Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2004-05) for the placing on the market of insect-protected and glufosinate and glyphosate-tolerant genetically modified maize 1507 x NK603, for food and feed uses, and import and processing under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred and Mycogen Seeds[1]

(Question No EFSA-Q-2004-139)

Opinion adopted on 28 March 2006

SUMMARY

This document provides an opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on genetically modified maize 1507 x NK603 (Unique Identifier DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6) developed to provide protection against specific lepidopteran pests and tolerance to the herbicides glufosinate and glyphosate.

In delivering its opinion the Panel considered the application EFSA-GMO-UK-2004-05, additional information provided by the applicant and the scientific comments submitted by the Member States. Further information from applications for placing the single events maize 1507 and maize NK603 on the market under EU regulatory procedures was taken into account, when appropriate.

The GMO Panel assessed 1507 x NK603 maize 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. The scientific assessment included molecular characterisation of the inserted DNA and expression of target proteins. A comparative analysis of agronomic traits and composition was undertaken and the safety of the new proteins and the whole food/feed was evaluated with respect to toxicity and allergenicity. Both a nutritional and an environmental assessment were undertaken, the latter including an environmental monitoring plan.

The single events maize 1507 and NK603 have been the subjects of earlier assessments. Maize 1507 was developed to be tolerant to the herbicide glufosinate by the introduction of a gene encoding phosphinothricin-N-acetyltransferase (PAT) from *Streptomyces viridochromogenes* and to provide protection against certain lepidopteran pests such as the European corn borer (*Ostrinia nubilalis*) and species belonging to the genus *Sesamia* by the introduction of a truncated *cry*1F gene from *Bacillus thuringiensis* ssp. *aizawai*. Maize 1507 was assessed previously for import and processing under Part C of Directive 2001/18/EC. It was also assessed for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC and for food use, under Regulation (EC) No 1829/2003. It was approved for import, processing and feed uses under Directive 2001/18 by Commission Decision

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2005/772/EC and for food uses under Regulation 1829/2003 by Commission Decision 2006/197/EC. NK603 was developed to be tolerant to the herbicide glyphosate by the introduction of a gene coding for 5-enolpyruvylshikimate-3-phosphate synthase from *Agrobacterium* sp. strain CP4 (CP4 EPSPS). NK603 has received EFSA opinions in favour of its authorisation and was authorised under Directive 2001/18/EC by Commission Decision 2004/643/EC. The use of food and food ingredients from NK603 maize was authorised under Regulation (EC) No 258/97 by Commission Decision 2005/448/EC.

Maize 1507 x NK603 is produced by crosses between maize inbred lines containing maize events 1507 and NK603 to combine the lepidopteran resistance trait and glufosinate tolerance in maize 1507 with glyphosate tolerance in maize NK603. No new genetic modifications were introduced.

Molecular analysis of the DNA inserts present in maize 1507 x NK603 confirmed that both maize event 1507 and maize event NK603 are present and the structure of their inserts is retained.

Cry1F and CP4 EPSPS protein levels in kernels of maize 1507 x NK603 were comparable with the levels in the parental maize lines 1507 and NK603, previously assessed. PAT was expressed below the lower limit of quantification of the assay both in kernels of maize 1507 and in kernels of maize 1507 x NK603. The safety of the Cry1F, PAT and CP4 EPSPS proteins has previously been assessed and positive opinions on the single 1507 and NK603 maize events have been given by EFSA. The Panel found no evidence of any interactions between the newly expressed Cry1F, PAT and CP4 EPSPS proteins.

Maize 1507 x NK603 contains transgenic proteins resulting in an insect- resistant and herbicide-tolerant phenotype. Besides these deliberate changes, this maize neither showed marked alterations in composition, agronomy and phenotype compared with a non-GM hybrid maize with a genetic background similar to the maize 1507 x NK603, nor with several non-GM reference lines. The Panel therefore concludes that except for the introduced traits, maize 1507 x NK603 is compositionally and phenotypically equivalent to conventional counterparts.

A feeding study conducted with maize 1507 x NK603 on broilers confirmed the nutritional wholesomeness. The Panel considers that the nutritional properties of this maize would be no different from those of conventional counterparts.

The application EFSA-GMO-UK-2004-05 concerns food and feed uses, import and processing. There is therefore no requirement for scientific information on possible environmental effects associated with the cultivation of the maize lines. The GMO Panel agrees that unintended environmental effects due to the establishment and spread of GM maize will not be different from that of conventionally bred maize. The monitoring plan provided by the applicant is in line with the intended uses for the GMO.

In conclusion, the Panel considers that the information available for maize 1507 x NK603 addresses the scientific comments raised by the Member States and that the GM maize 1507 x NK603 is as safe as its conventional counterparts with respect to effects on human and animal health and the environment. Therefore the Panel concludes that this maize is unlikely to have any adverse effect on human and animal health and the environment in the context of its intended uses.

Key words: GMOs, maize, 1507, NK603, 1507 x NK603, insect protection, DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6, gluphosinate tolerance, glyphosate tolerance, Cry1F, PAT, CP4 EPSPS, food/ feed safety, human health, environment, import, Regulation (EC) No 258/97, Directive 2001/18/EC, Regulation (EC) No 1829/2003.

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BACKGROUND

On 1 October 2004 EFSA received from the United Kingdom Competent Authority an application (Reference EFSA-GMO-UK-2004-05), for authorisation of maize 1507 x NK603 (Unique Identifier DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6), submitted by Pioneer Hi-Bred International and Mycogen Seeds within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (EC, 2003).

After receiving the application EFSA-GMO-UK-2004-05 and in accordance with Articles 5(2)(b) and 17(2)b of Regulation (EC) No 1829/2003, EFSA informed the Member States and the Commission and made the summary of the dossier available to the public on the EFSA website[2]. 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 13 January 2005 EFSA received additional information (requested on 10 November 2004) and declared the application as formally valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003 on 1 April 2005.

EFSA made the valid application available to Member States and the 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 1 July 2005) within which to make their opinion known.

On 15 July 2005 the GMO Panel asked for additional data on the molecular characterisation of maize 1507 x NK603. The applicant provided the complete requested information on 3 February 2006. After receipt of the full data package, the GMO Panel finalised its risk assessment of maize 1507 x NK603.

