

Application (Reference EFSA-GMO-UK-2005-11) for the placing on the market of insect-resistant genetically modified maize MIR604 event, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Seeds S.A.S on behalf of Syngenta Crop Protection AG

Scientific Opinion of the Panel on Genetically Modified Organisms

(Question No EFSA-Q-2005-046)

Adopted on 2 July 2009

SUMMARY

Following a request from Syngenta Seeds S.A.S on behalf of Syngenta Crop Protection AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to deliver a scientific opinion on the authorisation of the insect-resistant genetically modified maize MIR604 (Unique Identifier SYN-IR604-5) for food and feed uses, import and processing.

In delivering its scientific opinion, the EFSA GMO Panel considered the new application EFSA-GMO-UK-2005-11, additional information provided by the applicant and the scientific comments submitted by the Member States. The scope of application EFSA-GMO-UK-2005-11 is for food and feed uses, import and processing of genetically modified maize MIR604 and all derived products, but excluding cultivation in the EU.

The EFSA GMO Panel assessed maize MIR604 with reference to the intended uses and 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 the newly expressed proteins. A comparative analysis of agronomic traits and composition was undertaken, and the safety of the new proteins and the whole food/feed were 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 MIR604 was engineered with a modified *cry3A* coding sequence (*mcry3A*) derived from *Bacillus thuringiensis* subsp. *tenebrionis* that encodes an insecticidally active mCry3A protein conferring resistance to the Western Corn rootworm (WCR) (*Diabrotica virgifera virgifera*) and other related coleopteran pests of maize like the Northern Corn rootworm (NCR) (*Diabrotica barberi*). In addition maize MIR604 was engineered with the *pmi* (*manA*) gene from *Escherichia coli*, which encodes the enzyme PMI (PhosphoMannose Isomerase) as a selectable marker. PMI allows transformed maize cells to utilize mannose as a sole carbon source, while maize cells lacking the *pmi* gene fail to grow with mannose as single carbon source.

The molecular characterisation data established that a single insert with one copy of the expression cassette containing the *mCry3A* gene and the *pmi* gene is integrated in the maize genomic DNA. Appropriate analyses of the integration site including sequence determination of the inserted DNA and flanking regions. Bioinformatic analysis of junction regions demonstrated the absence of any potential new ORFs coding for known toxins or allergens. The expression of the gene introduced by genetic modification has been sufficiently analysed and the stability of the genetic modification has been demonstrated over several generations. The EFSA GMO Panel is of the opinion that the molecular characterisation of the DNA insert and flanking regions of maize MIR604 does not raise any safety concern, and that sufficient evidence for the stability of the genetic modification was provided.

Based on the results of the comparative analysis of samples from a representative range of environments and growing seasons, it is concluded that maize MIR604 is compositionally, phenotypically and agronomically equivalent to conventional maize varieties, except for the presence of the PMI and mCry3A proteins.

The functional characteristics and the potential toxicity and allergenicity of the newly expressed PMI protein have been explored through various studies, for which *in-vitro*, *in-vivo*, and bioinformatic-supported methods have been employed. It was concluded that the PMI protein did not show characteristics that would indicate potential toxicity or allergenicity.

A subchronic (90-day) feeding study revealed no indications of adverse effects in rats fed diets containing grains from maize MIR604. In addition, a feeding study in broiler chickens provided evidence of nutritional equivalence of maize MIR604 to conventional maize. These studies, therefore, support the conclusion of the compositional and agronomical comparison that the genetic modification resulted in no unintended effects.

The application EFSA-GMO-UK-2005-11 concerns food and feed uses, import and processing, but excludes 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 maize MIR604 viable grains 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 MIR604 since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. Furthermore the EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in the general surveillance plan.

In conclusion, the EFSA GMO Panel considers that the information available for maize MIR604 addresses the scientific comments raised by Member States and that maize MIR604 is as safe as its conventional counterpart with respect to potential effects on human and animal health or the environment. Therefore the EFSA GMO Panel concludes that maize MIR604 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 (*Zea mays*), MIR604, insect-resistant, mCry3A, PMI, import, processing, food safety, feed safety, human and animal health, environment, Regulation (EC) No 1829/2003