

Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds¹
(Question No EFSA-Q-2004-072)

Opinion adopted on 19 January 2005

SUMMARY

This document provides an opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on 1507 maize, genetically modified to provide protection against specific lepidopteran pests. The maize also contains a gene providing tolerance to the herbicide glufosinate.

The opinion is based on a question raised by the Commission relating to an application for the placing on the market of 1507 maize under Directive 2001/18/EC. The GMO Panel was asked to consider whether there is any scientific reason to believe that placing 1507 maize on the market, for cultivation, import, processing and use as any other maize (excluding food uses), is likely to cause any adverse effects on human health and the environment (Notification C/ES/01/01). The question followed a scientific assessment which was made initially by the Competent Authorities of Spain and evaluated subsequently by all other Member States. An assessment of the 1507 maize was requested by the Commission because of questions raised by several Member States following the evaluations at the national level. When this is the case, EU legislation requires that EFSA carries out a further assessment and provides an opinion.

In delivering its opinion the Panel considered the notification, additional information provided by the applicant and the specific questions and concerns raised by the Member States. Further information from other applications for the placing on the market of 1507 maize under current regulatory procedures were taken into account where appropriate, as were comments from the Member States. The information from other applications were notification C/NL/00/10 for import and processing and an application under the novel foods Regulation (EC) 258/97 which was transformed into application EFSA-GMO-NL-2004-02 for the authorisation of food products under Regulation (EC) No 1829/2003 on GM food and feed. For regulatory reasons the latter applications resulted in separate opinions.

1507 maize was assessed with reference to its intended use employing the appropriate principles as 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, 2004b). The scientific assessment included examination of the DNA inserted

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into 1507 maize and the nature and safety of the target proteins produced by the transgenic plants with respect to toxicology and allergenicity. Furthermore, a comparative analysis of agronomic traits and composition was undertaken and the safety of the whole feed was evaluated. A nutritional and an environmental assessment, including monitoring plan, were both undertaken.

1507 maize has been developed for protection against specific lepidopteran pests such as the European corn borer (*Ostrinia nubilalis*) and *Sesamia* spp. 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 *cry1F* and *pat* genes, under the control of the maize ubiquitin and the 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 *cry1F* 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.

Analysis of kernel chemical composition from field trials in South America and Europe showed that 1507 maize was substantially equivalent to its non-GM comparator. Furthermore, appropriate animal feeding trials indicated that 1507 maize is nutritionally equivalent to its non-GM comparator.

Notification C/ES/01/01 concerns cultivation, import, processing and use as any other maize, excluding food uses. 1507 maize is comparable with maize bred traditionally, except for the expression of tolerance to glufosinate herbicide and certain lepidopterans. Maize does not colonise and rarely survives outside the cultivated environment. It is winter-hardy only in parts of Southern Europe, and it has no cross-compatible wild relatives in Europe. Therefore, no unintended environmental effects due to the establishment and spread are anticipated. The likelihood of adverse effects on non-target organisms or on soil functions due to the expression of the *cry* gene or the *pat* gene is considered to be very low. The possible development of resistance of target organisms to *Bt* toxin has been identified as a potential risk due to large scale cultivation and/or long term exposure. Thus, an appropriate case-specific monitoring plan to record the development of resistance has been provided. In addition, the GMO Panel agrees in principle with the approach proposed by the applicant in the general surveillance plan.

In conclusion, the Panel considers that the information available for 1507 maize addresses the outstanding questions raised by the Member States and considers that 1507 maize will not have an adverse effect on human and animal health or the environment in the context of its proposed use.

Key words: GMO, maize, *Zea mays*, 1507, insect protection, Cry1F, PAT, feed safety, human health, cultivation, environment, import, Regulation (EC) 258/97, Regulation (EC) 1829/2003, Directive 90/220/EEC, Directive 2001/18/EC.