

## SCIENTIFIC OPINION

### **Statement complementing the EFSA GMO Panel scientific opinion on maize MON 89034 x 1507 x MON 88017 x 59122 (application EFSA-GMO-CZ-2008-62), to cover all sub-combinations independently of their origin<sup>1</sup>**

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

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#### **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 MON 88017 x 59122 (EFSA-GMO-CZ-2008-62) 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 MON 88017 x 59122 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 MON 88017 x 59122 and two of the possible sub-combinations, namely maize 1507 x 59122 (EFSA-GMO-NL-2005-15) and MON 89034 x MON 88017 (EFSA-GMO-NL-2007-39), 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 MON 88017 x 59122 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 its intended uses which cover food and feed uses, import and processing. This conclusion was further supported by the assessments of maize 1507 x 59122 and maize MON 89034 x MON 88017. The EFSA GMO Panel concludes that the present statement can complement its scientific opinion on maize MON 89034 x 1507 x MON 88017 x 59122 to cover all sub-combinations independently of their origin.

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<sup>1</sup> On the request from the European Commission to complement the EFSA overall opinion on maize MON 89034 x 1507 x MON 88017 x 59122 to cover all sub-combinations independently of their origin, Question No. EFSA-Q-2011-00170, adopted on 29 September 2011.

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**KEY WORDS**

MON89034 x 1507 x MON88017 x 59122, SmartStax, 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.....	6
3. Food/feed safety assessment.....	6
4. Environmental risk assessment.....	6
Conclusions .....	7
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 MON 88017 x 59122 (application EFSA-GMO-CZ-2008-62), issued in September 2010, “to cover all sub-combinations<sup>4</sup> of their single events independently of their origin”<sup>5</sup>.

On 27 September 2010, the EFSA GMO Panel issued a scientific opinion on application EFSA-GMO-CZ-2008-62 for the placing on the market of insect resistant and herbicide tolerant genetically modified (GM) maize MON 89034 x 1507 x MON 88017 x 59122 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 (EFSA, 2010b). The EFSA GMO Panel evaluated the intended uses of maize MON 89034 x 1507 x MON 88017 x 59122 in accordance with the scope of application EFSA-GMO-CZ-2008-62. The initial scope of this application<sup>6</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 other 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 MON 88017 x 59122 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 MON 88017 x 59122, the EFSA GMO Panel reconsidered all relevant available information on maize MON 89034 x 1507 x MON 88017 x 59122, on the single maize events and its sub-combinations 1507 x 59122 and MON 89034 x MON 88017. 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 MON 89034 x 1507 x MON 88017 x 59122 for food and feed uses, import and processing, to cover all sub-combinations independently of their origin.

<sup>4</sup> Sub-combinations on which the EFSA GMO Panel has not previously published specific opinions are MON 89034 x 1507 x MON 88017, MON 89034 x 1507 x 59122, MON 89034 x MON 88017 x 59122, 1507 x MON 88017 x 59122, MON 89034 x 1507, MON 89034 x 59122, MON 88017 x 59122, 1507 x MON 88017; sub-combinations previously evaluated by the EFSA GMO Panel are 1507 x 59122 and MON 89034 x MON 88017

<sup>5</sup> i.e., whether arising from segregation or from conventional breeding programs

<sup>6</sup> Application EFSA-GMO-NL-2009-62, page 11 of the technical dossier states 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 MON 88017 x 59122 grain<sup>1</sup> equivalent to the uses of any other 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 MON 88017 x 59122 grain includes the combined event product and any combination of these events.”

## ASSESSMENT

### 1. Introduction

Upon request of the European Commission to complement the EFSA GMO Panel scientific opinion on maize MON 89034 x 1507 x MON 88017 x 59122 (EFSA, 2010b), the GMO Panel reconsidered all relevant available information on maize MON 89034 x 1507 x MON 88017 x 59122, on the single maize events and its sub-combinations 1507 x 59122 and MON 89034 x MON 88017 which were assessed previously without identifying safety concerns (EFSA, 2004, 2005a, 2005b, 2007, 2008, 2009a, 2009b, 2009c, 2010a, 2010b). It is noted that for the sub-combinations<sup>7</sup> of maize MON 89034 x 1507 x MON 88017 x 59122 for which a scientific opinion has not been issued, no experimental data were available in the application EFSA-GMO-CZ-2008-62.