The Scientific Panel on Genetically Modified Organisms carried out a scientific assessment of the genetically modified (GM) maize 1507 x NK603 for food and feed uses and 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 events on the market under EU regulatory procedures was also taken into account, when appropriate.

[2] http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html

Maize with the single events 1507 and NK603 have been the subjects of earlier assessments by the GMO Panel and have received EFSA opinions in favour of their authorisation. Maize 1507 was assessed previously for import and processing under Part C of Directive 2001/18/EC (EFSA, 2004a). It was also assessed for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC and for food use, under Regulation (EC) No 1829/2003 (EFSA, 2005a,b). It was approved for import, processing and feed uses under Directive 2001/18 by Commission Decision 2005/772/EC (EC, 2005b) and for food uses under Regulation 1829/2003 by Commission Decision 2006/197/EC (EC, 2006). NK603 has received EFSA opinions in favour of its authorisation (EFSA, 2003a,b) and was authorised under Directive 2001/18/EC by Commission Decision 2004/643/EC (EC, 2004a). The use of food and food ingredients from NK603 maize was authorised under Regulation (EC) No 258/97(EC, 1997b) by Commission Decision 2005/448/EC (EC, 2005a).

In giving its opinion on maize 1507 x NK603 to the 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 opinion shall include a report describing the assessment of the food and feed and stating the reasons for its opinion and the information on which its 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) including the particulars (a) to (g).

TERMS OF REFERENCE

The GMO Panel was requested, in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, to carry out a scientific assessment of the genetically modified maize 1507 x NK603 for food and feed uses, import and processing.

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/environment 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 Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. The Panel did also not consider 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 risk management.

ASSESSMENT

1. Introduction

The genetically modified (GM) maize 1507 x NK603 is assessed with reference to its intended uses and the appropriate principles described in the guidance document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed (EFSA, 2004b). The combination of separate events as a result of a cross between GM plants raises questions about the extent to which data on maize 1507 and NK603 can be extrapolated to assess the

safety of maize 1507 x NK603. The GMO Panel considers this on a case-by-case basis depending on the nature of the genetic modifications in maize 1507 x NK603.

2. Molecular characterisation

2.1. Issues raised by Member States

Comments were made regarding: (1) the lack of consistency between the expected sizes of the Southern blot bands using *Sac*I and *Eco*RV when comparing 1507 maize with lines with combined 1507X NK603 traits; (2) the adequacy of data on protein expression from the introduced genes, and (3) the choice of the controls and the methodology used.

2.2. Evaluation of relevant scientific data

The EFSA GMO Panel guidance document (EFSA, 2004b) 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 of maize 1507.

2.2.1. Method of production of maize 1507x NK603

Traditional breeding methods were used to produce maize 1507 × NK603 and no new genetic modification was involved. The two inserts that are present in 1507 × NK603 were derived from maize lines containing two independent events: 1507 and NK603. 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, 2003a,b; 2004a; 2005a,b). Maize 1507 × NK603 combines the insect protection and glufosinate tolerance traits from 1507 with the glyphosate tolerance in NK603.

2.2.2. Summary of the previous evaluation of the single events

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Maize 1507 has been developed for protection against specific lepidopteran pests such as the European corn borer (*Ostrinia nubilalis*) and *Sesamia* species. and for tolerance to the herbicide glufosinate. Insect resistance is achieved by production of a truncated Cry1F protein from *Bacillus thuringiensis* ssp. *aizawai* and tolerance to the herbicide is conferred by a phosphinothricin-N-acetyltransferase (PAT) from *Streptomyces viridochromogenes*. Maize embryos were transformed by particle bombardment to transfer a DNA fragment containing these two genes. As a result of the genetic modification, the 1507 event contains an insert bearing both *cry*1F and *pat* genes, under the control of the maize ubiquitin and 35S promoters, respectively.

Molecular analysis showed that 1507 maize contains one copy of the DNA fragment used for transformation and that this is present at a single locus in the nuclear genome of the GM plant. The complete DNA sequence of the insert was provided. In addition to the intact genes, the insert in 1507 maize includes DNA sequences originating from the fragment used for transformation as well as maize chloroplast and nuclear genome sequences at both ends of the

inserted sequence. While these sequences may have resulted from the transformation process (insertional events), there were no indications that these additional fragments would result in the 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. Analysis of DNA sequences flanking both ends of the insert shows that they correspond to maize genomic DNA.

The expression levels of Cry1F and PAT proteins in 1507 maize have been studied in leaf, pollen, silk, stalk, whole plant, grain and senescent whole plant tissue samples collected from field studies in Chile during the season 1998/1999 and in material of French and Italian field studies during 1999. None of the samples from Chile and France had been sprayed with glufosinate-ammonium. In the field trial in Italy both sprayed and non-sprayed material was collected. None of the proteins could be identified with an ELISA technique in control samples. The PAT protein was found at detectable levels only in leaf tissue and whole plant

NK603

Maize line NK603 was the subject of an earlier safety assessment (EFSA, 2003a,b). In the NK603 event glyphosate tolerance was achieved by the introduction of a gene encoding a glyphosate tolerant 5-enolpyruvylshikimate-3-phosphate synthase from *Agrobacterium* sp. strain CP4 (CP4 EPSPS). The EPSPS activity is needed for the biosynthesis of aromatic amino acids in plants and in micro-organisms but the structure of the normal plant enzyme (EPSPS) makes it commonly vulnerable to glyphosate, thereby causing the plants to be killed by the herbicide. Use of the CP4 EPSPS gene in the transgenic plant confers tolerance to the herbicide.

Molecular analysis showed that NK603 contains a single inserted copy of the DNA present in the construct used for the transformation. The plasmid vector used for the transformation contained two adjacent plant gene expression cassettes each containing a single copy of the *cp*4 *epsps* gene with different promoters. The insert in NK603 does include some molecular rearrangements at one end of the insert and also includes a fragment of chloroplast DNA. These rearrangements and the insertion of chloroplast DNA do not lead to new traits and are not considered to pose a safety risk. In the unlikely event that a new peptide or protein is produced as a consequence of the insertion event, bioinformatics analysis showed that these would have no homology to known toxins or allergens. Moreover, the toxicological assessment does not indicate adverse effects from consumption of maize NK603.

