

## REPORT OF EFSA

### **Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on application (reference 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<sup>1</sup>**

**European Food Safety Authority<sup>2</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### **SUMMARY**

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize MON 89034 x 1507 x NK603 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of application EFSA-GMO-NL-2009-65 covers 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<sup>3</sup>, food and feed containing, produced from or consisting of genetically modified maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In conclusion, the EFSA GMO Panel considers that the information available for maize MON 89034 x 1507 x NK603 addresses the scientific comments raised by the Member States and concludes that the maize MON 89034 x 1507 x NK603, assessed in this application, is as safe as its conventional counterpart and other appropriate comparators with respect to potential effects on human and animal health and the environment. In

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<sup>1</sup> On request from the Competent Authority of The Netherlands for an application (EFSA-GMO-NL-2009-65) submitted by Dow AgroSciences and Monsanto, Questions No EFSA-Q-2010-00929 (EFSA overall opinion) and EFSA-Q-2009-00413 (Scientific opinion of the EFSA GMO Panel), issued on 27 September 2010.

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<sup>3</sup> This does include genetically modified maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny for import and processing as designated under part C of Directive 2001/18/EC.

For citation purposes: European Food Safety Authority; Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on application (reference 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 on request from Dow AgroSciences and Monsanto.

addition, the EFSA GMO Panel is of the opinion that crossing of single maize events MON 89034, 1507 and NK603 to produce maize MON 89034 × 1507 × NK603 does not result in interactions between the events which would affect the safety of maize MON 89034 × 1507 × NK603 with respect to potential effects on human and animal health and on the environment, in the context of its intended uses. Based on data provided for maize stack MON 89034 × 1507 × NK603, the single maize events (MON 89034, 1507 and NK603), and for the two double stacks 1507 × NK603 and MON 89034 × NK603, the EFSA GMO Panel is of the opinion that there is no biological reason to expect that any of the other sub-combinations of the individual events as present in its segregating progeny would raise a safety concern. The EFSA GMO Panel concludes that maize MON 89034 × 1507 × NK603 is unlikely to have adverse effects on human and animal health and the environment, in the context of its intended uses. The Community Reference Laboratory considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize MON 89034, maize 1507 and maize NK603 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements and at the American Oil Chemists' Society.

The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan is in line with Regulation (EC) No 1829/2003.

Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Articles 6 and 18 for the placing on the market of genetically modified maize MON 89034 x 1507 x NK603.

#### **KEY WORDS**

Overall opinion, GMO, maize, MON 89034 x 1507 x NK603, insect resistance, herbicide tolerance, food and feed uses, import and processing, food safety, feed safety, environmental safety, Regulation (EC) No 1829/2003.

## TABLE OF CONTENTS

Summary .....	1
Table of contents .....	3
Background .....	4
Terms of reference .....	5
Considerations .....	6
1. Applicant(s) .....	6
2. Designation and specification of the product .....	6
3. Scientific opinion of the EFSA GMO Panel .....	6
4. Cartagena Protocol .....	7
5. Labelling .....	7
6. Method for detection .....	7
7. Certified reference materials .....	7
8. Post-market environmental monitoring .....	7
9. Member States' Comments .....	7
Conclusions .....	8
List of annexes .....	9

## BACKGROUND

On 6 February 2009, the European Food Safety Authority (EFSA) received from the Competent Authority of The Netherlands an application for authorisation of genetically modified maize MON 89034 x 1507 x NK603 (MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6) submitted by Dow AgroSciences and Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2009-65).

The scope of application EFSA-GMO-NL-2009-65 covers 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<sup>4</sup>, food and feed containing, produced from or consisting of genetically modified maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny. The scope does not include cultivation.

In accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission and made the summary of the application publicly available on the EFSA website<sup>5</sup> on 9 February 2009. EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Articles 5 and 17 of Regulation (EC) No 1829/2003. On 27 January 2009 and 20 March 2009, the Community Reference Laboratory (CRL) received the detection method, samples and control samples in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. EFSA declared the application valid on 6 August 2009 and started the clock in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003.

