

## SCIENTIFIC OPINION

### **Statement complementing the EFSA GMO Panel scientific opinion on maize MON 89034 x 1507 x NK603 (application EFSA-GMO-NL-2009-65), to cover all sub-combinations independently of their origin<sup>1</sup>**

#### **EFSA Panel on Genetically Modified Organisms<sup>2,3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### **SUMMARY**

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to complement its scientific opinion on insect resistant and herbicide tolerant genetically modified (GM) maize MON 89034 x 1507 x NK603 (application EFSA-GMO-NL-2009-65) issued in 2010, to cover all sub-combinations independently of their origin. The EFSA GMO Panel scientific opinion covered the safety assessment of maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny, for food and feed uses, import and processing under Regulation (EC) No 1829/2003. Each single event present in maize MON 89034 x 1507 x NK603 and two of the three possible sub-combinations, namely maize 1507 x NK603 (EFSA-GMO-UK-2004-05) and maize MON 89034 x NK603 (EFSA-GMO-NL-2007-38), were previously assessed by the EFSA GMO Panel. In view of the European Commission's request and, having considered all relevant available information on maize MON 89034 x 1507 x NK603 and on the single maize events, the EFSA GMO Panel considers it unlikely that the sub-combinations have an adverse effect on human and animal health and the environment in the context of their intended uses, which cover food and feed uses, import and processing. This conclusion was further supported by the previous assessments of maize 1507 x NK603 and maize MON 89034 x NK603. The EFSA GMO Panel concludes that the present statement can complement the scientific opinion on maize MON 89034 x 1507 x NK603 to cover all sub-combinations independently of their origin.

© European Food Safety Authority, 2011

<sup>1</sup> On request from the European Commission to complement the EFSA overall opinion on maize MON 89034 x 1507 x NK603 to cover all sub-combinations independently of their origin, Question No EFSA-Q-2011-00169, adopted on 08 September 2011.

<sup>2</sup> Panel members: Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Patrick du Jardin, Gerhard Flachowsky, Lieve Herman, Huw Jones, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Harry Kuiper, Antoine Messéan, Kaare Magne Nielsen, Joe Perry, Annette Pötting, Jeremy Sweet, Christoph Tebbe, Atte Johannes von Wright, and Jean-Michel Wal. Correspondence: [GMO@efsa.europa.eu](mailto:GMO@efsa.europa.eu)

<sup>3</sup> Acknowledgement: The Panel wishes to thank the members of the Working Groups on Molecular Characterisation, Food and Feed and Environment for the preparatory work on this statement: Boet Glandorf and EFSA's staff members Yann Devos, Zoltán Divéki, Antonio Fernandez Dumont, Yi Liu, Claudia Paoletti and Nancy Podevin, for the support provided to this scientific opinion.

Suggested citation: EFSA Panel on Genetically Modified Organisms; Statement complementing the EFSA GMO Panel scientific opinion on maize MON 89034 x 1507 x NK603 (application EFSA-GMO-NL-2009-65), to cover all sub-combinations independently of their origin. EFSA Journal 2011;9(9):2377. [8 pp.] doi:10.2903/j.efsa.2011.2377. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

**KEY WORDS**

MON 89034 x 1507 x NK603, GMO, maize (*Zea mays*), insect resistance, herbicide tolerance, risk assessment, Regulation (EC) No 1829/2003.

## TABLE OF CONTENTS

Summary .....	1
Table of contents .....	3
Background .....	4
Terms of reference.....	4
Assessment .....	5
1. Introduction .....	5
2. Molecular characterisation.....	5
3. Food/feed safety assessment.....	6
4. Environmental risk assessment.....	6
Overall conclusions and recommendations .....	6
Documentation provided to EFSA .....	7
References .....	7

## BACKGROUND

On 1 February 2011, the European Commission requested the Scientific Panel on Genetically Modified Organisms of EFSA (EFSA GMO Panel) to complement its scientific opinion on maize MON 89034 x 1507 x NK603 (application EFSA-GMO-NL-2009-65) issued in September 2010, to cover the sub-combinations maize MON 89034 x 1507, 1507 x NK603 and MON 89034 x NK603 independently of their origin (i.e., whether arising from segregation or from conventional breeding programs).

