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SCIENTIFIC OPINION

Application (Reference EFSA-GMO-NL-2005-15) for the placing on the market of the insect-resistant and herbicide-tolerant genetically modified maize 1507 x 59122, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Mycogen Seeds, c/o Dow AgroSciences LLC and Pioneer Hi-Bred International, Inc. as represented by Pioneer Overseas Corporation[1]

Scientific Opinion of the Panel on Genetically Modified Organisms

(Question No EFSA-Q-2005-123)

Adopted on 21 April 2009

PANEL MEMBERS[*]

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SUMMARY

Following a request from Mycogen Seeds, c/o Dow AgroSciences LLC, and Pioneer Hi-Bred International, Inc. within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed, the Panel on Genetically Modified Organisms was asked to deliver a scientific opinion on the authorisation of the insect-resistant and glufosinate-tolerant genetically modified maize 1507 x 59122 (Unique Identifier DAS-Ø15Ø7-1 x DAS-59122-7) for food and feed uses, import and processing.

[1] For citation purposes: Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-NL-2005-15) for the placing on the market of the insect-resistant and herbicide-tolerant genetically modified maize 1507 x 59122, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Mycogen Seeds, c/o Dow AgroSciences LLC and Pioneer Hi-Bred International, Inc. as represented by Pioneer Overseas Corporation, *The EFSA Journal* 1074, 1-28.

[*] (minority opinion) This opinion is not shared by 0 members of the Panel. / (conflict of interest) 0 members of the Panel did not participate in (part of) the discussion on the subject referred to above because of possible conflicts of interest.

In delivering its scientific opinion, the GMO Panel considered the new application EFSA-GMO-NL-2005-15, additional information provided by the applicant (Mycogen Seeds, c/o Dow AgroSciences LLC, and Pioneer Hi-Bred International, Inc.) and the scientific comments submitted by the Member States. Further information from applications for placing the single insert lines 59122, 1507 on the market under EU regulatory procedures was taken into account where appropriate. The scope of application EFSA-GMO-NL-2005-15 is for food and feed uses, import and processing of genetically modified maize 1507 x 59122 and all derived products, but excluding cultivation in the EU.

The GMO Panel assessed maize 1507 x 59122 with reference to the intended uses and the appropriate principles described in 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) and 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). The scientific assessment included molecular characterization of the inserted DNA and expression of the newly expressed proteins. A comparative analysis of agronomic traits and composition was undertaken and the safety of the newly expressed proteins and the whole food/feed was evaluated with respect to potential toxicity, allergenicity and nutritional quality. An assessment of environmental impacts and the post-market environmental monitoring plan was also undertaken.

Maize 59122 was developed to express the Cry34Ab1 and Cry35Ab1 proteins rendering maize 59122 resistant to certain coleopteran pests and the PAT (phosphinothricin-N-acetyltransferase) protein which was used as a selectable marker and confers tolerance to glufosinate-ammonium. The maize 59122 was authorised under Regulation (EC) No 1829/2003 with Commission Decision 2007/702/EC. The maize 1507 was developed to express Cry1F and PAT proteins rendering maize 1507 resistant to certain lepidopteran pests and tolerant to glufosinate-ammonium herbicide. The maize 1507 was authorised under Directive 2001/18/EC by Commission Decision 2005/772/EC. The placing of maize 1507 on the market for food use received authorization under Regulation 1829/2003 with Commission Decision 2006/197/EC.

Maize 1507 x 59122 was produced by crosses between maize inbred lines containing 59122, and 1507 events to combine resistance to certain coleopteran species (59122 trait) and certain lepidopteran species (1507 trait), and to confer tolerance to glufosinate-ammonium (59122 and 1507 trait) herbicide.

The molecular characterisation data established that the structure of the individual inserts in the stacked hybrid maize 1507 x 59122 was the same as for the individual events 1507 and 59122. This indicates stability of the individual events in the stacked hybrid. Appropriate analyses of the integration sites in maize 1507 x 59122, including flanking regions, were carried out together with an updated bioinformatics analysis of the single events. The bioinformatics analysis demonstrated the absence of any potential new ORFs coding for known toxins or allergens. The expression of the proteins encoded by the target genes introduced by genetic modification was shown to be comparable for the single events and the events stacked in the hybrid.

Based on the results of comparative analysis it was concluded that maize 1507 x 59122 is compositionally and agronomically equivalent to conventional maize, except for the presence of Cry34Ab1, Cry35Ab1, Cry1F, and PAT proteins in maize 1507 x 59122. Based on the

assessment of data available, including responses to requests of the GMO Panel to the applicant for additional information on 1507 x 59122 maize, for the single events and for appropriate non-GM controls, the GMO Panel has found no indication that crossing of maize 1507 and maize 59122 results in an interaction of the newly expressed proteins which causes compositional or agronomic changes. The Cry34Ab1, Cry35Ab1 proteins and PAT proteins expressed in the parental maize line 59122 and the Cry1F and PAT proteins expressed in the parental maize 1507 have been assessed previously and no safety concerns were identified.

Given all the information provided, the Panel concludes that interactions between the proteins expressed by the single events that might impact on food and feed safety are unlikely and that the nutritional properties of maize 1507 x 59122 are not different from those of conventional maize. In conclusion the Panel considers that maize 1507 x 59122 is as safe and as nutritious as its non GM counterpart and that the overall allergenicity of the whole plant is not changed and concludes that maize 1507 x 59122 is unlikely to have any adverse effect on human and animal health in the context of its intended uses.

The application EFSA-GMO-NL-2005-15 concerns food and feed uses, import and processing, but excluding cultivation in the EU. There are no indications of an increased likelihood of establishment or survival of feral maize plants in case of accidental release into the environment of 1507 x 59122 seeds during transportation and processing for food and feed uses. Taking into account the scope of the application, both the rare occurrence of sporadic feral plants and the low levels of exposure through other routes indicate that the risk to non-target organisms is negligible. The scope of the monitoring plan provided by the applicant is in line with the intended uses of maize 1507 x 59122 since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. Furthermore the GMO Panel agrees with the reporting intervals proposed by the applicant in the general surveillance plan.

In conclusion, the Panel considers that the information available for maize 1507 x 59122 addresses the scientific comments raised by the Member States and that it is as safe as its non genetically modified counterpart with respect to potential effects on human and animal health or the environment. Therefore the GMO Panel concludes that maize 1507 x 59122 is unlikely to have any adverse effect on human or animal health or on the environment in the context of its intended uses.

Key words: **GMO, maize, 1507, 59122 glufosinate-ammonium, human and animal health, environment, import, processing, food, feed, Regulation (EC) No 1829/2003, Cry1F, Cry34Ab1, Cry35Ab1, PAT.**

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BACKGROUND

On 30 May 2005, EFSA received from the Competent Authority of The Netherlands an application (Reference EFSA-GMO-NL-2005-15), for authorisation of placing on the market of maize 1507 x 59122 (Unique Identifier DAS-Ø15Ø7-1xDAS-59122-7), carrying resistance to certain lepidopteran and coleopteran insect pests along with tolerance to glufosinate-ammonium herbicide. The requested application was a joint application submitted by Mycogen Seeds, c/o Dow AgroSciences LLC, and Pioneer Hi-Bred International, Inc., as represented by Pioneer Overseas Corporation, within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (EC, 2003) for food and feed uses, import and processing.

