

Response to the request from the European Commission on the non- authorised genetically modified event DAS 59132-8 in US maize¹

Scientific opinion of the Panel on Genetically Modified Organisms

(Question No EFSA-Q-2008-216)

Adopted on 22 May 2008

SUMMARY

Following a request from the European Commission, the Panel on Genetically Modified Organisms was asked to deliver a scientific opinion on the non-authorised genetically modified maize event DAS 59132-8 found at low levels in certain maize hybrid lines of DAS 59122-7 in the US. Adventitious presence of DAS 59132-8 in DAS 59122-7 has until now not been found in Europe. The scope of the authorised use of 59122 maize includes import and processing for food, feed and industrial uses and excludes cultivation.

The maize events DAS 59132-8 and DAS 59122-7 have been developed by using the same genes and vector constructs as well as the same transformation process. Both maize events were produced by *Agrobacterium*-mediated transformation technology to express Cry34Ab1, Cry35Ab1 and PAT proteins. The GMO Panel has adopted an opinion on the maize event 59122 on 23 March 2007 concluding that, with regard to import and processing for food, feed and industrial uses, it is as safe as its non-genetically modified counterparts.

Limited information was available on maize event DAS 59132-8. The molecular characterisation established that maize DAS 59132-8 contains a single insert of the T-DNA. The structure of the insert was determined by Southern analysis and the results indicated that the insert was truncated up to 200 bp from the ubiquitin promoter driving *cry34Ab1* transcription. No vector backbone was detected. The 3'-junction was sequenced. No bioinformatic analysis was provided, which does not allow any conclusions about the insertion site in the maize genome. The summary of the expression data indicates that the expression of Cry34Ab1 is lower and that of Cry35Ab1 higher than in the maize event DAS 59122-7.

No studies concerning safety as food and feed, or safety to the environment were provided on DAS 59132-8 to draw conclusions about the safety of this particular maize event.

In conclusion, the available data are not sufficient to allow a full risk assessment of DAS 59132-8 in accordance with the EFSA guidance document for the risk assessment of GM plants. However, taking the data from a similar maize event DAS 59122-7 into account, and considering that the level of DAS 59132-8 in certain maize hybrid lines is low (less than 3 seeds/1000 seeds), the GMO Panel concludes that it is unlikely that there is a specific risk for human health or the environment from exposure to maize event DAS 59132-8 occurring as an admixture in maize DAS 59122-7 imported for food and feed purposes.

¹ For citation purposes: Scientific Opinion of the Panel on Genetically Modified Organisms on a request from the European Commission on the non-authorised genetically modified event DAS 59132-8 in US maize. *The EFSA Journal* (2008) 713, 1-2

Key words: GMO, maize, insect resistance, glufosinate ammonium, Cry34Ab1, Cry35Ab1, PAT protein, *pat* gene, DAS 59132-8, DAS 59122-7, human and animal health, environment, Regulation (EC) No. 1829/2003.