On 27 September 2010, the EFSA GMO Panel issued a scientific opinion on application EFSA-GMO-NL-2009-65 for placing on the market of insect resistant and herbicide tolerant genetically modified (GM) maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny, for food and feed uses, import and processing under Regulation (EC) No 1829/2003. The EFSA GMO Panel evaluated the intended uses of maize MON 89034 x 1507 x NK603 in accordance with the scope of application EFSA-GMO-NL-2009-65. The initial scope of this application<sup>4</sup> was confirmed by the applicants in their letter dated 30 July 2010, and accepted by EFSA and its GMO Panel. In its scientific opinion, the EFSA GMO Panel stated that there is no biological reason to expect that any of the sub-combinations of the individual events present in its segregating progeny would raise a safety concern. The EFSA GMO Panel concluded that maize MON 89034 x 1507 x NK603 is unlikely to have adverse effects on human and animal health and the environment in the context of its intended uses.

Upon request of the European Commission to complement the scientific opinion on maize MON 89034 x 1507 x NK603, the EFSA GMO Panel reconsidered all relevant available information on maize MON 89034 x 1507 x NK603, on the single maize events and its sub-combinations 1507 x NK603 and MON 89034 x NK603. According to Regulation (EC) No 1829/2003, this statement complements the scientific opinion, which is the report requested under Articles 6(6) and 18(6) of that Regulation, and will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5).

## TERMS OF REFERENCE

The EFSA GMO Panel was requested, in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, to complement its scientific opinion on maize MON89034 x 1507 x NK603 for food and feed uses, import and processing, to cover all sub-combinations independently of their origin.

---

<sup>4</sup> On page 2 of the technical dossier of application EFSA-GMO-NL-2009-65, the applicants stated that “*the scope of this application according to Articles 5 and 17 of Regulation (EC) No 1829/2003 on genetically modified food and feed includes all uses of MON 89034 x 1507 x NK603 maize grain*”. Footnote 1 of the technical dossier mentions that “*maize grain is the product of genetic segregation of the seed from which it is produced. Consequently MON 89034 x 1507 x NK603 grain includes the combined event product and any combination of these events*” (see also applicants’ letter dated 30 July 2010).

## ASSESSMENT

### 1. Introduction

Upon request of the European Commission to complement the scientific opinion on maize MON 89034 x 1507 x NK603 (EFSA, 2010a), the EFSA GMO Panel reconsidered all relevant available information on maize MON 89034 x 1507 x NK603, on the single maize events and its sub-combinations 1507 x NK603 and MON 89034 x NK603 which were assessed previously without identifying safety concerns (EFSA, 2003a,b, 2004, 2005a,b, 2006, 2008, 2009a,b,c, 2010a). It is noted that for the only remaining sub-combination of maize MON 89034 x 1507 x NK603, namely MON 89034 x 1507 for which a scientific opinion has not been issued, no experimental data were available in the application EFSA-GMO-NL-2009-65.

In accordance with the EFSA GMO Panel guidelines for the risk assessment of food and feed from GM plants and of their environmental impact (EFSA, 2010b, 2011), the applicant should address all possible sub-combinations of these events provided that the single events have been risk assessed. The risk assessment of GM plants containing stacked transformation events (hereafter: higher-stack) should focus on issues related to stability of the inserts, expression of the introduced genes and their products, and potential synergistic or antagonistic effects resulting from the combination of the events. Moreover, the risk assessment of these sub-combinations should take into account the different exposure levels covered by the scope of the application.

The EFSA GMO Panel notes that the genetic constitution of F<sub>2</sub> grains of any sub-combination of a higher-stack arising from conventional breeding programs differs from that of F<sub>2</sub> grains occurring by natural segregation from the higher-stack. Maize grains are composed of an embryo, endosperm and seed coat (including pericarp) which have different genetic constitutions. The DNA origin of the embryo and endosperm tissues is different. Whereas endosperms are triploid, resulting from the fusion of two maternal polar nuclei with one sperm nucleus, embryos are diploid, resulting from the fusion of one haploid maternal nucleus and one haploid male nucleus. Finally, seed coats are diploid and wholly of maternal origin (Trifa and Zhang, 2004; Holst-Jensen et al., 2006; Weighardt, 2006; Zhang et al., 2008; Paul et al., 2011). Therefore, the genetic constitution of the endosperm and seed coat in grains derived from maize MON 89034 x 1507 x NK603 is distinct from that of maize MON 89034 x 1507 grains arising from conventional breeding programs. In addition, the sub-combination might be grown in other environments than the higher-stack. Therefore, the EFSA GMO Panel considers that conclusions reached for segregating progeny cannot automatically be extended to sub-combinations bred using conventional breeding programs.