After receiving the application EFSA-GMO-NL-2005-15 and in accordance with Articles 5(2)(b) and 17(2)b of Regulation (EC) No 1829/2003, EFSA informed the Member States as well as the European Commission and made the summary of the dossier publicly available on the EFSA website. EFSA initiated a formal review of the application to check compliance with the requirements laid down in Articles 5(3) and 17(3) of Regulation (EC) No 1829/2003. On 6 June 2007 EFSA received satisfactory additional information requested under completeness check and on 13 July 2007 EFSA declared the application as valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003.

EFSA made the valid application available to Member States and the European Commission and consulted nominated risk assessment bodies of the Member States, including the national Competent Authorities within the meaning of Directive 2001/18/EC (EC, 2001) following the requirements of Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, to request their scientific opinion. The Member State bodies had three months after the date of receipt of the valid application (until 13 October 2007) within which to make their opinion known.

The GMO Panel carried out a scientific assessment of genetically modified (GM) maize 1507 x 59122 taking into account the appropriate principles described in 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) and 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).

On 24 October 2007, 14 December 2007, 18 April 2008 and 31 July 2008, the GMO Panel asked for additional data on maize 1507 x 59122. The applicant provided the requested information on 30 November 2007, 14 February 2008, 24 April 2008 and 17 September 2008. After receipt and assessment of the full data package, the GMO Panel finalized its risk assessment of maize 1507 x 59122.

The GMO Panel carried out a scientific assessment of the GM maize 1507 x 59122 for food and feed uses, import and processing in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, taking into consideration the scientific comments of the Member States and the additional information provided by the applicant. Further information from applications for placing the single insert lines on the market under EU regulatory procedures was taken into account where appropriate.

The single events 1507 and 59122 have been the subjects of earlier assessments and have received an EFSA opinion in favour of their authorisation (EFSA, 2004, 2005a, b and 2007b).

Maize 59122 was authorised under Regulation (EC) No 1829/2003 with Commission Decision 2007/702/EC (EC, 2007). Maize 1507 was authorised under Directive 2001/18/EC by Commission Decision 2005/772/EC (EC, 2005b) for feed use, import and processing. The placing of maize 1507 on the market for food use received authorisation under Regulation 1829/2003 with Commission Decision 2006/197/EC (EC, 2006).

In giving its opinion on maize 1507 x 59122 to the European Commission, the Member States and the applicant, and in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, EFSA has endeavoured to respect a time limit of six months from the receipt of the valid application. As additional information was requested by the EFSA GMO Panel, the time-limit of 6 months was extended accordingly, in line with Articles 6(1), 6(2), 18(1), and 18(2) of Regulation (EC) No 1829/2003.

According to Regulation (EC) No 1829/2003, the EFSA scientific opinion shall include a report describing the assessment of the food and feed and stating the reasons for its scientific opinion and the information on which its scientific opinion is based. This document is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation and thus will be part of the overall opinion in accordance with Articles 6(5) and 18(5).

TERMS OF REFERENCE

The GMO Panel was requested to carry out a scientific assessment of the genetically modified maize 1507 x 59122 for food and feed uses and import and processing in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. Where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food/feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environments and/or geographical areas should be indicated in accordance with Articles 6(5)(e) and 18(5)e of Regulation (EC) No 1829/2003.

The EFSA GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol, nor on the proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to GMO risk management.

ACKNOWLEDGEMENTS

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ASSESSMENT

1. Introduction

The genetically modified maize 1507 x 59122 (Unique Identifier DAS-Ø15Ø7-1xDAS-59122-7) was assessed with reference to its intended uses, taking account of the appropriate principles described in 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) and 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). The risk assessment presented here is based on the information provided in the application relating to maize 1507 x 59122 submitted in the EU including additional information from the applicant and information on the single events, as well as scientific comments that were raised by Member States.

2. Issues raised by Member States

Issues raised by Member States (MS) are addressed in Annex G of the overall opinion.

3. Molecular characterisation

3.1. Evaluation of relevant scientific data

The EFSA GMO Panel guidance document (EFSA, 2006a) states that when events have been combined by the interbreeding of existing approved GM lines, the need for further molecular analysis will depend, on a case-by-case basis, on the nature of the genetic modifications involved.

Having considered the information provided in the application and the comments of the Member States, the GMO Panel requested clarification from the applicant with regard to the molecular characterization. Additional information was requested on the integrity of the insertion locus in 59122, an update of the bioinformatics analyses for the junction regions of 59122 and 1507, on the plant comparators used in field trials for protein expression and on the choice of statistical tools used to conclude on expression levels of the transgenic proteins.

3.1.1. Method of production of maize 1507 x 59122

Conventional breeding methods were used to produce maize 1507 x 59122 and no new genetic modification was involved. The two inserts that are present in 1507 x 59122 were derived from two maize lines containing single independent events: 1507 and 59122. Each of these GM maize events was the subject of an earlier safety evaluation and separate opinions for each of them have been published (EFSA, 2007b; 2005a, b; 2004a), including for 1507 x NK603 (EFSA, 2006c). Maize 1507 x 59122 combines the insect protection and glufosinate-ammonium tolerance traits from 59122 with the insect protection and glufosinate-ammonium tolerance traits from 1507.

3.1.2. Description of the single events 1507 and 59122

1507

Maize 1507 was generated by particle bombardment. As a result of the genetic modification, the 1507 event expresses a truncated *cry*1F gene from *Bacillus thuringiensis* ssp. aizawai, conferring resistance to lepidopteran pests such as the European corn borer (*Ostrinia nubilalis*), and the *pat* gene from *Streptomyces viridochromogenes* that renders 1507 tolerant towards glufosinate-ammonium herbicides.

Molecular analysis showed that maize 1507 has one copy of the DNA fragment used for transformation (containing the *cry*1F and *pat* genes) and that this is present at a single locus in the nuclear genome of the GM plant. The structure of the insert in maize 1507 was determined by Southern analysis and DNA sequencing. In addition to the intact genes, the insert in maize 1507 includes DNA sequences originating from the fragment used for transformation as well as maize chloroplast sequences (EFSA, 2004a). Analysis of ORFs spanning the two junction regions was performed by bioinformatic analysis and no novel putative proteins with sequence similarity to known toxins or allergens were identified. Northern analysis and RT-PCR were performed on two ORFs (ORF3 and 4), but there were no indications of transcription of new RNA other than the mRNAs transcribed from the *cry*1F and *pat* genes. In the unlikely event that this does occur, bioinformatics analysis showed that any resulting peptides or proteins would have no homology to known toxins or allergens. An updated bioinformatic analysis confirmed earlier results. Analysis of DNA sequences flanking both ends of the insert shows that they correspond to maize genomic DNA. An updated BLAST analysis of the flanking DNA sequences suggests that the insert in 1507 is flanked by a putative RIRE2 retrotransposon (downstream) and a Huck1 retrotransposon (upstream).

Southern analysis and maintenance of the phenotype indicated genetic and phenotypic stability of the transgenic line and their progeny over several generations. No instability of the DNA sequences flanking the insert was observed.

