

Applications (EFSA-GMO-RX-MON810) for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto

Scientific Opinion of the Panel on Genetically Modified Organisms

(Question No EFSA-Q-2007-150, EFSA-Q-2007-153, EFSA-Q-2007-164)

Adopted on 15 June 2009

SUMMARY

This document provides a scientific opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on 3 applications submitted under Regulation (EC) No 1829/2003 for renewal of the authorisation of (1) existing food and food ingredients produced from genetically modified (GM) maize MON810 (Unique Identifier MON-ØØ81Ø-6); (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, developed by Monsanto to provide resistance to lepidopteran target pests.

The scopes of the 3 renewal applications cover the continued marketing of:

- existing food and food ingredients produced from maize MON810 (Reference EFSA-GMO-RX-MON810_[8-1a]) that have been placed on the market in accordance with Article 5 of Regulation (EC) No 258/97;
- feed consisting of and/or containing maize MON810 that were authorised under Directive 90/220/EEC (Commission Decision 98/294/EC), including the use of seed for cultivation (Reference EFSA-GMO-RX-MON810_[20-1a]);
- food additives produced from maize MON810 that were authorised under Directive 89/107/EEC, and feed produced from maize MON810, i.e., feed additives lawfully placed on the market under Directive 70/524/EEC and feed materials (Reference EFSA-GMO-RX-MON810_[8-1b/20-1b]).

After the date of entry into force of the Regulation (EC) No 1829/2003, the products mentioned above were notified to the European Commission according to Articles 8 or 20 of this Regulation and subsequently included in the Community Register of GM food and feed.

Maize MON810 expresses a Cry1Ab insecticidal protein, derived from *Bacillus thuringiensis* subsp. *kurstaki*, which confers protection against lepidopteran target pests such as the European corn borer (*Ostrinia nubilalis*) and species belonging to the genus *Sesamia*.

In delivering its scientific opinion, the EFSA GMO Panel considered the 3 renewal applications (EFSA-GMO-RX-MON810_[8.1.a], EFSA-GMO-RX-MON810_[20.1.a] and EFSA-GMO-RX-MON810_[8.1.b/20.1.b]); additional information supplied by the applicant; the scientific comments submitted by Member States; the report of the Spanish Competent Authority and its Biosafety Commission; and relevant information published in the scientific literature.

The EFSA GMO Panel assessed maize MON810 with reference to the intended uses and appropriate principles described in the guidance document of the EFSA GMO Panel for the risk assessment of GM 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 protein 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 were undertaken.

Maize MON810 was generated by particle acceleration technology. Maize MON810 expresses a *cry1Ab* coding sequence that encodes an insecticidally active Cry1Ab protein. The molecular characterisation data established that a single insert is integrated in the maize genomic DNA. Appropriate analyses of the integration site including sequence determination of the inserted DNA and flanking regions and bioinformatic analysis have been performed. Updated bioinformatic analysis of junction regions demonstrated the absence of any potential new open reading frames coding for proteins known to be toxic for humans and other mammals and/or allergens. The expression of the genes 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 MON810 does not raise any safety concern, and that sufficient evidence for the stability of the genetic modification was provided.

Analyses carried out on materials from maize MON810, including stacked GM maize events where maize MON810 was one of the parental lines, and their comparators indicate that maize MON810 is compositionally, phenotypically and agronomically equivalent to the non-GM counterparts and conventional maize, except for the newly expressed trait.

The Cry1Ab protein shows no homology with proteins known to be toxic for humans and other mammals and/or allergens. In addition, this protein is rapidly degraded under simulated gastric conditions. Furthermore, the Cry1Ab protein has been extensively assessed in previous opinions of the EFSA GMO Panel. No concerns for humans and animals were identified regarding the safety of the Cry1Ab protein.

In a 90-day feeding study in rats, no indications of adverse effects were observed. In addition, a 42-day broiler feeding study provided evidence of nutritional equivalence of maize

MON810 kernels to kernels of conventional maize. The toxicological and nutritional data on maize MON810 and appropriate non-GM maize control published during the last 10 years confirm that these maize varieties have comparable influence on the test systems. Therefore, the EFSA GMO Panel is of the opinion that maize MON810 is as safe as its non-GM counterparts and that the overall allergenicity of the whole plant is not changed through the genetic modification.

The Spanish Competent Authority and its Biosafety Commission provided to EFSA its report on the environmental risk assessment in line with Articles 6.3(e) and 18.3(e) of Regulation (EC) No 1829/2003. The Spanish Competent Authority and its Biosafety Commission conclude that *“according to the current state of scientific knowledge and after examining the existing information and the data provided by the Monsanto Company, the Spanish Commission on Biosafety could give a favourable opinion to the renewal of commercialisation in the EU of maize MON810 if the proposals and conditions defined in this environmental risk assessment report are implemented”*.

Since maize MON810 has no altered survival, multiplication or dissemination characteristics, the EFSA GMO Panel agrees with the assessment that the likelihood of unintended environmental effects due to the establishment and spread of maize MON810 will be no different from that of conventional maize varieties.

On the basis of the data provided by the applicant and obtained from a literature survey and a modelling exercise on the effect of the cultivation of maize MON810 on non-target lepidopteran species in representative maize cultivation regions in the European Union (EU), the EFSA GMO Panel concludes that the likelihood of adverse effects on non-target organisms or on ecological functions is very low, especially if appropriate mitigation measures are adopted. In agreement with the environmental risk assessment by the applicant and the assessment conducted by the Spanish Competent Authority and its Biosafety Commission, the EFSA GMO Panel identifies the possible evolution of resistance in target species, as a potential risk linked to the cultivation of maize MON810.

In conclusion, the EFSA GMO Panel considers that the information available for maize MON810 addresses the scientific comments raised by Member States and that maize MON810 is as safe as its conventional counterpart with respect to potential effects on human and animal health. The EFSA GMO Panel also concludes that maize MON810 is unlikely to have any adverse effect on the environment in the context of its intended uses, especially if appropriate management measures are put in place in order to mitigate possible exposure of non-target Lepidoptera. Moreover, the EFSA GMO Panel advises that pest resistance management strategies continue to be employed.

Key words: GMO, maize (*Zea mays*), MON810, insect resistant, Cry1Ab, food safety, feed safety, human and animal health, environment, Regulation (EC) No 1829/2003, Directive 2001/18/EC, Directive 90/220/EEC, renewal, existing products