From that date, EFSA has endeavoured to respect a time limit of six months in giving its overall opinion (Articles 6(1) and 18(1)). EFSA made the valid application available to Member States and the European Commission. Following the procedure laid down in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, EFSA consulted the Member States. In this context, the Member States risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC, were given three months after the date of receipt of the valid application (*i.e.* until 6 November 2009) within which to make their opinion known.

Making use of the provisions under Articles 6(2) and 18(2), EFSA requested additional information from the applicant and the clock was stopped from 28 October 2009 to 8 March 2010, from 22 March 2010 to 25 May 2010 and from 2 July 2010 to 19 August 2010<sup>6</sup>.

The overall opinion on application EFSA-GMO-NL-2009-65 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms together with the particulars required under Articles 6(5)(a-g) and 18(5)(a-g) of Regulation (EC) No 1829/2003: i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the information required under Annex II to the Cartagena Protocol, iv) the labelling proposal, v) the method for detection, validated by the Community Reference Laboratory, including sampling, identification of the transformation

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<sup>4</sup>This does include genetically modified maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny for import and processing as designated under part C of Directive 2001/18/EC.

<sup>5</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00413>

<sup>6</sup>Request for additional information from the EFSA GMO Panel: the applicant sent information spontaneously on 25/09/2009 and 06/10/2009; EFSA requested (1) on 28/10/2009 – received on 23/12/2009; requested (2), on information sent spontaneously on 25/09/2009, on 29/10/2009; requested (3) on 29/01/2010 – received on 04/02/2010; information sent spontaneously on 02/02/2010; clock re-started on 08/03/2010; requested (4) on 22/03/2010 – received on 07/04/2010; requested (5) on 22/04/2010 – received on 03/05/2010; clock restarted on 25/05/2010; information sent spontaneously on 16/06/2010 and 24/06/2010; requested (6) on 02/07/2010 – received on 19/07/2010; requested (7) on 26/07/2010 – received on 30/07/2010 and clock restarted on 19/08/2010.

event in the food-feed and/or foods-feeds produced from it, vi) an indication of where appropriate reference materials can be accessed, vii) the monitoring plan and, viii) the Member States' comments submitted during the three-month consultation period.

## **TERMS OF REFERENCE**

The European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified maize MON 89034 x 1507 x NK603 (MON-89034-3 x DAS-01507-1 x MON-00603-6) submitted by Dow AgroSciences and Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2009-65). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

## CONSIDERATIONS

### 1. Applicant(s)

The application was submitted by

Monsanto Europe S.A. Avenue de Tervuren 270-272 B-1150 Brussels BELGIUM	Monsanto Company 800 N. Lindbergh Boulevard St. Louis, Missouri 63167 U.S.A
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Dow AgroSciences Europe European Development Centre 2nd Floor, 3 Milton Park, Abingdon Oxon OX14 4RN United Kingdom	Mycogen Seeds c/o Dow AgroSciences LLC 9330 Zionsville Road Indianapolis, Indiana 46268-1054 U.S.A.
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### 2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2009-65 covers 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<sup>7</sup> and food and feed containing, consisting of or produced from maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny. The scope does not include cultivation.

Maize MON 89034 × 1507 × NK603 was produced by conventional crossing of the single maize events, to combine in the same stack resistance against certain lepidopteran and coleopteran target pests and tolerance to glufosinate-ammonium and glyphosate-based herbicides.