59122

Maize 59122 was transformed by *Agrobacterium*-mediated gene transfer technology and as a result expresses the *cry*34Ab1 and *cry*35Ab1 genes from *Bacillus thuringiensis* strain PS149B1, conferring resistance to the corn rootworm larvae, and the *pat* coding sequence from *Streptomyces viridochromogenes* resulting in tolerance towards glufosinate-ammonium herbicides. Molecular characterisation data established that maize 59122 contains a single copy of the T-DNA. The structure of the insert in maize 59122 was determined by Southern analysis and DNA sequencing. No vector backbone sequences were detected. BLAST sequence analysis revealed that flanking regions of the maize event 59122 show significant homology to maize genomic DNA and EST sequences. Updated BLASTn and BLASTx analyses indicated that the DNA in 59122 was inserted 1032 bp downstream of the coding region of a maize pentatricopeptide repeat (PPR) protein, the empty pericarp4 (*emp4*). This PPR protein is essential for seed development in maize. In event 59122 seed development is not affected suggesting that expression of *emp4* was not altered by the insertion. Analysis of ORFs spanning the two junction regions was performed by bioinformatic analysis and no novel ORFs with sequence similarity to known toxins or allergens were identified. This was confirmed by an updated ORF analysis.

Southern analysis of these plants and maintenance of the phenotype indicated genetic and phenotypic stability of the event 59122 over four generations.

3.1.3. Transgenic constructs in the maize 1507 x 59122

Maize 1507 x 59122 has been obtained from conventional breeding crosses between genetically modified maize 1507 and 59122. No new genetic modification has been introduced in the double hybrid. The molecular structures of the DNA inserts present in maize 1507 x 59122 were investigated using Southern analyses. This involved the use of DNA probes specific for the maize 1507 and 59122 inserts.

In order to confirm the molecular equivalence and identical copy number of the insert present in maize 1507 x 59122 to that present in maize 59122, samples of genomic DNA from the double hybrid and maize 59122 plants were digested with SacI and subjected to Southern analyses with the *cry*34Ab1 and *cry*35Ab1 probe. For comparison with the insert present in 1507, HindIII-digested genomic DNA of the triple hybrid and 1507 plants was probed with *cry*1F and *pat* gene probes. Further comparisons were made between SacI- and HindIII-digested DNA from 1507 x 59122 and the single events after digestion and probing with the *pat* gene. These analyses confirmed the intactness in the hybrid of the 1507 insert (including both borders) and of the 59122 insert (including the right border). Additional information was supplied on the intactness of the left border of the 59122 insert contained in the hybrid by using a 59122 event-specific PCR for the left border junction of the 59122 insert.

3.1.4. Expression of the introduced genes

Grain

Grain for studies of expression levels of the newly expressed proteins Cry34Ab1, Cry35Ab1, Cry1F and PAT was obtained from maize 1507 x 59122 harvested from six field trials in USA and Canada in the season 2003.

Additional expression data were supplied from a field trial in 2005 at three locations in Spain. In this trial expression levels of the newly expressed proteins were measured in roots, leaf, whole plant, stalk, forage grain and pollen in 1507 x 59122 and the respective single events. Plants were either sprayed or unsprayed with glufosinate-ammonium. The proteins were extracted and quantified using an ELISA (enzyme-linked immunosorbent assay) technique.

Expression levels in grain (ng/mg tissue dry weight) obtained from plants treated with glufosinate-ammonium are summarized in the table below. Levels of all measured proteins were unaffected by glufosinate-ammonium treatment and were in the same range as in the trials with single events in the USA, Canada and Chile.

Table 1. Expression levels in grain (ng/mg tissue dry weight) from plants treated with glufosinate-ammonium.

	1507x59122		1507		59122	
	Mean	Range	Mean	Range	Mean	Range
Cry1F	2.1	1.1 - 3.7	1.9	1.3 - 2.5	NA	NA
Cry34Ab1	52	28 - 88	NA	NA	41	30 - 51
Cry35Ab1	2.3	1.7 - 3.1	NA	NA	2.2	1.3 - 3.2
PAT	0.15	0.09 -0.27	< LOD	< LOD	0.09	0 - 0.18

NA - Non-applicable as the gene encoding the protein is not present

Forage

Expression levels in forage of the Cry34Ab1, Cry35Ab1, Cry1F and PAT proteins were obtained from maize 1507 x 59122 harvested from five trials in USA and Canada in the season 2003. Forage samples of 1507 x 159122 were either sprayed or unsprayed with glufosinate-ammonium. The proteins were extracted and quantified using ELISA. Summary information on expression levels in forage were supplied on request of the Panel. In forage of plants treated with glufosinate-ammonium, the mean protein levels were 9.74 ng/mg tissue dry weight (range 7.16 - 11.7) for Cry1F, 126.4 (range 101.1 - 145.7) for Cry34Ab1, 28.6 (range 20.2 - 33.8) for Cry35Ab1 and 2.53 (range 1.01 - 3.97) for PAT. Levels of all measured proteins were unaffected by glufosinate-ammonium treatment.

3.1.5. Inheritance and stability of inserted DNA

The genetic stability of the inserted DNA in events 59122 and 1507 was demonstrated previously (EFSA, 2007b; 2005a, b; 2004a). In maize 1507 x 59122 the two inserts are combined. The Southern and PCR data show that both inserts are present and their structures are retained. Furthermore, each of the traits has been conserved in this maize. The GMO Panel is of the opinion that there is no *a priori* reason to expect instability of the transgenes in maize 1507 x 59122.

3.2. Conclusion

As conventional breeding methods were used in the production of maize 1507 x 59122, no additional genetic modification was involved. Southern and PCR analyses demonstrated that the structures of the 1507 and 59122 events were retained in maize 1507 x 59122. The genetic stability of the integrated DNA has been demonstrated in the single events. Phenotypic analyses demonstrated that the traits were retained in the hybrid.

The expression levels of Cry34Ab1, Cry35Ab1, Cry1F and PAT proteins in maize 1507 x 59122 were measured in grain and forage. Taking into account the range of variation in gene expression, the levels of expression of these proteins in grain and forage of 1507 x 59122 were considered comparable with those in the single events.

The Panel concludes that these data do not raise safety concerns.

4. Comparative analysis

4.1. Evaluation of relevant scientific data

Having considered the information provided in the application and the Member States comments, the GMO Panel requested from the applicant further information with respect to appropriateness of comparator, compositional analysis, and potential interaction between the newly expressed proteins in maize1507 x 59122.

4.1.1. Summary of the previous evaluation of the single events

Maize 1507

Maize 1507 was compared with an appropriate non-GM control with comparable genetic background to 1507 maize. Whole crops and maize tissues, including kernels, were collected for compositional analysis from field trials. These field trials occurred during three seasons

and at different locations (six locations in Chile (1998-1999), three locations in France and Italy (1999), and six locations in France, Italy and Bulgaria (2000). GM maize plants in Chilean field trials were all treated with glufosinate-ammonium, while those in the European field trials were split into treated and untreated groups. Based on the results of compositional analysis of samples from a representative range of environments and grown in three seasons, it was concluded that forage and kernels of 1507 maize were compositionally equivalent to those of conventional maize, except for the presence of Cry1F and PAT proteins in maize 1507.

