European Food Safety Authority

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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 applications (references 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 authorisation of maize NK603 as existing products, both under Regulation (EC) No 1829/2003 from Monsanto[1]

Report of the GMO Unit

(Questions No EFSA-Q-2005-249 and EFSA-Q-2008-075)

Issued on 11 June 2009

SUMMARY

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

The scope of application EFSA-GMO-NL-2005-22 covers genetically modified maize NK603 for food and feed uses[2] and includes cultivation. The scope of application EFSA-GMO-RX-NK603 covers the continued marketing of existing food additives produced from maize NK603 and feed produced from maize NK603 (feed materials and feed additives) which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. The scope of application EFSA-GMO-RX-NK603 does not include cultivation.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out one scientific assessment of genetically modified maize NK603 for both applications, in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. The EFSA GMO Panel considers that the genetically modified maize NK603 is as safe as its conventional counterpart with respect to potential direct effects on human and animal health and the environment. However, the EFSA GMO Panel concludes that the cultivation management of maize NK603 could have adverse effects on the environment in the context of its intended uses. The EFSA GMO Panel therefore recommends managing the use of glyphosate on maize NK603 in regimes that have similar or reduced environmental impacts compared with conventional maize cultivation.

[1] For citation purposes: Technical report of EFSA prepared by the GMO Unit on applications EFSA-GMO-NL-2005-22 for the placing on the market of the genetically modified glyphosate tolerant maize NK603 for cultivation, food and feed uses, import and processing and EFSA-GMO-RX-NK603 for renewal of the authorisation of maize NK603 as existing products both under Regulation (EC) No 1829/2003 from Monsanto. ***EFSA Scientific Report*** (2009) 308, 1-9.

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

The Community Reference Laboratory considers the method validated as fit for the purpose of regulatory compliance. 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 are 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 NK603.

Key words: overall opinion, GMO, maize, *Zea mays*, NK603, herbicide tolerant, glyphosate, cultivation, food and feed uses, food safety, feed safety, human and animal health, environment, Regulation (EC) No 1829/2003, Directive 2001/18/EC, renewal, existing products.

TABLE OF CONTENTS

BACKGROUND

On 4 August 2005, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of GM maize NK603 (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-2005-22). The applicant has submitted this application jointly with an application for renewal of the authorisation of existing feed materials and food and feed additives produced from maize NK603, notified as existing product under Regulation (EC) No 1829/2003. In agreement with the European Commission (letter SANCO D4/SG/cc-D(05)440797 received 4 October 2005), it has been decided that the new and renewal application would be assessed together by the EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel).

The scope of application EFSA-GMO-NL-2005-22 covers genetically modified maize NK603 for food and feed uses and includes cultivation. The scope of application EFSA-GMO-RX-NK603 covers the continued marketing of existing food additives produced from maize NK603 and feed produced from maize NK603 (feed materials and feed additives) which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. The scope of application EFSA-GMO-RX-NK603 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[3] on 09 August 2005. 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 16 November 2004, 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 applications valid on 12 May 2006 and started the clock in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003.

On 19 December 2005, following a call for expression of interest among Competent Authorities under Directive 2001/18/EC and in accordance with Articles 6(3)(c) and 18(3)(c) of Regulation (EC) No 1829/2003, EFSA requested the Spanish Competent Authority to conduct the initial environmental risk assessment of application EFSA-GMO-NL-2005-22 concerning the placing on the market of maize NK603 for cultivation.

From that date, EFSA has endeavoured to respect a time limit of 6 months in giving its overall opinion (Articles 6(1) and 18(1)). EFSA made the valid applications 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 applications (*i.e.* until 12 August 2006) within which to make their opinion known.

[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2005-249
http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2005-075

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 22 September 2006 to 6 March 2009[4].

The overall opinion on applications EFSA-GMO-NL-2005-22 and EFSA-GMO-RX-NK603 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, viii) the Member States' comments submitted during the three-month consultation period, and ix) the Environmental Risk Assessment report of a National Competent Authority.