2.2.3. Transgenic constructs in the maize 1507 x NK603

A cross between the two transgenic maize lines 1507 and NK603 was used to produce the maize 1507 x NK603. The molecular structures of the DNA inserts present in this maize were investigated using Southern analyses. This involved the use of DNA probes specific for the 1507 or NK603 maize inserts, respectively. In order to confirm the molecular equivalence and identical copy number of the insert present in maize 1507 x NK603 to that present in 1507 maize, samples of genomic DNA from four individual maize 1507 x NK603 plants and from six individual 1507 maize plants were digested with the restriction enzyme *Hind*III and subjected to Southern blot analysis with the *cry*1F and *pat* gene probes. Further comparisons were made between maize 1507 x NK603 and 1507 and NK603 maize using DNA from four individual plants from each of 1507 x NK603, 1507 and NK603 maize. On this occasion *Eco*RV and *Sac*I restriction enzymes were selected for DNA digestion and three probes selected for detection: a) the 35S promoter, (common to both 1507 and NK603); b) the *cry*1F gene probe and c) the *pat* gene probe. Additional Southern blot analyses were carried out on *Eco*RV digests with a DNA probe containing the coding region of the *cp4 epsps* gene.

The applicant provided sequence information for maize 1507 to confirm the presence of a *Sac*I site in the 5' border and so to confirm its reasoning that this was responsible for the additional band detected in Southern blots. The length of the sequence provided by the applicant was 896 bp and a detailed analysis of this sequence confirmed the presence of a *Sac*I star site in the 5' border at positions 693-698 of the newly identified sequence. This confirmed that the faint 6.97 kb band observed in the original Southern blot analyses originated from altered site specificity of the *Sac*I restriction enzyme (star activity) when applied to the 1507 and 1507xNK603 maize DNA. The data confirms that the existing molecular information is consistent with a single insertion in the 1507 maize genome.

The inserted genetic material from 1507 maize and NK603 maize, integrated in the genome of maize 1507 x NK603, was inherited as dominant genes in a Mendelian fashion. These analyses confirmed that both insert structures were retained in this maize. The Panel is of the opinion that the stability of the trait phenotypes also provides evidence that the transgenes are combined as described in the application.

2.2.4. Information on the expression of the insert

Grains and forage material for studies of expression levels of the transgenic proteins Cry1F, PAT, and CP4 EPSPS were obtained from maize 1507 x NK603 harvested from field trials in Chile the season 2002-2003 (see section 3.2.2.).

The concentrations of transgenic proteins were studied in grain material of maize 1507 x NK603 that had been exposed to i) glyphosate, ii) glufosinate-ammonium, iii) glyphosate followed by glufosinate-ammonium, or iv) none of the herbicides during the field trials, as well as in forage material of maize 1507 x NK603 exposed to glyphosate followed by glufosinate-ammonium. The proteins were extracted and quantified using an ELISA (enzyme-linked immunosorbent assay) technique.

The PAT protein was expressed at undetectable levels in grains of maize 1507 x NK603. PAT was also undetectable in grains of control maize, except for one control sample that was most likely contaminated. The other two proteins, Cry1F and CP4 EPSPS were found in grains of 1507 x NK603 but not in the control material. The average levels of these proteins were similar under the three different herbicide treatments. Thus, average levels of Cry1F ranged from 1.37 to 1.57 ng per mg dry weight, and average CP4 EPSPS levels from 6.62 to 8.25 ng per mg dry weight.

All three transgenic proteins were expressed at higher levels in forage material. The mean protein concentration of the PAT protein was 0.58 ng/mg dry weight, whereas the mean levels of Cry1F and CP4 EPSPS was 5.57 and 62.0 ng/mg dry weight, respectively.

A member state noted there was no comparison of the expression levels of PAT, Cry1F and CP4 EPSPS in maize 1507 x NK603 and its transgenic parental lines presented in the application. However, the expression levels of these proteins in maize 1507 x NK603 grain material were comparable with the levels demonstrated in grain material of maize NK603 and 1507 presented in the respective applications. The GMO Panel is of the opinion that within these comparable ranges, the differences in expression of the transgenes in maize 1507 x NK603 and the single parental lines are of no significance for safety assessment.

2.2.5. Inheritance and stability of inserted DNA

The genetic stability of the inserted DNA in events 1507 and NK603 was demonstrated previously (EFSA, 2003a,b; 2004a; 2005a,b). In maize 1507 x NK603 the two inserts are

combined. The Southern data presented show that both events are present and the structure of each insert is retained. Furthermore, each of the traits has been conserved in this maize.

2.3. Conclusion

As conventional breeding methods were used in the production of maize 1507 x NK603, no additional genetic modification was involved and thus the molecular structures of the DNA inserts are expected to remain unchanged as indicated by the preservation of the phenotypes. Further analysis using Southern blots demonstrated that the structures of the 1507 and NK603 events were retained in maize 1507 x NK603. The genetic stability of the integrated DNA has been demonstrated in the single events and during the breeding process.

The expression levels of Cry1F, PAT and CP4 EPSPS proteins in maize 1507 x NK603 were measured. Taking into account the variation in gene expression, the expression levels of these proteins in 1507 x NK603 are comparable with those reported previously for the single maize events 1507 and NK603 (EFSA, 2003a,b; 2004a; 2005a,b).

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

3. Comparative analysis

3.1. Issues raised by Member States

There were comments from Member States that (1) the field studies should be performed during more than one season, with specific control plants; (2) additional controls in the form of the single GM events 1507 and NK603 maize were asked for and (3) the statistical evaluation of the experimental data should be improved, and an explanation was required as to why the vitamin B_1 level of the non-GM control maize fell outside the normal range of vitamin B_1 content found in the literature.

3.2. Evaluation of relevant scientific data

3.2.1. Evaluation of the single events

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In its previous opinions on maize 1507 (EFSA, 2004a; 2005a,b), the Panel summarized the compositional comparison between maize 1507 and a non-GM hybrid maize with genetic background similar to maize 1507 that had been grown during three seasons in areas representative for maize cultivation. The Panel concluded that forage and grains of maize 1507 are compositionally equivalent to forage and grains of conventional counterparts, except for the presence of Cry1F and PAT proteins.