In addition, during field trials over several seasons and at different locations (USA in 1999, France, Italy, and Bulgaria in 2000, Spain in 2002) agronomic data did not show indications for unexpected changes of agronomic characteristics and performance.

Maize 59122

Maize 59122 was compared with an appropriate non-GM control with comparable genetic background to maize 59122. Whole crops and maize tissues, including kernels, were collected for compositional analysis from field trials. These field trials were carried out over several seasons and at different locations (six locations in Chile (2002-2003), three locations in the USA (2003), two locations in Canada (2003), three locations in Bulgaria (2003 and 2004), and three locations in Spain (2004). Maize 59122 plants treated with glufosinate-containing herbicide, untreated and the non-GM control maize were included in these field trials. Based on the results of compositional analysis of samples from a representative range of environments and grown in several seasons, it was concluded that forage and kernels of maize 59122 were compositionally equivalent to those of conventional maize, except for the presence of Cry34Ab1 and Cry35Ab1 and PAT proteins in maize 59122.

In addition, during field trials over several seasons and at different locations (six locations in Chile (2002-2003), three locations in the USA (2003), two locations in Canada (2003), three locations in Bulgaria (2003), three locations in Spain (2004), and three locations in Bulgaria (2004)) agronomic data did not show indications for unexpected changes of agronomic characteristics and performance.

4.1.2. Choice of comparator and production of material for the comparative assessment

Maize 1507 x 59122 was compared to a control non-GM line. Upon request of the GMO Panel, the applicant provided additional information on the breeding scheme used to produce the control non-GM maize. The pedigree information on the control non-GM maize showed that the control had a genetic background comparable with that of maize 1507 x 59122 and thus represented an appropriate comparator for maize 1507 x 59122 in the field trials.

Field trials were carried out at five locations in North America during the 2003 growing season. Maize 1507 x 59122 plants treated or untreated with glufosinate-containing herbicide and the non-GM control maize were included in these field trials. Whole crops (forage) and maize tissues, including kernels, were collected from field trials for compositional analysis.

In addition, data derived from material obtained from field trials with the single events and the respective appropriate comparators were provided by the applicant (see section 4.1.1). The GMO Panel had previously assessed these data and had concluded that maize 59122 and maize 1507 are agronomically and compositionally equivalent to their respective

comparators, except for the newly introduced traits. Therefore, the non-inclusion of the single events in the field trials with the stacked event was accepted by the Panel.

The GMO Panel considered the studies and the derived spectrum of data which was available for the comparative agronomic and compositional assessment as sufficient.

4.1.3. Compositional analysis

Compositional data were obtained by analysis of forage and kernels harvested from field trials performed in maize growing regions of North America in 2003. Statistical analysis was performed on data on maize material from both individual and combined field trial sites. The selection of compounds follows the recommendations of OECD (2002).

Forage from maize 1507 x 59122 treated or untreated with glufosinate-containing herbicide and the non-GM control was analysed for proximates, fibre and minerals (fat, protein, total carbohydrate, ash, crude fibre, acid detergent fibre (ADF), neutral detergent fibre (NDF), phosphorus, and calcium). The compositional analysis of kernels of maize 1507 x 59122 and its control included proximates (fat, protein, ash, moisture, carbohydrates, starch), fatty acids (palmitic, stearic, oleic, linoleic, and linolenic acid), amino acids (eighteen amino acids including aromatic amino acids), minerals (calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium, selenium and zinc), vitamins and vitamin precursors (vitamin B1, vitamin B2, folic acid, β-carotene, vitamin E), phytic acid, raffinose, anti-nutrients (trypsin inhibitor) and other constituents (inositol, furfural, p-coumaric acid, and ferulic acid). Data obtained for these constituents in forage and kernels were compared to ranges reported in the literature for commercial maize (ILSI, 2006; OECD, 2002).

No statistically significant differences between maize 1507 x 59122 and the control were observed in the forage analysis. The data obtained were within the literature ranges reported for commercial maize varieties.

The analysis of composition of kernels from maize 1507 x 59122 treated or untreated with glufosinate-containing herbicide and its control occasionally revealed statistically significant differences in some parameters such as ash, iron, potassium, and p-coumaric acid contents. However, none of these differences was consistently observed at each location. In addition, the levels of those compounds which were different from the level in the corresponding control were within the literature ranges reported for commercial maize varieties.

4.1.4. Agronomic traits and GM phenotype

During field trials at different locations in North America during the 2003 growing season, extensive agronomic data (e.g. grain yield, number of emerged plants, ear height, plant height, early population, final population), were collected for maize 1507 x 59122 and for the corresponding non-GM control. Some statistically significant differences were detected at individual field trial sites, e.g. for early and final population count and plant height. None of these differences were consistently observed over locations.

The GMO Panel concludes that the expression of the newly introduced genes in maize 1507 x 59122 did not result in any unexpected agronomic effect and that the agronomic performance and phenotypic characteristics of maize 1507 x 59122 are comparable to its non-GM control except for the introduced traits.

4.2. Conclusion

Based on the results of comparative analysis it is concluded that maize 1507 x 59122 is compositionally and agronomically equivalent to conventional maize, except for the presence of Cry1F, Cry34Ab1, Cry35Ab1 and PAT proteins in maize 1507 x 59122. Based on the assessment of available data, including the additional information provided by the applicant in response to the Panel request regarding maize 1507 x 59122, the single events and the appropriate non-GM controls, the GMO Panel has found no indication that crossing of maize 1507 and maize 59122 results in an interaction of the newly expressed proteins which causes compositional or agronomic changes.

5. Food/feed safety assessment

5.1. Evaluation of relevant scientific data

5.1.1. Summary of the previous evaluation of the single events

Maize 1507

Given the low expression level of Cry1F in the maize 1507, the applicant used a trypsinised microbial analogue, MR872, of the truncated Cry1F protein expressed in maize 1507 for safety testing. To this end, a fusion protein consisting of the non-truncated Cry1F (N-terminal) linked to Cry1Ab (C-terminal) was produced by recombinant Pseudomonas fluorescens. Enzymatic cleavage with trypsin of the fusion protein yielded a 'core' protein, MR872, identical to the truncated Cry1F protein expressed in maize 1507, except for i) phenylalanine (Phe) instead of leucine (Leu) at position 604 and ii) a C-terminal extension of trypsinised MR872 with seven amino acid residues (606-612, Ala-Glu-Tyr-Asp-Leu-Glu-Arg). Taking into account all the evidence provided, the Panel was of the opinion that the trypsinised MR872 analogue is an appropriate substitute of the Cry1F protein expressed in maize 1507 for safety testing. Bacterially produced recombinant PAT showed the same electrophoretic mobility as PAT expressed in maize 1507 during Western blotting. As noted, levels of PAT were not quantifiable in kernels of maize 1507.

The Cry1F protein induced no adverse effects in an acute oral toxicity study in mice. In addition, Cry1F is rapidly degraded in simulated gastric fluid and inactivated by thermal treatment.

The sequence of the Cry1F protein did not show any significant similarity with the sequences of known allergens and toxins. None of the identified ORFs showed significant similarity to allergens or toxins (see section 3.1.2).

