TECHNICAL 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-2007-38) for the placing on the market of the genetically modified insect resistant and herbicide tolerant maize MON89034 x NK603 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize MON89034 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-2007-38 is for food and feed uses, food and feed containing, consisting of or produced from maize MON89034 x NK603. 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 MON89034 x NK603 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that the genetically modified maize MON89034 x NK603 is unlikely to have any adverse effect on human and animal health or on 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 MON89034 can be accessed at the American Oil Chemists' Society (AOCS-USA). The certified reference materials of maize NK603 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements.

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 MON89034 x NK603.

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1 On request from the Competent Authority of the Netherlands for an application (EFSA-GMO-NL-2007-38) submitted by Monsanto, Questions No EFSA-Q-2009-00759 (EFSA overall opinion) and EFSA-Q-2007-046 (Scientific opinion of the EFSA GMO Panel), issued on 29 September 2009.

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KEY WORDS

Overall opinion, GMO, maize, *Zea mays*, MON89034 x NK603, insect resistance, herbicide tolerance, risk assessment, food and feed uses, import, processing, food and feed safety, environmental safety, Regulation (EC) No 1829/2003.

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BACKGROUND

On 1 February 2007, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of GM maize MON89034 x NK603 (MON-89Ø34-3 × MON-ØØ6Ø3-6) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2007-38).

The scope of application EFSA-GMO-GMO-NL-2007-38 covers genetically modified maize MON89034 x NK603 for food and feed uses[3], food and feed containing, consisting of or produced from maize MON89034 x NK603.

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[4] on 6 February 2007. 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 30 January 2007 and 25 March 2007, the Community Reference Laboratory (CRL) confirmed receipt of 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 24 August 2007 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 24 November 2007) 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 10 September 2007 to 7 January 2008, from 23 January 2008 to 19 December 2008 and from 28 January 2009 to 04 September 2009[5].

The overall opinion on application EFSA-GMO-NL-2007-38 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 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.

[3] This does include GM maize MON89034 x NK603 for import and processing as designated under part C of Directive 2001/18/EC.

[4] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-046

[5] Request for additional information from the EFSA GMO Panel: requested (1) on 23/01/2008 - received on 14/02/2008, requested (2) on 29/02/2008 - received on 08/05/2008, requested (3) on 02/07/2008 – received on 04/08/2008, requested (4) on 20/10/2008 – received on 30/10/2008, clock restarted on 19/12/2008, requested (5) on 28/01/2009 – received on 13/03/2009, requested (6) on 02/02/2009 – received on 03/06/2009, and clock restarted on 04/09/2009.
Request for additional information from the JRC-CRL: requested on 10/09/2007 – received on 15 November 2007, and clock restarted on 07/01/2008.

TERMS OF REFERENCE

The European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of GM maize MON89034 x NK603 (MON-89Ø34-3 × MON-ØØ6Ø3-6) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2007-38). 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

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.

2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2007-38 covers genetically modified maize MON89034 x NK603 for food and feed uses[6]. The scope does not include cultivation.

Maize MON89034 x NK603 is produced by crosses between maize inbred lines containing the events MON89034 and NK603 to confer resistance to certain lepidopteran species (MON89034 trait) and tolerance to glyphosate-containing herbicides (NK603 trait).

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize MON89034 x NK603 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 9 September 2009. The EFSA GMO Panel considered all comments submitted by Member State bodies and where deemed necessary, requested additional information from the applicant before finalising its scientific assessment. The EFSA GMO Panel concludes that the information available for GM maize MON89034 x NK603 addresses the scientific comments raised by the Member States and considers that the genetically modified maize MON89034 x NK603 is unlikely to have any adverse effect on human and animal health or 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 that GM maize MON89034 x NK603 is compositionally and phenotypically equivalent to its non-genetically modified maize except for the introduced traits, 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] This does include GM maize MON89034 x NK603 for import and processing as designated under part C of Directive 2001/18/EC.

6. Method for detection

The Joint Research Centre (JRC) as Community Reference Laboratory for the GM Food and Feed has carried out an in-house verification study to assess the performance of two quantitative event specific methods on the hybrid maize line MON89034 x NK603 which combines the MON89034 and NKK603 transformation events. The two methods have been validated individually on single-trait events, to detect and quantify each event in maize samples. The reports were published on 21 October 2008 and 9 September 2009. 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. to Commission Regulation (EC) No 641/2004 (Annexes D1, D2a, D2b).

7. Certified reference materials

The certified reference materials of genetically modified maize MON89034 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E1). The certified reference materials of maize NK603 (ERM-BF415) can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (Annex E2).

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 MON89034 x NK603.

LIST OF ANNEXES[7]

Annex A: Scientific opinion of the EFSA GMO Panel (maize MON89034 x NK603)
Annex B: Cartagena Protocol (maize MON89034 x NK603)
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Annex D3: Sampling and extraction (maize MON89034 x NK603)
Annex E1: Certified reference materials report (maize MON89034)
Annex E2: Certified reference materials report (maize NK603)
Annex F: Post-market environmental monitoring plan (maize MON89034 x NK603)
Annex G: Member States' comments (maize MON89034 x NK603)

[7] 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-2007-046