

## SCIENTIFIC OPINION

**Application (Reference EFSA-GMO-UK-2005-21) for the placing on the market of the insect-resistant and herbicide-tolerant genetically modified maize 59122 x 1507 x NK603 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International, Inc.**

**Scientific opinion of the Panel on Genetically Modified Organisms**

**(Question No EFSA-Q-2005-248)**

**Adopted on 03 April 2009**

### SUMMARY

Following a request from 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, glyphosate- and glufosinate-tolerant genetically modified maize 59122 x 1507 x NK603 (Unique Identifier DAS-59122-7 x DAS-Ø1507-1 x MONØØ6Ø3-6) for food and feed uses, import and processing

In delivering its scientific opinion, the GMO Panel considered the new application EFSA-GMO-UK-2005-21, additional information provided by the applicant (Pioneer Hi Bred) and the scientific comments submitted by the Member States. Further information from applications for placing the single insert lines 59122, 1507 and NK603 on the market under EU regulatory procedures was taken into account where appropriate. The scope of application EFSA-GMO-UK-2005-21 is for food and feed uses, import and processing of genetically modified maize 59122 x 1507 x NK603 and all derived products, but excluding cultivation in the EU.

The GMO Panel assessed maize 59122 x 1507 x NK603 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, 2006) 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 characterisation 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 were also undertaken.

Maize 59122 was developed to express 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. 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 1507 maize on the market for food use received authorization under Regulation 1829/2003 with Commission Decision 2006/197/EC. Maize NK603 was developed to be tolerant to glyphosate by the introduction of the gene coding for 5-enolpyruvylshikimate-3-phosphate synthase proteins (CP4 EPSPS and CP4 EPSPS L214P) from *Agrobacterium* sp. strain CP4. Maize NK603 has received an opinion 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 59122 x 1507 x NK603 was produced by crosses between maize inbred lines containing 59122, 1507 and NK603 events to combine resistance to certain coleopteran species (59122 trait) and certain lepidopteran species (1507 trait), and to confer tolerance to glyphosate (NK603 trait) and glufosinate ammonium (59122 and 1507 trait) herbicide.

The molecular characterisation data established that the structure of the individual inserts in the stacked hybrid maize 59122 x 1507 x NK603 was the same as for the individual events 59122, 1507 and NK603. This indicates stability of the individual events in the stacked hybrid. Appropriate analyses of the integration sites in maize 59122 x 1507 x NK603, including flanking regions, was 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 59122 x 1507 x NK603 maize is compositionally and agronomically equivalent to conventional maize, except for the presence of Cry34Ab1, Cry35Ab1, Cry1F, CP4 EPSPS, CP4 EPSPS L214P and PAT proteins in maize 59122 x 1507 x NK603. Based on the assessment of data available, including the additional information provided by the applicant in response to the Panel request, for 59122 x 1507 x NK603 maize, for the single events and for appropriate non-GM controls, the GMO Panel has found no indication that crossing of NK603 maize, 1507 maize and 59122 maize results in an interaction of the newly expressed proteins which causes compositional or agronomic changes. The Cry34Ab1, Cry35Ab1 and PAT proteins expressed in the parental maize line 59122, the Cry1F and PAT proteins expressed in the parental maize 1507, as well as the CP4 EPSPS and CP4 EPSPS L214P present in the NK603 parental maize line 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 59122 x 1507 x NK603 maize would be no different from those of conventional maize. Nutritional value of 59122 x 1507 x NK603 maize has been studied in a feeding study with broilers which confirmed that the nutritional properties of 59122 x 1507 x NK603 maize would be no different from those of conventional maize. In conclusion the Panel considers that

maize 59122 x 1507 x NK603 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 59122 x 1507 x NK603 is unlikely to have any adverse effect on human and animal health in the context of its intended uses.

The application EFSA-GMO-UK-2005-21 concerns food and feed uses, import and processing, but excluding cultivation in the EU. There are no indications of increased likelihood of establishment or survival of feral maize plants in case of accidental release into the environment of 59122 x 1507 x NK603 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 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 59122 x 1507 x NK603 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 59122 x 1507 x NK603 maize 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 59122 x 1507 x NK603 maize 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, 59122, 1507, NK603, glufosinate, glyphosate, human and animal health, environment, import, processing, food, feed, Regulation (EC) No 1829/2003, Cry1F, Cry34Ab1, Cry35Ab1, PAT, CP4 EPSPS, CP4 EPSPS L214P.