NK603

The Panel has also concluded on the chemical composition of the other parental GM event, maize NK603 (EFSA, 2003a,b). Compositional data for maize NK603 and its non-GM comparators from two growing seasons revealed a minor, but statistically significant difference in the stearic acid content (C18:0) of maize oil in kernels. This difference was noted in material harvested one year, but not in material from the other year. The Panel considered maize NK603 to have the same composition as non-GM hybrid maize with a genetic background similar to the maize NK603, except for the presence of the CP4 EPSPS protein.

3.2.2. Choice of comparator and production of material for the compositional assessment

Maize 1507 x NK603 was obtained by crossing elite lines containing the separate genetically modified maize events 1507 and NK603, whereas the comparator was a non-genetically modified hybrid maize with a genetic background similar to the maize 1507 x NK603. The GMO Panel considers this choice of comparator as appropriate.

Field studies were conducted at six separate geographical sites in the major maize growing regions of Chile (2 in Buin, 2 in Linderos, and 2 in Viluco) during one season (2002-2003) in order (1) to estimate the level of expression of Cry1F, PAT and CP4 EPSPS proteins in grain obtained from maize 1507 x NK603, (2) to estimate whether maize 1507 x NK603 differs from the comparator in important agronomic factors such as reproduction, dissemination, and survivability, and (3) to estimate whether maize 1507 x NK603 differs from the comparator in composition. Irrigation systems differed between the sites of the field trials.

The experimental design at each location was a randomised block design containing four blocks. Each block contained the herbicide treated maize 1507 x NK603 and the comparator. Three of the four blocks were used to obtain material for the comparative assessment and the fourth block to obtain samples for protein expression analysis (see section 2.2.4).

The samples studied in these field trials were harvested from plots of maize 1507 x NK603 sprayed at two different growth stages with (i) glyphosate herbicide only; (ii) glufosinate-ammonium herbicide only; or (iii) glyphosate followed by glufosinate-ammonium herbicide. The comparator was not sprayed with these herbicides.

3.2.3. Compositional analysis

Whole crops and maize tissues, including ears with grains, were collected for compositional analysis from field trials. With regard to composition, grains of maize 1507 x NK603 and its comparator were analysed for 53 different parameters. The compounds analysed included proximates (ash, carbohydrates, acid detergent fiber, neutral detergent fiber, crude fibre, moisture, crude protein, crude total fat), amino acids (methionine, cysteine, lysine, tryptophan, threonine, isoleucine, histidine, valine, leucine, arginine, phenylalanine, glycine, alanine, aspartic acid, glutamic acid, proline, serine and tyrosine), fatty acids (palmitic, stearic, oleic, linoleic and linolenic acids), minerals (Ca, Cu, Fe, K, Mg, Mn, Na, P and Zn), vitamins (β-carotene, vitamin B_1, vitamin B_2, folic acid, and vitamin E [α-tocopherol]), secondary metabolites (inositol, raffinose, furfural, *p*-coumaric acid and ferulic acid) and anti-nutrients (phytic acid and trypsin inhibitor). Forage was analysed for proximates (ash, carbohydrates, acid detergent fibre, neutral detergent fibre, crude fibre, moisture, crude protein and crude total fat) and the minerals calcium and phosphorus. The constituents analysed in the grain and forage samples were largely in accordance with guidelines for assessment of genetically modified maize (OECD, 2002).

The statistical analysis of compositional data was carried out both on a per location basis, using data from 3 replicates, and on combined data from all replicates and all locations. In addition to comparing the composition of maize 1507 x NK603 with that of a non-GM hybrid maize with a similar genetic background it was compared with data available in the literature on the composition of commercial maize hybrids. The GMO Panel found the presentation of data and its statistical analysis as adequate.

Compositional comparisons were made between the genetically modified maize 1507 x NK603 treated with glyphosate, glufosinate-ammonium or both herbicides and the comparator, and occasionally the comparison revealed statistically significant differences in the level of some compounds.

When data from all trial sites were combined, the amount of crude fat in forage differed between control maize and maize 1507 x NK603 sprayed sequentially with both herbicides. However, no significant difference in crude fat between these crops was observed when the data from each individual site were examined using separate statistical analyses. Furthermore, neither application of glyphosate nor glufosinate-ammonium alone influenced the crude fat level of forage from maize 1507 x NK603.

In the statistical analysis of combined compositional data on kernels of maize 1507 x NK603 and of the comparator, the compounds displaying significant differences under all three herbicide treatments included palmitic acid, manganese, potassium, zinc, vitamins B_1 and vitamin E. Additional differences in the combined data included linolenic acid after glyphosate treatment; crude fat, stearic acid, oleic acid, linolenic acid, cysteine, methionine, magnesium, *p*-coumaric acid, and ferulic acid after glufosinate treatment; and stearic acid, aspartic acid, cysteine, methionine, and folic acid after treatment with both herbicides. However, none of these differences were consistently observed in material from different locations, and in some cases not in material from a single site. Neither were any of these levels outside the ranges reported in the literature for these compounds in conventional hybrid maize kernels. The slightly elevated level of vitamin B_1 in kernels of control maize was not consistent and observed in grain material from four out of six locations.

The Panel considered the observed compositional differences between maize 1507 x NK603 and its comparator in the light of the field trial design, measured biological variation and the level of the studied compounds in conventional and commercial maize hybrids. The Panel concluded that maize 1507 x NK603 can be considered to have a composition equivalent to its conventional counterparts.

3.2.4. Agronomic traits and GM phenotype

Agronomic characteristics of maize 1507 x NK603 and its non-GM comparator were recorded over the course of the growing season. The characteristics measured were: early plant population counts, silking, pollen shed, plant height, ear height, stalk lodging, root lodging, final population, leaf greenness, disease incidence, insect damage, pollen shape and pollen colour. There was no statistically significant difference when comparing the agronomic characteristics of maize 1507 x NK603 and the comparator. Similarly, no unexpected changes in pollen production, seed production, seed viability and germination were observed for 1507 x NK603 when compared with the non-GM maize.

3.3 Conclusion

In earlier opinions from the GMO Panel, 1507 maize and NK603 maize were assessed and found to have a similar composition to the genetically related non-GM maize lines (EFSA, 2003a,b; 2004a; 2005a,b). As both parental lines have been assessed in detail by the GMO Panel, the Panel accepts that data for comparative assessment are obtained from one growing season of maize 1507 x NK603.