For PAT protein no adverse effects were noted in an acute oral toxicity study. Furthermore, rapid degradation in simulated gastric fluid was proven.

With regard to animal studies with the whole product, no toxicity of maize 1507 was observed in a 90-day rat feeding study. In addition, nutritional data comprising target animal feeding studies with the whole maize kernel on broilers and dairy cows indicate that maize 1507 is nutritionally equivalent to conventional maize cultivars. These animal studies therefore further support the findings of the compositional analysis of no changes beyond the intended introduction of the PAT and Cry1F proteins. Based on the data provided, the Panel was of the opinion that there is no need for additional safety studies, or for testing in other animal species.

Maize 59122

Pseudomonas fluorescens produced Cry34Ab1 and Cry35Ab1 proteins and *E.coli* produced PAT protein were used for toxicity studies after it has been demonstrated experimentally that they are equivalent to those extracted from leaf material of maize event 59122. The newly expressed proteins Cry34Ab1, Cry35Ab1 proteins induced no adverse effects in acute and repeated dose oral toxicity studies in mice at high dose levels and they are rapidly degraded in simulated gastric fluid and inactivated during heat treatments. The PAT protein is expressed at very low levels in maize 59122 and it has also been proved to be safe in toxicity studies and it is rapidly degraded by proteases. The sequence of the transgenic Cry34Ab1, Cry35Ab1 and PAT proteins did not show any significant similarity with the sequences of known toxins or allergens. With regard to animal studies with the whole product, there were no indications of adverse effects in a 90-day subchronic toxicity study on rats fed diets containing maize 59122 grains. In addition, nutritional data comprising a target animal feeding study with maize 59122 grains on broilers indicate that maize 59122 is nutritionally equivalent to the non-GM comparator. These animal studies therefore further supported the findings of the compositional analysis of no effect beyond the intended introduction of the Cry34Ab1, Cry35Ab1 and PAT proteins (EFSA, 2007b).

5.1.2. Product description and intended use

The scope of application EFSA-GMO-NL-2005-15 includes the import and processing of maize 1507 x 59122 and its derived products for use as food and feed. Thus, the possible uses of maize 1507 x 59122 include the production of animal feed, but it is also processed into valuable food products, including e.g. starch, syrups and oils.

The genetic modification of maize 1507 x 59122 is intended to improve agronomic performance only and is not intended to influence the nutritional properties, processing characteristics and overall use of maize 1507 x 59122 as a crop.

5.1.3. Effects of processing

Since maize 1507 x 59122 is compositionally equivalent to conventional maize, except for the newly expressed proteins (see Section 3.2.3), the characteristics of processed products derived from this GM maize are not expected to be different from conventional maize varieties.

5.1.4. Toxicology

5.1.4.1. Toxicological assessment of expressed novel proteins

The Cry34Ab1, Cry35Ab1 and PAT proteins expressed in the parental maize 59122, the Cry1F and PAT proteins expressed in the parental maize 1507 have been assessed for their safety previously (EFSA, 2004a; EFSA, 2005a,b; EFSA, 2007b) and no safety concerns were identified. The Panel is not aware of any new information that would change this conclusion.

Given that no adverse effects were observed in toxicity studies performed with the PAT protein, the Panel is of the opinion that an increased expression level of PAT protein in the maize 1507 x 59122 compared to the single events does not raise concern regarding human and animal health.

No new genes in addition to those occurring in the parental maize varieties have been introduced in maize 1507 x 59122. The applicant submitted the results of a 90-day rodent feeding study performed with kernels from the maize 1507 x 59122 in order to investigate the likelihood of possible interactions between the newly expressed proteins Cry34Ab1, Cry35Ab1 and Cry1F that might impact on the human and animal health. A few statistically significant differences were observed between rats fed the maize 1507 x 59122 and those fed the non-GM comparator. Red blood cell counts and hematocrit were higher in female rats fed the GM maize 1507 x 59122 than in those fed the non-GM maize whereas mean cell haemoglobin was lower. Serum chloride and sodium concentrations were lower in female rats fed the GM maize 1507 x 59122 than in those fed the non-GM maize. Based on the overall data of this study, the Panel considers that these differences do not raise concern for human and animal health and that interactions between the proteins expressed in the single events that might impact on food and feed safety are unlikely.

5.1.4.2. Toxicological assessment of new constituents other than proteins

No new constituent other than Cry34Ab1, Cry35Ab1, Cry1F and PAT proteins are expressed in maize 1507 x 59122 and no relevant changes in the composition of maize 1507 x 59122 were detected by the compositional analysis.

5.1.5. Toxicological assessment of the whole GM food/feed

The genetically modified maize events 1507 and 59122 have been found as safe as the conventional counterparts for human and animal consumption (EFSA, 2004a; EFSA, 2005a,b; EFSA, 2007b). A molecular characterization undertaken on maize 1507 x 59122 identified no altered stability of the two events when these were brought together by crossing, and expression analysis of the proteins Cry34Ab1, Cry35Ab1, the Cry1F and PAT proteins, similarly revealed no change in protein expression levels that could raise concerns for human and animal health. As the composition of maize 1507 x 59122 is comparable with that of non-GM maize varieties and the single events and also no indication for interaction between the newly expressed proteins was found (see section 5.1.4.1), the GMO Panel is of the opinion that no additional animal safety studies are required.

5.1.6. Allergenicity

The strategies used when assessing the potential allergenic risk focus on the characterisation of the source of the recombinant protein, the potential of the newly expressed protein to induce sensitisation or to elicit allergic reactions in already sensitised persons and whether the transformation may have altered the allergenic properties of the modified food. A weight-of-evidence approach is recommended, taking into account all of the information obtained with various test methods, since no single experimental method yields decisive evidence for allergenicity (CAC, 2003; EFSA, 2006a).

5.1.6.1. Assessment of allergenicity of the newly expressed proteins

The proteins present in maize 1507 x 59122 have been assessed previously and it was found unlikely that they are allergenic (EFSA, 2004a; EFSA, 2005a,b; EFSA 2007b). Based on the information provided, the GMO Panel considers it unlikely that potential interactions occur that might change the allergenicity of the expressed proteins.

5.1.6.2. Assessment of allergenicity of the whole GM plant

The issue of a potential for increased allergenicity of maize 1507 x 59122 does not appear relevant to the Panel since maize is not considered a common allergenic food. Food allergies to maize are of low frequency and mainly occur in populations of specific geographic areas. Rare cases of occupational allergy to maize dust have been reported. There is no reason to expect that the use of GM maize 1507 x 59122 will significantly increase the intake and exposure to maize. Therefore a possible over-expression of any endogenous protein, which is not known to be allergenic, would be unlikely to alter the overall allergenicity of the whole plant or the allergy risk for consumers.

5.1.7. Nutritional assessment of GM food/feed

The applicant has provided a poultry feeding study where broiler chickens were fed over a 42-day period with diets containing grain from maize1507 x 59122, grain from a non-GM control maize with a genetic background comparable to that of maize 1507 x 59122 and two non-GM commercial hybrid maize (i.e. four treatments). However this study was considered of limited value by the Panel due to an accidental contamination of a non-GM reference diet with the newly expressed proteins.