Based on all relevant available information on maize MON 89034 x 1507 x NK603 and on the single maize events, the EFSA GMO Panel presents its view on whether the scientific opinion on maize MON 89034 x 1507 x NK603 can cover all sub-combinations independently of their origin. In addition, information from the previous assessments of maize 1507 x NK603 and maize MON 89034 x NK603 was also considered.

### 2. Molecular characterisation

Maize MON 89034 x 1507 x NK603 is a GM plant containing stacked transformation events of the single maize events MON 89034, 1507 and NK603, all of which had been risk assessed previously by the EFSA GMO Panel (EFSA, 2003a,b, 2004, 2005a,b, 2008, 2009a,b, 2010a). The ranges of the levels of newly expressed proteins in maize MON 89034 x 1507 x NK603 and its sub-combinations 1507 x NK603 and MON 89034 x NK603 did not raise safety concern (EFSA, 2006, 2009c, 2010a).

With regard to unintended effects in maize MON 89034 x 1507 x NK603, there was no indication of interactions between insertion sites. This conclusion was further supported by the previous assessments of maize 1507 x NK603 and maize MON 89034 x NK603 (EFSA 2006, 2009c).

Based on all available information from the molecular characterisation, the EFSA GMO Panel is of the opinion that the information provided for maize MON 89034 x 1507 x NK603 is sufficient to conclude also on the safety of all sub-combinations as requested by the European Commission. No safety issues were raised.

### **3. Food/feed safety assessment**

The evaluations performed by the applicant and the EFSA GMO Panel on maize MON 89034 x 1507 x NK603, its single maize events and its sub-combinations 1507 x NK603 and MON 89034 x NK603 did not raise food/feed safety concerns (EFSA, 2003a,b, 2004, 2005a,b, 2006, 2008, 2009a,b,c, 2010a).

Based on the known functional characteristics and modes of action of the newly expressed proteins and the outcomes of the comparative analysis of compositional, phenotypic and agronomic characteristics of maize MON 89034 x 1507 x NK603, the EFSA GMO Panel considers it unlikely that interactions between the single maize events in all possible sub-combinations will occur that may impact on the food and feed safety and the nutritional properties of the whole food and feed. This conclusion was further supported by the previous assessments of maize 1507 x NK603 and maize MON 89034 x NK603 (EFSA 2006, 2009c).

### **4. Environmental risk assessment**

The evaluations performed by the applicant and the EFSA GMO Panel on maize MON 89034 x 1507 x NK603, its single maize events and its sub-combinations 1507 x NK603 and MON 89034 x NK603 did not raise environmental safety concerns (EFSA, 2003a,b, 2004, 2005a,b, 2006, 2008, 2009a,b,c, 2010a).

The EFSA GMO Panel is of the opinion that, in the context of their intended uses, potential interactions between the newly expressed proteins in plants containing the individual events present in maize MON 89034 x 1507 x NK603 would not raise environmental safety concerns for any of the sub-combinations independently of their origin, as compared with conventional maize plants with a similar genetic background. To support this statement, the EFSA GMO Panel considered the mode of action of the newly expressed proteins in plants containing each single event and their potential interactions, the characteristics of maize and its limited ability to persist, overwinter or establish feral populations outside of cultivation within Europe, pathways of exposure, the risk assessment conclusions of each individual event of maize MON 89034 x 1507 x NK603 (EFSA, 2003a,b, 2004, 2005a,b, 2008, 2009a,b, 2010a), the information provided by the applicants, and all relevant information published in the scientific literature. This conclusion was further supported by the previous assessments of maize 1507 x NK603 and maize MON 89034 x NK603 (EFSA 2006, 2009c).

## **OVERALL CONCLUSIONS AND RECOMMENDATIONS**

In view of the European Commission's request and, having considered all relevant available information on maize MON 89034 x 1507 x NK603 and on the single maize events, the EFSA GMO Panel considers it unlikely that the sub-combinations have an adverse effect on human and animal health and the environment in the context of their intended uses, which cover food and feed uses, import and processing. This conclusion was further supported by the previous assessments of maize 1507 x NK603 and maize MON 89034 x NK603 (EFSA 2006, 2009c). The EFSA GMO Panel

concludes that the present statement can complement the scientific opinion on maize MON 89034 x 1507 x NK603 to cover all sub-combinations independently of their origin.