After evaluating the nutrient and anti-nutrient composition of forage and grain of maize 1507 x NK603, the GMO Panel concludes that the composition of maize 1507 x NK603 is comparable with that of a non-GM hybrid maize with a similar genetic background, with exception of the three newly expressed proteins. Furthermore, 1507 x NK603 was shown to have the same agronomic characteristics as the non-GM control maize except for the introduced traits.

4. Food/feed safety assessment

4.1. Issues raised by Member States

Member States requested: (1) an extension of the testing program for potential toxicity and allergenicity, including a 90-day feeding study in rodents and allergenicity testing of the whole product. Concern was raised that the Cry1F protein expressed in maize 1507 x NK603 might not be as inert as expected in relation to allergenic potency. This concern was raised because another Cry protein, Cry1Ac, has been suggested to be a systemic and mucosal adjuvant; (2) a post market monitoring plan for food and feed; and (3) data on herbicide residues.

4.2. Evaluation of relevant scientific data

4.2.1. Evaluation of the single events

1507

No oral toxicity of maize 1507 was observed in a rat study where the experimental animals were fed *ad libitum* a diet containing up to 33% 1507 maize. In addition, nutritional data comprising target animal feeding studies with whole maize kernels on broilers and dairy cows indicate that 1507 maize is nutritionally equivalent to other conventional maize cultivars. The allergenicity of the Cry1F and PAT proteins have been already assessed in 1507 maize indicating low propability of potential allergenicity. The allergenicity of the whole crops does not appear relevant to the Panel since maize is not considered a common allergenic food. The GMO Panel concluded that these animal studies support the findings of the molecular characterization and the compositional analysis and indicates 1507 maize to be as safe as conventional counterparts (EFSA, 2004a; 2005a,b).

NK603

As a result of the genetic modification NK603 contains two slightly different CP4 EPSPS proteins expressed from two copies of the *cp4 epsps* gene using different promoters. The proteins differ from each other in one amino acid. Analysis of the impact of this change indicated no apparent changes in EPSPS protein structure, activity, toxicity or allergenicity using appropriate bioinformatics approaches, *in vitro* digestion procedures and studies on experimental animals. Furthermore, appropriate animal feeding trials including a 90-day subchronic rodent study and nutritional feeding studies with broilers, Angus-continental cross steers and Holstein diary cows indicated that NK603 is as safe and nutritious as its non-GM comparator. Analysis of the grain from field trials in the USA and Europe showed that NK603 had the same composition as its non-GM comparator. The Panel considered the nutritional and toxicological properties of maize NK603 to be no different from those of conventional maize (EFSA, 2003a,b).

4.2.2. Product description and intended use

The 1507 x NK603 maize application covers the use of 1507 x NK603 maize as food and feed as for any other maize, i.e. food and feed consisting or derived from the genetically modified maize 1507 x NK603. Maize kernels are used mainly for animal feed and in smaller scale for direct human consumption i.e. sweet maize kernels. Products from maize kernels such as flour, starch and its by-products gluten, syrups, bran and maize germ oil can be regarded as important base materials for food production.

As the modification in 1507 x NK603 maize is only intended to improve the agronomic performance but not to influence nutritional aspects, production processes and overall use of maize as a crop are not expected to be influenced as a result of the introduction of the GM plants to the market.

4.2.3. Stability during processing

As the molecular characterization of maize 1507 x NK603 did not identify any alterations indicating a potential for altered expression of proteins and metabolites in the GM maize, and, furthermore, the chemical composition of maize 1507 x NK603 was shown to be comparable to the non-GM control maize, the GMO Panel does not expect the stability of maize 1507 x NK603 grain during processing to be any different from conventional maize grain.

4.2.4. Toxicology

4.2.4.1. Toxicological assessment of expressed novel proteins in maize 1507 x NK603

The transgenic Cry1F protein expressed in the parental maize line 1507 has been assessed in earlier applications. No adverse effects of Cry1F were observed in an acute oral mouse study. In addition, Cry1F was easily degraded. The protein displayed instability towards conditions (heating) prevailing during fish feed production, and was rapidly degraded in simulated gastric fluid. The amino acid sequence of the transgenic Cry1F protein did not show any significant similarity to sequences of known allergens. Neither did hypothetical peptide sequences, corresponding to 24 open reading frames (ORFs) that are present on the insert in maize 1507, nor ORF4 on fragment PHI8999A, show significant similarity to allergens or toxins (EFSA,2004a; 2005a,b).

Also the PAT protein has been assessed in previous applications and been found safe for human and animal consumption (SCP, 1998; EFSA, 2004a; 2005a,b,c).

The endogenous maize EPSPS enzyme is sensitive to the action of the herbicide glyphosate. No adverse effects have been linked to the occurrence of this enzyme in maize and other plant foods and feeds. The CP4 EPSPS and CP4 EPSPS L214P variants present in the NK603 parental maize line are tolerant to the action of glyphosate. The variant enzymes have been evaluated and found to be safe for human and/or animal consumption in several earlier applications (EFSA, 2003a,b).

No new genes in addition to those occurring in the parental maize lines have been introduced in maize 1507 x NK603. Given the functional properties of the proteins, the Panel concludes that interactions between the expressed proteins are unlikely.

4.2.4.2. Toxicological assessment of new constituents other than proteins

As summarized in section 3.2.3., no relevant changes in composition of maize 1507 x NK603 in relation to the non-GM comparator has been observed. Therefore no further safety assessment of new constituents in 1507 x NK603 is warranted.

4.2.4.3. Toxicological assessment of the whole GM food/feed

The genetically modified maize events 1507 and NK603 have previously been found safe for human and animal consumption, and for the environment (EFSA, 2003a,b; 2004a; 2005a,b). A molecular characterization undertaken on maize 1507 x NK603 identified no altered stability of the two events when these were brought together by crossing, and expression analysis of the Cry1F, PAT and CP4 EPSPS proteins similarly revealed no change in protein expression. As also

no indication for interaction between the newly expressed proteins was found and the composition of maize 1507 x NK603 is comparable with that of non-GM maize hybrids, the GMO Panel is of the opinion that the maize 1507 x NK603 is as safe as any other commercial maize hybrid. These interpretations have been strengthened by a 42-day nutritional feeding study with maize 1507 x NK603 on broiler chicken. Therefore, the Panel has found no reason to ask for a 90-day feeding toxicology study in rats.