As maize 1507 x 59122 has been shown to be compositionally and agronomically equivalent to conventional maize and there are no indications for unintended effects based on the preceding molecular analysis, testing of whole GM food/feed is not considered necessary which is in line with EFSA Guidance Document (REF).

5.1.8. Post-market monitoring of GM food/feed

The risk assessment concluded that there are no data to indicate that maize 1507 x 59122 is any less safe than its non-GM comparator and parental GM lines. In addition, maize 1507 x 59122 is, from a nutritional point of view, equivalent to conventional maize. Given the intended use of maize 1507 x 59122, the overall intake or exposure is thus not expected to be different from that of conventional maize. Therefore, and in line with the Guidance document (EFSA, 2006a), the GMO Panel is of the opinion that post-market monitoring of the food/feed derived from maize 1507 x 59122 is not necessary.

5.2. Conclusion

The Cry34Ab1, Cry35Ab1 and PAT proteins expressed in the parental maize 59122 as well as the Cry1F and PAT proteins present in maize 1507 have been assessed previously and no safety concerns were identified.

Given all the information provided, the Panel concludes that interactions between the proteins expressed by the single events that might impact on food and feed safety are unlikely and that the nutritional properties of maize 1507 x 59122 would be no different from those of conventional maize.

In conclusion the Panel considers that the maize 1507 x 59122 is as safe and as nutritious as its non-GM counterpart and that the overall allergenicity of the whole plant is not changed and concludes that maize 1507 x 59122 is unlikely to have any adverse effect on human and animal health in the context of its intended uses.

6. Environmental risk assessment and monitoring plan

6.1. Evaluation of relevant scientific data

The scope of application EFSA-GMO-NL-2005-15 is for food (e.g. syrup, starch, oil) and feed (e.g. meal, oil) uses, import and processing of maize 1507 x 59122 and does not include cultivation. Considering the intended uses of maize 1507 x 59122, the environmental risk assessment is concerned with indirect exposure through manure and faeces from the gastrointestinal tracts mainly of animals fed on the GM maize and with accidental release into the environment of GM seeds during transportation and processing.

As the scope of the present application excludes cultivation, environmental concerns related to the use of glufosinate-ammonium herbicides on maize 1507 x 59122 apply only to imported and processed maize products that may have been treated with glufosinate-ammonium in the countries of origin. The GMO Panel is aware that the risk assessment of active substances falls within the scope of Directive 91/414/EEC concerning the placing of plant protection products on the market (EC, 1991).

6.1.1. Evaluation of the single events

Maize 1507 and 59122

Maize 1507 and 59122 have been developed for tolerance to glufosinate-ammonium and for protection respectively against specific lepidopteran (e.g. European corn borer (*Ostrinia nubilalis*)) and coleopteran (e.g. Western corn rootworm larvae (*Diabrotica virgifera virgifera* LeConte)) pests. Insect resistance is achieved by production of a truncated Cry1F protein in maize 1507 and of Cry34Ab1 and Cry35Ab1 proteins in maize 59122 from two *Bacillus thuringiensis* strain PS149B1 (see Section 3) and tolerance to the glufosinate-ammonium is conferred by phosphinothricin-N-acetyltransferase (PAT) from Streptomyces viridochromogenes in both events.

The assessed dossiers for maize 1507 (notifications C/NL/00/10 under Directive 2001/18/EC (EC, 2001) and application EFSA-GMO-NL-2004-02 under Regulation (EC) No 1829/2003 (EC, 2003)) and the assessed application EFSA-GMO-NL-2005-12 for maize 59122 concerned import and processing for food and feed uses, while notification C/ES/01/01 for maize 1507 included cultivation. The GMO Panel was of the opinion that maize 1507 and 59122 are as safe as conventional maize. Therefore their placing on the market for food and feed uses as well as processing and, in the case of maize 1507, for cultivation, is unlikely to have an adverse effect on human or animal health or, in that context, on the environment (EC, 2005; EC, 2006; EFSA, 2004a; EFSA, 2005a,b; EFSA, 2007b).

An environmental post-market monitoring plan, including general surveillance, was proposed by the applicant and accepted by the GMO Panel for maize 1507 subject to some recommendations in the case of cultivation of maize 1507 (EFSA, 2005a). The GMO Panel also agreed with the environmental post-market monitoring plan provided by the applicant for maize 59122 since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. Both monitoring plans were subject to some recommendations to prevent seeds of GM maize entering cultivation, as the latter requires specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003.

6.1.2. Environmental risk assessment

6.1.2.1. Potential unintended effects on plant fitness due to the genetic modification

Maize is highly domesticated and generally unable to survive in the environment without cultivation. Maize plants are not winter hardy in many regions of Europe, they have lost their ability to release seeds from the cob and they do not occur outside cultivated land or disturbed habitats in agricultural landscapes of Europe, despite cultivation for many years.

The herbicide tolerance trait can only be regarded as providing a selective advantage for the GM maize plant where and when glufosinate-based herbicides are applied. Similarly insect resistance against certain lepidopteran and coleopteran pests provides a potential advantage in cultivation under infestation conditions. However survival of maize outside cultivation in Europe is mainly limited by a combination of low competitiveness, absence of a dormancy phase, susceptibility to diseases and to cold climate conditions. Since these general characteristics of this GM maize are unchanged, the insect resistance and herbicide tolerance traits are not likely to provide a selective advantage outside cultivation in Europe. Therefore it is considered very unlikely that plants or volunteers of this GM maize, 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.

In addition to the field trials carried out with the parental GM maize 1507 and 59122 (EFSA, 2004a; 2005a,b; 2007b), field trials with maize 1507 x 59122 were carried out at 5 locations (in USA) in 2003. The field data provided in the application do not show increased fitness and invasiveness or enhanced weediness, except in the presence of glufosinate-based herbicides. In addition to the data presented by the applicant, the GMO Panel is not aware of any scientific report of increased spread and establishment of maize 1507 x 59122, and of any change in survival capacity, including over-wintering.

Since maize 1507 x 59122 has no altered survival, multiplication or dissemination characteristics except in the presence of glufosinate-based herbicides and/or under infestation conditions, the GMO Panel is of the opinion that the likelihood of unintended environmental effects as a consequence of spread of genes from this maize will not differ from that of maize 1507 or 59122 or of conventional maize varieties.

6.1.2.2. Potential for gene transfer

A prerequisite for any gene transfer is the availability of pathways for the transfer of genetic material, either through horizontal gene transfer of DNA, or vertical gene flow via seed dispersal and cross-pollination.

(a) Plant to bacteria gene transfer

Current scientific knowledge (see EFSA, 2004b; EFSA 2007a) suggest that gene transfer from GM plants to microorganisms under natural conditions is extremely unlikely, and that its establishment would occur primarily through homologous recombination in microorganisms (Keese, 2008).

Transgenic DNA is a component of many food and feed products derived from GM maize. Therefore, microorganisms in the digestive tract of humans and animals (domesticated animals and other animals feeding on fresh and decaying GM plant material) may be exposed to transgenic DNA.

In the case of accidental release and establishment of maize 1507 x 59122 in the environment, exposure of microorganisms to transgenic DNA derived from GM maize plants would take place during natural decay of GM plant material and/or pollen in the soil of areas where GM plants might establish.