The EFSA GMO Panel emphasises that the conclusions reached pertain to the particular case of maize MON 89034 x 1507 x NK603 and the sub-combinations maize 1507 x NK603, MON 89034 x NK603 and MON 89034 x 1507 only.

## DOCUMENTATION PROVIDED TO EFSA

1. Letter, dated 01 February 2011, from the Head of Unit of the Safety of the Food chain Biotechnology of the European Commission for Health and Consumers Ms Dorotheé André with a request for complementing the EFSA scientific opinion related to maize MON 89034 x 1507 x NK603 to cover all sub-combinations of its single events independently of their origin.
2. Acknowledgement letter, dated 07 April 2011, from EFSA to the Director-General of the European Commission/Directorate-General for Health and Consumers.

## REFERENCES

- EFSA, 2003a. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference CE/ES/00/01) for the placing on the market of herbicide-tolerant genetically modified maize NK603, for import and processing, under Part C of Directive 2001/18/EC from Monsanto (Question No EFSA-Q-2003-003). EFSA Journal 10, 1-13.
- EFSA, 2003b. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of foods and food ingredients derived from herbicide-tolerant genetically modified maize NK603, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto (Question No EFSA-Q-2003-002). EFSA Journal 9, 1-14.
- EFSA, 2004. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/00/10) for the placing on the market of insect-tolerant genetically modified 1507 maize, for import and processing, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds. EFSA Journal 124, 1-18.
- EFSA, 2005a. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (reference EFSA-GMO-NL-2004-02) for the placing on the market of insect-tolerant genetically modified 1507 maize, for food use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International/Mycogen Seeds. EFSA Journal 182, 1-22.
- EFSA, 2005b. 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 Seeds. EFSA Journal 181, 1-33.
- EFSA, 2006. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2004-05) for the placing on the market of insect-protected and glufosinate and glyphosate-tolerant genetically modified 1507 x NK603 maize, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred and Mycogen Seeds. EFSA Journal 355, 1-23.
- EFSA, 2008. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-NL-2007-37) for the placing on the market of the insect-resistant

- genetically modified maize MON 89034, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 909, 1-30.
- EFSA, 2009a. Scientific Opinion of the Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-NL-2005-22, EFSA\_GMO-RX-NK603) for the placing on the market of the genetically modified glyphosate tolerant maize NK603 for cultivation, food and feed uses, import and processing and for renewal of the authorization of maize NK603 as existing products, both under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 1137, 1-50.
- EFSA, 2009b. Scientific Opinion of the Panel on Genetically Modified Organisms on an application (EFSA-GMO-RX-1507) for renewal of authorisation for the continued marketing of existing products produced from maize 1507 for feed use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International, Inc./Mycogen Seeds. EFSA Journal 1138, 1-11.
- EFSA, 2009c. Scientific Opinion on application (EFSA-GMO-NL-2007-38) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize MON 89034 x NK603 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 7(9):1320.
- EFSA, 2010a. Scientific Opinion on an application (EFSA-GMO-NL-2009-65) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Dow AgroSciences and Monsanto. EFSA Journal 8(9):1782.
- EFSA, 2010b. Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 8(11):1879.
- EFSA, 2011. Guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 9(5):2150.
- Holst-Jensen A, De Loose M, van den Eede G, 2006. Coherence between legal requirements and approaches for detection of genetically modified organisms (GMOs) and their derived products. Journal of Agricultural and Food Chemistry 54, 2799-2809.
- Paul L, Angevin F, Collonnier C, Messéan A, 2011. Impact of gene stacking on gene flow: the case of maize. Transgenic Research, DOI:10.1007/s11248-011-9527-5.
- Trifa Y, Zhang D, 2004. DNA content in embryo and endosperm of maize kernel (*Zea mays* L.): Impact on GMO quantification. Journal of Agricultural and Food Chemistry 52, 1044-1048.
- Weighardt F, 2006. European GMO labeling thresholds impractical and unscientific. Nature Biotechnology 24, 23-25.
- Zhang D, Corlet A, Fouilloux S, 2008. Impact of genetic structures on haploid genome-based quantification of genetically modified DNA: theoretical considerations, experimental data in MON 810 maize kernels (*Zea mays* L.) and some practical applications. Transgenic Research 17, 393-402.