4.2.5. Allergenicity

The strategies used when assessing the 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, 2004b).

4.2.5.1 Assessment of allergenicity of the newly expressed proteins

An allergy risk evaluation of CP4 EPSPS, PAT and Cry1F proteins has been completed using different approaches. From indirect evidence the risk of allergenicty for either protein was determined as being very low. This evidence included the absence of known allergenicity of the source, absence of sequence homology with known allergens and rapid and extensive degradation by pepsin (Metcalfe et al., 1996; CAC, 2003; EFSA, 2004b). Previous applications of maize hybrids expressing the CP4 EPSPS, PAT or Cry1F protein have used the same strategy and have been evaluated by national competent authorities, the EC Scientific Committees and EFSA (SCP, 1998; EFSA, 2003a,b; 2004a; 2005a,b,c) and also been approved within the European Community (EC, 1997a; 2004a,b; 2005a,b; 2006). The GMO Panel is not aware of any new information on allergenicity that requires a change in this opinion. Also, the GMO Panel is not aware of any new validated tests, that produce more relevant or accurate information on possible allergenicity of the protein, and that would provide a higher guarantee of safety.

A European country mentioned literature on immunogenicity and adjuvanticity of Cry proteins. After intraperitoneal or intragastric administration of Cry1Ac to mice at relatively high dosage, IgG, IgM and mucosal IgA response were induced, but no IgE response was observed (Vazquez-Padron *et al*., 1999a; 2000). This demonstrates that Cry1Ac has no or low allergenic potential. This is also supported by recent bioinformatic studies carried out by the Swedish National Food Administration using a newly developed methodology (Soeria-Atmadja *et al*., 2004; Bjorklund *et al*., 2005) showing the absence of sequence homology between Cry1Ac and known allergens (unpublished results).

In the same mouse model, Cry1Ab has been shown to act as an adjuvant *e.g.* it enhances the mucosal and/or the systemic antibody response to a protein which is co-administered with the Cry protein (Vazquez *et al*., 1999b; Moreno-Fierros *et al*., 2003). As maize is not a common allergenic food and as the newly expressed proteins present in maize1507 x NK603 have not been shown to be allergenic, any adjuvant effect of Cry proteins, observed after high dosage intragastric or intranasal administration will not raise any concerns regarding allergenicity.

4.2.5.2 Assessment of allergenicity of the whole GM plant or crop

Risk assessment of the whole GM plant must consider whether allergenicity of the whole crop could be increased as an unintended effect of the random insertion of the transgene in the genome of the host, for example through qualitative or quantitative modification of the pattern of expression of endogenous proteins. Such unintended effects may occur at each genetic modification (*i.e.* in maize 1507 and in NK603). The issue of a potential increased allergenicity

of maize 1507 x NK603 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 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.

4.2.6. Nutritional assessment of GM food/feed

In previous assessments the nutritional equivalence between maize 1507 or maize NK603 and their respective non-GM comparators was established (EFSA, 2003a,b; 2004a; 2005a,b).

A total of 840 Ross/Cobb commercial broiler chicks were used in a 42-day study to evaluate the nutritional characteristics of maize grain derived from the GM maize 1507 x NK603. The study consisted of seven treatments in which maize grain derived from crops treated with either two consecutive applications of glyphosate or two consecutive applications of glufosinate-ammonium or one application each of both herbicides were compared with grain produced from a near-isogenic non-GM variety and three commercial hybrids. Each treatment consisted of 12 replicates each of which contained 10 broilers (5 male and 5 female), which gave 120 broilers/treatment. Study diets were formulated to National Research Council (NRC) requirements and contained 53 to 62% maize grain. Animal performance on the various diets were evaluated by measuring feed intake, mortality, weight gain, carcass yields (pre and post chill) for thighs, breasts, wings, abdominal fat, kidney and liver, and feed efficiency. The comprehensive data provided during the starter, growing and finishing periods, in which the growth and performance of broilers fed control, reference and test diets were compared, supports the conclusion that the transgenic maize 1507 x NK603 is nutritionally comparable with its near-isogenic non-GM counterpart and the commercial varieties included in the study.

4.2.7. Post-market monitoring of GM food/feed

Maize 1507 x NK603 is intended to have improved agronomic properties. From a nutritional point of view, maize 1507 x NK603 is equivalent to conventional maize and will be used as any other maize. The risk assessment concluded that maize 1507 x NK603 is as safe as its non-GM comparators. The GMO Panel is of the opinion that a post-market monitoring of the GM food/feed is not regarded necessary.

4.2.8. Residues and metabolites of the herbicides

A Member State raised the issue of the possible occurrence of glufosinate and glyphosate residues and their metabolites in maize 1507 x NK603, and the effects of these compounds on animal and human health, and the environment. The GMO Panel recognizes the importance of the issue and notes that the risk assessment of such compounds is within the scope of Directive 91/414/EEC (EC, 1991).

4.3. Conclusion

Evidence has been provided in previous evaluations that there is no acute toxicity from the Cry1F, PAT and CP4 EPSPS proteins. The results of 90-day sub-chronic rodent studies in rats with 1507 and NK603 maize, respectively, have been assessed in previous applications by the GMO panel and do not indicate adverse effects from consumption of 1507 and NK603 maize.

No new genes in addition to those occurring in the parental maize lines have been introduced in maize 1507 x NK603. The molecular characterization of 1507 x NK603 revealed no unexpected changes. No interactions between the newly expressed proteins were identified, or any risks from altered allergenicity. In addition, no relevant differences in composition between 1507 x NK603 maize and its appropriate non-transgenic comparators were found. The GMO Panel therefore accepts the applicant's argument that no rodent toxicity study with grains of 1507 x NK603 is required to conclude that 1507 x NK603 maize is as safe for human and animal health as conventional maize.

1507 and NK603 maize have been studied in separate nutritional feeding studies with broilers and showed no adverse effects. A 42-day feeding study on broiler chicken with 1507 x NK603 was also adequate to establish nutritional equivalence, confirmed that the nutritional properties of maize 1507 x NK603 would be no different from those of conventional maize.