The *cry*1F, *cry*34Ab1 and *cry*35Ab1 genes are under the control of eukaryotic promoters (see section 3) with limited, if any, activity in prokaryotes in the unlikely event of horizontal gene transfer.

The *pat* gene is a component of soil microbial populations (Herouet *et al.*, 2005) and the *cry*1F, *cry*34Ab1/*cry*35Ab1 genes, which occur naturally in bacterial populations (Schnepf *et al.*, 2005), were cloned from naturally occurring *Bacillus thuringiensis*. Taking into account the origin and nature of the *cry*1F, *cry*34Ab1/*cry*35Ab1 and *pat* genes and the lack of selective pressure in the intestinal tract and/or the environment, the likelihood that horizontal gene transfer of the *cry*1F, *cry*34Ab1/*cry*35Ab1 and *pat* genes would confer selective advantage or increased fitness to microorganisms is very limited. For this reason it is very unlikely that genes from maize 1507 x 59122 would become transferred and established in the genome of microorganisms in the environment or human and animal digestive tract. In the very unlikely event that such horizontal gene transfer would take place, no adverse effects on human and animal health or the environment are expected, as no principally new traits would be introduced or expressed in microbial communities.

(b) Plant to plant gene transfer

The extent of cross-pollination of other maize varieties will mainly depend on the scale of accidental release during transportation and processing. For maize, any vertical gene transfer is limited to other *Zea mays* plants as populations of sexually compatible wild relatives of maize are not known in Europe (Eastham and Sweet, 2002; OECD, 2003).

The flowering of occasional GM plants originating from accidental release occurring during transportation and processing is unlikely to disperse significant amounts of GM maize pollen to other maize plants.

Herbicide tolerance and insect resistance provide agronomic advantages in cultivation where and when the specific herbicides are applied and/or under infestation conditions. However survival of maize outside cultivation in Europe is mainly limited by a combination of low competitiveness, absence of a dormancy phase, susceptibility to diseases and to cold climate conditions. Since these general characteristics of this GM maize are unchanged, herbicide tolerance and insect resistance are not likely to provide selective advantages outside cultivation in Europe. Therefore, as for any other maize varieties, plants of this GM maize would only survive in subsequent seasons in the warmer regions of Europe and are not likely to establish feral populations under European environmental conditions (see Section 5.2.1.1).

In conclusion, since maize 1507 x 59122 has no altered survival, multiplication or dissemination characteristics except when cultivated in the presence of glufosinate-ammonium-based herbicides and/or under infestation conditions, the GMO Panel is of the opinion that the likelihood of unintended environmental effects as a consequence of spread of genes from this maize in Europe will not differ from that of maize 1507 or 59122 or of conventional maize varieties.

6.1.2.3. Potential interactions of the GM plant with target organisms

Maize 59122 was transformed to co-express Cry34Ab1 and Cry35Ab1 proteins from *Bacillus thuringiensis*. This binary insecticidal toxin is made of two components, the Cry34Ab1 and the Cry35Ab1 proteins, acting together in the control of certain coleopteran pests, such as the western corn rootworm (*Diabrotica virgifera virgifera* LeConte), the northern corn rootworm (*D. barberi* Smith & Lawrence) and the southern corn rootworm (*D. undecimpunctata howardi* Barber) (Masson *et al.*, 2004). Maize 1507 was transformed to express Cry1F protein conferring resistance to the European corn borer (*Ostrinia nubilalis*) and *Sesamia* spp.

A study showed that Cry35Ab1 protein alone is not active against corn rootworm larvae and that Cry34Ab1 alone causes mortality and growth inhibition to corn rootworm larvae, but for maximal insecticidal activity both the Cry34Ab1 and Cry35Ab1 proteins are required. The binary protein formulation enhances the insect toxicity (Herman *et al.*, 2002). The hypothetical mode of action for this kind of association (i.e. binary toxins) is that Cry34Ab1 is responsible for specific binding to receptors on the insect midgut epithelium while Cry35Ab1 is active on membrane pore formation (de Maagd *et al.*, 2003).

Considering that the intended uses of maize 1507 x 59122 specifically exclude cultivation, the environmental exposure is limited to exposure through manure and faeces from the gastrointestinal tracts mainly of animals fed on the GM maize as well as to the accidental release into the environment of 1507 x 59122 seeds during transportation and processing and subsequently to potential occurrence of sporadic feral plants. Thus the level of exposure of target organisms to Cry1F, Cry34Ab1 and Cry35Ab1 proteins is likely to be extremely low and of no ecological relevance.

6.1.2.4. Potential interactions of the GM plant with non-target organisms

Considering the intended uses of maize 1507 x 59122, the environmental risk assessment is concerned with indirect exposure through manure and faeces from the gastrointestinal tracts mainly of animals fed on the GM maize and with accidental release into the environment of GM seeds during transportation and processing.

The GMO Panel assessed whether Cry proteins might potentially affect non-target organisms by entering the environment in manure and faeces from the gastrointestinal tracts mainly of animals fed on this maize. Data supplied by the applicant and published data (Herman *et al.*, 2003) on Cry1F, CRY34Ab1 and Cry35Ab1 and literature on other Cry proteins (Ahmad *et al.*, 2005 and references therein; Lutz *et al.*, 2005) suggest that most Cry proteins are degraded by the enzymatic activity in the gastrointestinal tract so that only low amounts of Cry proteins would remain intact to pass out in faeces. There would subsequently be further degradation of these proteins in the manure and faeces due to microbial processes. In addition other sources of environmental exposure for example soil and water, and disposal of organic wastes are likely to be very low and localized (Baumgarte & Tebbe, 2005; Hopkins & Gregorich, 2003).

In conclusion the GMO Panel considers that the level of exposure of any potential non-target organisms to the Cry proteins expressed in maize 1507 x 59122 in combination with the PAT protein is likely to be very low and of no ecological relevance.

6.1.2.5. Potential interaction with the abiotic environment and biogeochemical cycles

Considering the scope of the application and the intended uses of maize 1507 x 59122 and due to the low level of exposure to the environment, potential interactions with the abiotic environment and biogeochemical cycles were not considered an issue by the GMO Panel.

6.1.3. Monitoring

The objectives of a monitoring plan according to Annex VII of Directive 2001/18/EC are to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO, or its use, in the environmental risk assessment are correct and to identify the occurrence of adverse effects of the GMO, or its use, on human health or the environment which were not anticipated in the environmental risk assessment.

Monitoring is related to risk management, and thus a final adoption of the monitoring plan falls outside the mandate of EFSA. However, the GMO Panel gives its opinion on the scientific quality of the monitoring plan provided by the applicant (EFSA, 2006b). The potential exposure to the environment of maize 1507 x 59122 would be through manure and faeces from the gastrointestinal tracts mainly of animals fed on the GM maize or through accidental release into the environment of GM seeds during transportation and processing.

No specific environmental impact of this GM maize was indicated by the environmental risk assessment and thus no case specific monitoring is required.