### 3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny, in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 8 September 2010. In conclusion, the EFSA GMO Panel considers that the information available for maize MON 89034 × 1507 × NK603 addresses the scientific comments raised by the Member States and concludes that the maize MON 89034 × 1507 × NK603, assessed in this application, is as safe as its conventional counterpart and other appropriate comparators with respect to potential effects on human and animal health and the environment. In addition, the EFSA GMO Panel is of the opinion that crossing of single maize events MON 89034, 1507 and NK603 to produce maize MON 89034 × 1507 × NK603 does not result in interactions between the events which would affect the safety of maize MON 89034 × 1507 × NK603 with respect to potential effects on human and animal health and on the environment, in the context of its intended uses. Based on data provided for maize stack MON 89034 × 1507 × NK603, the single maize events

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<sup>7</sup> This does include genetically modified maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny, for import and processing as designated under part C of Directive 2001/18/EC.

(MON 89034, 1507 and NK603), and for the two double stacks 1507 × NK603 and MON 89034 × NK603, the EFSA GMO Panel is of the opinion that there is no biological reason to expect that any of the other sub-combinations of the individual events as present in its segregating progeny would raise a safety concern. The EFSA GMO Panel concludes that maize MON 89034 × 1507 × NK603 is unlikely to have adverse effects on human and animal health and the environment, in the context of its intended uses (Annex A).

#### **4. Cartagena Protocol**

The information presented in the application and as required under Annex II of the Cartagena Protocol on Biosafety is in line with the scientific opinion of the EFSA GMO Panel (Annex B).

#### **5. Labelling**

The labelling proposal provided in the application is in line with the requirements in Regulation (EC) No 1829/2003. On the basis of the scientific opinion of the EFSA GMO Panel, EFSA is of the opinion that there is no need for a specific labelling in accordance with Articles 13(2)(a) and 25(2)(c) (Annex C).

#### **6. Method for detection**

The Joint Research Centre (JRC) as Community Reference Laboratory for the genetically modified Food and Feed has carried out an in-house verification study to assess the performance of three quantitative event specific methods on the hybrid maize line MON 89034 x 1507 x NK603 which combines the MON 89034, the 1507 and the NK603 transformation events. The three methods have been validated individually on single-trait events, to detect and quantify each event in maize samples. The reports were issued on 10 January 2005, 21 February 2005, 21 October 2008 and 9 July 2010. The Community Reference Laboratory considers that the methods are applicable to the control samples provided in accordance with the requirements of Annex I-2.C.2. of the Commission Regulation (EC) No 641/2004 (Annexes D1, D2a, D2b, D2c).

#### **7. Certified reference materials**

The certified reference materials of genetically modified of maize 1507 and maize NK603 (ERM-BF418 and ERM-BF415) can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements; the certified reference materials of genetically modified maize MON 89034 can be accessed at American Oil Chemists' Society (Annexes E1, E2, E3).

#### **8. Post-market environmental monitoring**

The EFSA GMO Panel evaluated the post-market environmental monitoring plan proposed by the applicant. The EFSA GMO Panel considered that the monitoring plan provided by the applicant is in line with the intended uses for the GMO (Annex F).

#### **9. Member States' Comments**

The EFSA GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period (Annex G).

## CONCLUSIONS

Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Articles 6 and 18 for the placing on the market of genetically modified maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny.



## LIST OF ANNEXES<sup>8</sup>

- Annex A: Scientific opinion of the EFSA GMO Panel (maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny)
- Annex B: Cartagena Protocol (maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny)
- Annex C: Labelling (maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny)
- Annex D1: Validation report (maize MON 89034 x 1507 x NK603)
- Annex D2a: Validated method (maize MON 89034)
- Annex D2b: Validated method (maize 1507)
- Annex D2c: Validated method (maize NK603)
- Annex E1: Certified reference materials report (maize MON 89034)
- Annex E2: Certified reference materials report (maize 1507)
- Annex E3: Certified reference materials report (maize NK603)
- Annex F: Post-market environmental monitoring plan (maize MON 89034 x 1507 x NK603 and all sub-combinations of the individual events as present in its segregating progeny)
- Annex G: Member States' comments (maize MON 89034 x 1507 x NK603)

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<sup>8</sup> The annexes of the EFSA overall opinion can be found in the Register of Questions (“Question documents”) on the EFSA website under the following link: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-00929>