An allergy risk evaluation of the CP4 EPSPS and Cry1Ab proteins was completed, providing indirect evidence for a low probability of allergenicity. A hypothetical altered allergenicity of the whole crop due to the genetic modification does not appear to be relevant to the GMO Panel since maize is not considered a common allergenic food.

The GMO Panel concludes that maize 1507 x NK603 is as safe and nutritious as conventional counterparts.

5. Environmental risk assessment and monitoring plan

5.1. Issues raised by Member States

Comments from Member States included the following: (1) a need to address the impact of unintended release and the effects of the combination of newly expressed proteins on non-target species; (2) a need to address the consequence of water and soil exposure to the toxins present in maize 1507 x NK603 via organic waste material and litter or sewage, which occur during processing or through spillage; (3) a need for a more detailed post-market monitoring plan including more details on general surveillance methods.

5.2. Evaluation of relevant scientific data

5.2.1. Evaluation of the single events

1507 and NK603

The assessed notifications C/NL/00/10 for maize 1507 and C/ES/00/01 for maize NK603 concerned import, while notification C/ES/01/01 for maize 1507 includes cultivation. Thus, there was no requirement for scientific information on possible environmental effects associated with the cultivation of maize NK603. The GMO Panel agreed with the conclusions of the environmental risk assessment by the applicant that the likelihood of unintended environmental effects due to the adventitious release and spread of NK603 maize will not be different from that of traditionally bred maize. Moreover, a monitoring plan including general surveillance was proposed by the applicant and accepted by the EFSA GMO Panel for maize 1507. In conclusion, the Panel having considered all the evidence provided, was of the opinion that maize 1507 and maize NK603 are as safe as conventional maize and therefore their placing on the market for food or feed or processing and, in the case of 1507, for cultivation, is unlikely to have an adverse effect on human or animal health or, in that context, on the environment (EFSA, 2003a,b; 2004a; 2005a,b).

5.2.2. Environmental risk assessment

5.2.2.1. 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 parts of Europe. They have lost their ability to release seeds from the cob and they do not occur outside cultivated or disturbed land in Europe, despite cultivation for many years. In addition, there are no cross-compatible wild relatives in Europe, and gene flow via pollen is largely restricted to neighbouring crops.

This application is for food and feed uses, import and processing only. Maize is a hybrid crop and thus imported grain will be a segregated F2 generation with individual grains containing differing levels of the transgenic components of this hybrid. The herbicide tolerance traits can only be regarded as providing a selective advantage where and when glufosinate-ammonium or glyphosate containing herbicides are applied, *e.g.* on arable land. Insect protection against lepidopteran pests is also not regarded as providing a selective advantage for maize in Europe, as survival is mainly determined by the absence of a dormancy phase, susceptibility to diseases and susceptibility to cold climate conditions. Therefore it is considered very unlikely that volunteers of this GM maize or its progeny will differ from conventional hybrid maize in their ability to survive until subsequent seasons or establish undesirable populations under European environmental conditions.

Since maize 1507 x NK603 has no altered survival, multiplication or dissemination characteristics except in the presence of the specific herbicide or target organisms, the Panel is of the opinion that the likelihood of unintended environmental effects due to the establishment and spread of this maize will be no different to that of 1507 or NK603 maize and conventional maize varieties.

5.2.2.2. Potential for gene transfer

A prerequisite for any horizontal gene transfer is the availability of pathways for the transfer of transgenic DNA.

Exposure of microorganisms to transgenic DNA derived from GM maize plants takes place in the environment during natural decay of the plant material in agricultural areas. In addition transgenic DNA is a component of many of the food and feed products derived from the 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.

Gene flow between plants can occur when transgenic pollen is shed and distributed from cultivated GM maize or from plants resulting from the adventitious presence of GM kernels in conventionally bred maize seeds. A further but less likely pathway of dispersal of transgenic maize pollen is the flowering of volunteer GM maize plants originating from accidental spillage of GM seed during transport and/or processing. For *Zea mays* any vertical gene transfer is limited to other maize plants as populations of sexually compatible wild relatives of maize are not known in Europe.

(a) Plant to bacteria gene transfer

Based on present scientific knowledge and elaborated recently in more detail (EFSA, 2004c), gene transfer from GM plants to bacteria under natural conditions is extremely unlikely, and would occur primarily through homologous recombination in microbes.

The *cry*1F, *pat,* and *cp4 epsps* genes are under the control of eukaryotic promoters with little or no activity in prokaryotic organisms. Genes under control of prokaryotic regulatory elements conferring the same traits as expressed in the GM plants are widespread in microorganisms in natural environments.

Taking into account the origin and nature of the *cry, pat* and *cp4 epsps* genes and the lack of selective pressure in the intestinal tract and/or the environment, the likelihood that horizontal gene transfer would result in increased fitness on microorganisms or other selective advantages is very small. For this reason it is very unlikely that *cry, pat* and *cp4 epsps* genes from maize 1507 x NK603 would become established in the genome of microorganisms in the environment or in the human and animal digestive tract. In the very unlikely event that such a horizontal gene transfer would take place, no adverse effects on human and animal health and the environment are expected as no specifically new traits would be introduced into microbial communities.

(b) Plant to plant gene transfer

Transgenic pollen is shed and distributed from cultivated GM hybrids or from plants resulting from the adventitious presence of GM kernels in conventionally bred maize seeds. A further but less likely pathway of dispersal of transgenic maize pollen is the flowering of volunteer GM maize plants originating from accidental seed spillage during transport and/or processing. The extent of cross-pollination to conventionally bred hybrids will mainly depend on the scale of accidental release and/or adventitious presence in conventional seeds. For *Zea mays* any vertical gene transfer is limited to other maize plants as populations of sexually compatible wild relatives of maize are not known in Europe.

The applicant's field trials have shown that there are no indications for an altered fitness of the GM maize in comparison to conventionally bred hybrids with similar genetic background.

Insect protection against lepidopteran pests is also not regarded as providing a selective advantage for maize in Europe, as maize survival is mainly limited by the absence of a dormancy phase, susceptibility to disease and susceptibility to cold climate conditions. Therefore, as for any other maize cultivars, volunteers would only survive in subsequent seasons in the warmer regions of Europe and are not likely to establish feral or undesirable populations under European environmental conditions.

Studies in Europe and elsewhere with maize 1507 and maize NK603 have not shown any enhanced weediness or fitness, except in the presence of the specific herbicides.

