directive (EC) No 18/2001 and Regulation (EC) No 258/97 for use as food for animals and humans. Having examined the additional data furnished by the petitioner, AFSSA had concluded that the consumption of maize event TC 1507 presents the same level of food safety for humans and animals as the consumption of non-genetically modified maize. AFSSA believes that the conclusions of the analysis conducted within the framework of these procedures can be applied to the present application for renewal. This transmission does not prejudge the final position taken by the French authorities on this GMO.	The GMO Panel is in agreement with the conclusions of AFSSA and MEIE–DGCCRF.

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Italy	Ministero dell'Ambiente e della Tutela del Territorio	C. Information relating to the genetic modification	-The molecular analysis performed by the notifier shows the presence of unexpected sequences both in the 5' and 3' side of the insert. On this basis, the Italian National Competent Authority has considered that it seems reasonable to argue that similar, and further, genomic rearrangements and insertions could occur in other sites of the plant genome. The italian national Competent Authority has requested a better quantitative and/or qualitative characterisation of the event, but no new data has been received by the notifier to allow an appropriate risk analysis. -Italian national CA didn't find if PCR analysis on isogenic WT genomic DNA have been performed using primers homologous to the genomic sequences flanking the insertion (at the 5' and 3'), these data are important to exclude deletion and/or rearrangement of genomic plant DNA at the insertion site. -Moreover, in the figures supported by notifier of PCR analysis of genomic DNA border regions, we didn't see the lines corresponding to the negative control to check the adequacy of the PCR reaction. -Referring to the presence of specific bands in the non transgenic control DNA that are absent in the transgenic samples. To ensure that the above mentioned bands could be due to incomplete digestion of the DNA by these restriction enzymes as declared by the notifier, the italian CA request for further Southern blot analysis with a complete digestion performed EcoRI and BamHI/EcoRI.	Some of the comments pertain to data which were addressed by the Panel in its previous opinions. Updated bionformatic analysis of the insert has been received from the applicant and the new results confirm the safety evaluation previously issued by the GMO Panel. This additional study includes characterization of the flanking regions of the insert and the possible interruption of known genes.

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The Netherlands	Ministry of Agriculture, Nature and Food Quality The Netherlands	D, 07.08 Toxicology | D, 07.09 Allergenicity	The dossier contains no update of the bioinformatics-supported comparisons between the transgenic proteins (Cry1F, PAT) and allergens, toxins, and general proteins. Given the continuing expansion of databases and knowledge of allergens and toxins, it would be useful to update the bioinformatics-supported comparisons. This also holds true for the comparison of the hypothetical peptides encoded by open reading frames (ORFs) in the flanking sequences (including ORF3) as well as the previously considered ORF4 between the pat and cry1f genes within the inserted construct inside maize 1507.	The GMO Panel requested additional information to the applicant in relation to update the bioinformatics-supported comparisons. Updated bionformatics analyses (2008) has confirmed the original data provided by the applicant and no safety concerns are raised.