The general surveillance plan proposed by the applicant includes (1) the description of an approach involving operators (federations involved in maize import and processing), reporting to applicants, via a centralised system, any observed adverse effect(s) of GMOs on human health and the environment, and (2) a coordinating system established by EuropaBio for the collection of the information recorded by the various operators (Lecoq *et al.*, 2007; Windels *et al.*, 2008). The applicant will submit a general surveillance report on an annual basis and a final report at the end of the consent. In case of confirmed adverse effects, the applicant will immediately inform the European Commission and Member States.

The GMO Panel is of the opinion that the scope of the monitoring plan provided by the applicant is in line with the intended uses of maize 1507 x 59122 since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. The GMO Panel agrees with the reporting intervals proposed by the applicant in the general surveillance plan. The GMO Panel advises that appropriate management systems should be in place to prevent seeds of maize 1507 x 59122 entering cultivation as the latter requires specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003.

6.2. Conclusion

The scope of the application is for food and feed uses, import and processing of maize 1507 x 59122 and excludes cultivation. Considering the intended uses of maize 1507 x 59122, the environmental risk assessment is concerned with indirect exposure through manure and faeces from the gastrointestinal tracts mainly of animals fed on the maize 1507 x 59122 and with accidental release into the environment of 1507 x 59122 seeds 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 1507 x 59122 seeds during

transportation and processing for food and feed uses. Taking into account the scope of the application, both the rare occurrence of feral plants and the low levels of exposure through other routes indicate that the risk to non-target organisms is negligible.

The scope of the monitoring plan provided by the applicant is in line with the intended uses of maize 1507 x 59122 since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. Furthermore the GMO Panel agrees with the reporting intervals proposed by the applicant in the general surveillance plan.

CONCLUSIONS AND RECOMMENDATIONS

The GMO Panel was requested to carry out a scientific risk assessment of the maize 1507 x 59122 for food and feed uses, import and processing and all derived products.

The GMO Panel is of the opinion that the molecular characterisation provided for maize 1507 x 59122 produced by conventional breeding is sufficient for the safety assessment. The bioinformatic analysis of the inserted DNA and the flanking regions of the single events 1507 and 59122 does not raise any safety concern. The expression of the genes introduced by the genetic modification has been sufficiently analysed and the stability of the genetic modification has been demonstrated over several generations. The GMO panel considers that the molecular characterisation does not indicate any safety concern.

Based on the results of comparative analysis it was concluded that maize 1507 x 59122 is compositionally and agronomically equivalent to conventional maize, except for the presence of Cry34Ab1, Cry35Ab1, Cry1F and PAT. Based on the assessment of data available, including the additional information provided by the applicant in response to the Panel request, for maize 1507 x 59122, for the single events and for appropriate non-GM controls, the GMO Panel does not see a reason to assume that crossing of maize 1507 and 59122 results in an interaction of the newly expressed proteins which causes compositional or agronomic changes. The Cry34Ab1, Cry35Ab1 proteins and PAT proteins expressed in the parental maize line 59122, the Cry1F and PAT proteins expressed in the parental maize 1507 have been assessed previously and no safety concerns were identified. Given all the information provided, the Panel concludes that interactions between the proteins expressed by the single events that might impact on food and feed safety are unlikely and that the nutritional properties of maize 1507 x 59122 would be no different from those of conventional maize. In conclusion the Panel considers that maize 1507 x 59122 is as safe and as nutritious as its non GM counterpart and that the overall allergenicity of the whole plant is not changed and concludes that maize 1507 x 59122 is unlikely to have any adverse effect on human and animal health in the context of its intended uses.

There are no indications of increased likelihood of establishment or survival of feral maize plants in case of accidental release into the environment of 1507 x 59122 seeds during transportation and processing for food and feed uses. Taking into account the scope of the application, both the rare occurrence of feral plants and the low levels of exposure through other routes indicate that the risk to target and non-target organisms is negligible.

The scope of the monitoring plan provided by the applicant is in line with the intended uses of maize 1507 x 59122 since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. Furthermore the GMO Panel agrees with the reporting intervals proposed by the applicant in the general surveillance plan.

In conclusion, the GMO Panel considers that information available for maize 1507 x 59122 addresses the comments raised by the Member States and considers that it is unlikely that

maize 1507 x 59122 will have any adverse effect on human and animal health or on the environment in the context of its proposed uses.

DOCUMENTATION PROVIDED TO EFSA

Letter from the Competent Authority of The Netherlands dated 26 May 2005, concerning a request fro placing on the market of genetically modified 1507x59122 maize in accordance with Regulation (EC) 1829/2003, submitted by Mycogen seeds c/o Dow AgroSciences LLC and Pioneer Hi-Bred.

Acknowledgement letter dated 3 June 2005, from EFSA to the Competent Authority of The Netherlands (Ref SR/KL/sp (2005) 649).

Letter from EFSA to applicant dated 30 November 2005 with request for clarifications under completeness check (Ref. SR /AC/jq (2005) 1356).

Letter from Applicant to EFSA dated 21st February 2007 providing EFSA with an updated version of the Application EFSA-GMO-NL-2005-15 submitted by Dow AgroSciences under Regulation (EC) 1829/2003.

Letter from EFSA to Applicant dated 30 March 2007 with request for clarifications under completeness check (Ref. SR/SM/DC/KL/shv (2007) 2064646).

Letter from Applicant to EFSA dated 10 April 2007 providing EFSA with an updated version of the Application EFSA-GMO-NL-2005-15 submitted by Dow AgroSciences under Regulation (EC) 1829/2003.

Letter from EFSA to Applicant dated 29 May 2007 with request for clarifications under completeness check (Ref. SR/CP/shv (2007) 2165082).

Letter from Applicant to EFSA dated 4 June 2007 providing EFSA with an updated version of the Application EFSA-GMO-NL-2005-15 submitted by Dow AgroSciences under Regulation (EC) 1829/2003.

Letter from EFSA to Applicant dated 13 July 2007 delivering the "Statement of validity" for Application EFSA-GMO-NL-2005-15 for authorisation of the genetically modified maize 1507 x 59122 submitted by Dow AgroSciences under Regulation (EC) No 1829/2003 (Ref SR/KL/eb (2007) 2252356).

Letter from Applicant to EFSA dated 24 July 2007, providing EFSA with additional copies of the Valid Application EFSA-GMO-NL-2005-15 submitted by Dow AgroSciences under Regulation (EC) 1829/2003.

Letter from EFSA to Applicant dated 24 October 2007, with request for additional information (Ref. SR/CP/shv (2007) 2463868).

Letter from Applicant to EFSA dated 29 November 2007, providing additional information.

Letter from EFSA to Applicant dated 14 December 2007, with request for additional information (Ref. SR/CP/shv (2007) 2570566).

Letter from Applicant to EFSA dated 13 February 2008, providing additional information.

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Letter from Applicant to EFSA dated 23 April 2008, providing additional information.

Letter from EFSA to Applicant dated 31 July 2008, with request for additional information (Ref. PB/CP/shv (2008) 3194780).

Letter from Applicant to EFSA dated 16 September 2008, providing additional information.

Letter from EFSA to Applicant dated 07 November 2008, with request for additional information (Ref. PB/CP/md (2008) 3430062).

Letter from Applicant to EFSA dated 19 December 2008, providing additional information.

Letter from EFSA to Applicant dated 03 June 2009, restarting the clock (PB/KL/CP/shv (2009) 3727247).

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