Since enhanced survival, multiplication or dissemination characteristics are only likely when maize 1507 x NK603 is cultivated in the presence of the specific herbicides or target insects, the Panel is of the opinion that the likelihood of unintended environmental effects due to the establishment and spread of this maize in Europe will be no different to that of maize 1507 or maize NK603 and conventionally bred maize.

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

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 of animals fed on this maize. Data supplied by the applicant and literature on other Cry proteins (Ahmad *et al*., 2005 and references therein; Lutz *et al*., 2005) suggests that most proteins would be degraded by the enzymatic activity in the gastrointestinal tract so that 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). Thus

exposure of potentially sensitive non-target organisms to the Cry1F toxin is likely to be very low and of no ecological significance. No evidence of released Bt toxins, PAT or EPSPS proteins causing significant negative effects on soil microorganisms has been published.

5.2.3. Monitoring

The objectives of a monitoring plan according to Annex VII of Directive 2001/18/EC (EC, 2001) 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. The scope of the monitoring plan provided by the applicant is in line with the intended uses for the GMO since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental impacts.

General surveillance is related to risk management, and thus a final adoption of the general surveillance plan falls outside the mandate of EFSA. However, the GMO Panel gives its opinion on the scientific quality of the general surveillance plan provided by the applicant. The only significant exposure of the environment to the transgenic maize would be related to accidental spillage.

Since the main use of maize 1507 x NK603 will be animal feeds, the applicant proposed that general surveillance should concentrate on monitoring the health of those exposed to the processing of the animal feed as well as the animals fed on this maize.

The GMO Panel recommends that the applicant should consider appropriate management and monitoring systems to restrict environmental exposure of viable grains, as recommended by the EFSA Guidance on post-market environmental monitoring (EFSA, 2006). In other respect the GMO Panel is of the opinion that the general approaches and measures of the monitoring plan proposed by the applicant are in line with the intended uses of maize 1507x NK603 since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects.

5.3. Conclusion

Maize 1507 x NK603 is being assessed for import, processing and uses as food/feed and thus there is no requirement for scientific information on environmental effects associated with cultivation. Maize is highly domesticated and not able to survive in the environment without cultivation. The GMO Panel considered the environmental comments raised by the Member States in the above sections of Chapter 5 and concludes as follows: the likelihood of the establishment and spread of this maize is very low and the unintended environmental effects due to this GM maize will be no different to that of conventional maize varieties. The GMO Panel also considers unlikely that the newly expressed proteins will have any adverse effects on the environment, including on non target organisms.

The scope of the monitoring plan provided by the applicant is in line with the intended uses for the GMO since this does not include cultivation. The GMO Panel recommends that the applicant should consider appropriate management and monitoring systems to restrict environmental exposure of viable grains.

CONCLUSIONS AND RECOMMENDATIONS

The GMO Panel assessed maize 1507 x NK603, which is produced by a cross between inbred lines of maize containing the 1507 and NK603 events, for food and feed uses, import and processing. Maize 1507 and maize NK603 were evaluated previously (EFSA, 2003a,b; 2004a; 2005a,b). Both maize NK603 and maize 1507 have been authorized by the European Commission (EC, 2004a; 2005a,b; 2006). In assessing the maize 1507 x NK603, both the single events and the maize 1507 x NK603 were considered. The Panel concluded that it was acceptable to use data for the single events 1507 and NK603 in support of the safety assessment of the maize 1507 x NK603 and that the information available for maize 1507 x NK603 addresses the scientific comments raised by the Member States.

The Panel considers that the maize 1507 x NK603 is as safe as its conventional counterparts with respect to effects on human and animal health and the environment and therefore concludes that this maize is unlikely to have any adverse effect on human and animal health and the environment in the context of its indented uses.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the UK Competent Authority (Food Standards Agency), dated 1 October 2004 concerning the submission to EFSA of application maize 1507 x NK603 within the framework of Regulation (EC) No 1829/2003.

2. Letter from EFSA to applicant, dated 11 November 2005, requesting additional information during the completeness check (Ref. SR/MR/jq/ (2004) 959).

3. Letter from applicant to EFSA, dated 12 January 2005, providing the information requested during the completeness check.

4. Letter from EFSA to applicant, dated 1 April 2005, concerning the "Statement of Validity" for application EFSA-GMO-UK-2004-05 on maize 1507 x NK603 submitted under Regulation (EC) No 1829/2003 (Ref. SR/KL/jq (2005) 065).

5. Submission of the application EFSA-GMO-UK-2004-05 by the applicant to EFSA, containing:

   Part I – technical dossier
   Part II – summary
   Part III – Cartagena Protocol
   Part IV – labelling proposal
   Part V – samples and detection method
   Part VI – additional information for GMOs

6. Letter from CRL (IHCP-JRC), dated 22 March 2005, concerning the completeness of application EFSA-GMO-UK-2004-05 in accordance with Article 5(3)(i) and (j) and Article 17(3)(i) and (j) of Regulation (EC) 1829/2003 (JRC 106-BGMO/GVDE/ D (2005)(70)6949).

7. Letter from EFSA to applicant, dated 15 July 2005, to stop the clock, requesting additional information for application EFSA-GMO-UK-2004-05 on 1507 x NK603 maize submitted under Regulation (EC) No 1829/2003 (Ref. SR/AC/jq/ (2005) 944).

8. Comments of the Member States, including the national Competent Authorities within the meaning of Directive 2001/18/EC following the requirements of Article 6(4) and 18(4) of Regulation (EC) No 1829/2003 (GMO EFSAnet).

9. Letter from applicant to EFSA, dated on 28 September 2005, providing additional information requested on 15 July, in the context of application EFSA-GMO-UK-2004-05 on 1507 x NK603 maize submitted under Regulation (EC) No 1829/2003 .

10. Letter from EFSA to applicant, dated 24 October 2005, requesting complete additional information for application EFSA-GMO-UK-2004-05 on 1507 x NK603 maize submitted under Regulation (EC) No 1829/2003 (Ref. SR/AC/KL/jq/ (2005) 1264).

11. Letter from applicant to EFSA, dated on 3 February 2006, providing the complete additional information requested on 15 July, in the context of application EFSA-GMO-UK-2004-05 on 1507 x NK603 maize submitted under Regulation (EC) No 1829/2003.

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