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, 2010c, 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). In summary, the genetic constitution of the endosperm and seed coat in grains derived from maize MON 89034 x 1507 x MON 88017 x 59122 is distinct from that of maize sub-combinations grains arising from conventional breeding programs. In addition, these sub-combinations might be grown in receiving environments which differ from those of 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 MON 88017 x 59122 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 MON 88017 x 59122 can cover all sub-combinations independently of their origin. In addition, information from the previous assessments of maize 1507 x 59122 and maize MON 89034 x MON 88017 was also considered.

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<sup>7</sup> Sub-combinations on which the EFSA GMO Panel has not previously published specific opinions are MON 89034 x 1507 x MON 88017, MON 89034 x 1507 x 59122, MON 89034 x MON 88017 x 59122, 1507 x MON 88017 x 59122, MON 89034 x 1507, MON 89034 x 59122, MON 88017 x 59122, 1507 x MON 88017; sub-combinations previously evaluated by the EFSA GMO Panel are 1507 x 59122 and MON 89034 x MON 88017

## **2. Molecular characterisation**

Maize MON 89034 x 1507 x MON 88017 x 59122 is a GM plant containing stacked transformation events of the maize events MON 89034, 1507, MON 88017 and 59122, all of which had been risk assessed previously by the EFSA GMO Panel (EFSA, 2004, 2005a, 2005b, 2007, 2008, 2009a, 2009b, 2010b). The ranges of the levels of newly expressed proteins in maize MON 89034 x 1507 x MON 88017 x 59122 did not raise safety issues. In addition, the comparison of the expression levels in the analysed higher stack and the single events did not indicate unintended interactions. With regard to the possible occurrence of unintended effects in maize MON 89034 x 1507 x MON 88017 x 59122 there was no indication of interactions between insertion sites. This conclusion was further supported by the previous assessments of maize 1507 x 59122 and MON 89034 x MON 88017 (EFSA, 2009c, 2010a).

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 MON 88017 x 59122 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 MON 88017 x 59122, its single maize events and its sub-combinations 1507 x 59122 and MON 89034 x MON 88017 did not raise food/feed safety concerns (EFSA, 2004, 2005a, 2005b, 2007b, 2008, 2009a, 2009b, 2009c, 2010a, 2010b).

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 MON 88017 x 59122, 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 assessment of maize 1507 x 59122 and maize MON 89034 x MON 88017 (EFSA 2009c, 2010a).

## **4. Environmental risk assessment**

The evaluations performed by the applicant and the EFSA GMO Panel on maize MON 89034 x 1507 x MON 88017 x 59122, its single maize events and its sub-combinations 1507 x 59122 and MON 89034 x MON 88017 did not raise environmental safety concerns (EFSA, 2004, 2005a, 2005b, 2007, 2008, 2009a, 2009b, 2009c, 2010a, 2010b).

The EFSA GMO Panel is of the opinion that, in the context of their intended uses, potential interactions between the newly expressed proteins in the individual events present in maize MON 89034 x 1507 x MON 88017 x 59122 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 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 MON 88017 x 59122 (EFSA, 2010b), 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 59122 and maize MON 89034 x MON 88017 (EFSA 2009c, 2010a).

## CONCLUSIONS

In view of the European Commission's request and, having considered all relevant available information on maize MON 89034 x 1507 x MON 88017 x 59122 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 59122 and maize MON 89034 x MON 88017. The EFSA GMO Panel concludes that the present statement can complement the scientific opinion on maize MON 89034 x 1507 x MON 88017 x 59122 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 MON 88017 x 59122 and all its sub-combinations only.

## DOCUMENTATION PROVIDED TO EFSA

1. Letter, received 7 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 opinions related to MON 89034 x 1507 x MON 88017 x 59122 maize and MON 89034 x 1507 x NK603 with the missing scope.
2. Acknowledgement letter, dated 7 April 2011, from EFSA to the Director-General of the European Commission/Directorate-General for Health and Consumers.

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