TERMS OF REFERENCE

The European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of GM maize NK603 (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-2005-22). The applicant has submitted this application jointly with an application for renewal of the authorisation of existing feed materials and food and feed additives produced from maize NK603, notified as existing product under Regulation (EC) No 1829/2003. EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

ACKNOWLEDGEMENTS

This technical report was prepared by the GMO Unit. The European Food Safety Authority wishes to thank the members of its staff Christina Ehlert and Karine Lheureux for the preparation of this report.

[4] Request for additional information from the Spanish Competent Authority and its Biosafety Commission: requested (1) on 22/09/006 – received on 15/12/2006, requested (2) on 15/02/2007 – received on 10/10/2007, requested (3) on 19/11/2007 – received on 11/12/2007.

Request for additional information from the EFSA-GMO Panel: requested (4) on 08/02/2007 - received on 08/08/2007, requested (5) on 28/04/2008 - received on 01/10/2008, requested (6) on 07/11/2008 - received on 15/12/2008, requested (7) on 16/02/2009 - received on 25/02/2009, and clock restarted on 06/03/2009.

RESULTS

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-2005-22 covers genetically modified maize NK603 for food and feed uses[5]. The scope includes cultivation.

The scope of application EFSA-GMO-RX-NK603 covers the continued marketing of existing food additives produced from maize NK603 and feed produced from NK603 (feed materials and feed additives) which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. The scope does not include cultivation. After the date of entry into force of Regulation (EC) No 1829/2003 these products were notified to the European Commission according to Articles 8 and 20 of that Regulation and included in the Community Register of genetically modified food and feed[6]. The scope does not include cultivation.

Maize NK603 has been developed for tolerance to glyphosate by the introduction of a gene coding for 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from *Agrobacterium* sp. strain CP4 (CP4 EPSPS).

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out one scientific assessment of the genetically modified maize NK603 for both applications in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 27 May 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 NK603 addresses the scientific comments raised by the Member States and considers that the genetically modified maize NK603 is as safe as its conventional counterpart with respect to potential direct effects on human and animal health and the environment. However, the EFSA GMO Panel concludes that the cultivation management of maize NK603 could have adverse effects on the environment in the context of its intended uses. The EFSA GMO Panel therefore recommends managing the use of glyphosate on maize NK603 in regimes that have similar or reduced environmental impacts compared with conventional maize cultivation (Annex A).

[5] This does include GM maize NK603 for import and processing as designated under part C of Directive 2001/18/EC.
[6] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=16

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 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. Method for detection

The Joint Research Centre (JRC) as Community Reference Laboratory for the GM Food and Feed has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the NK603 transformation event in maize DNA. The reports were published on 30 December 2004. The validity of the method was verified and confirmed by the Community Reference Laboratory in January 2008. The Community Reference Laboratory considers that the method is 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, D2, D3).

7. Certified reference materials

The certified reference materials of genetically modified maize NK603 (ERM-BF415) can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (Annex E).

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).

10. Environmental Risk Assessment by a National Competent Authority

In accordance with Articles 6.3(c) and 18.3(c) of Regulation (EC) No 1829/2003, EFSA requested the Spanish Competent Authority to carry out an initial Environmental Risk Assessment (ERA) of application EFSA-GMO-NL-2005-22 concerning the placing on the market of maize NK603 for cultivation, food and feed uses. The reports were submitted on 25 March 2008 (Annexes H1 and H2).

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 NK603.

LIST OF ANNEXES

Annex A: Scientific opinion of the EFSA GMO Panel (maize NK603)
Annex B: Cartagena Protocol (maize NK603)
Annex C: Labelling (maize NK603)
Annex D1: Validation report (maize NK603)
Annex D2: Validated method (maize NK603)
Annex D3: Validated method (maize NK603)
Annex E: Certified reference materials report (maize NK603)
Annex F: Post-market environmental monitoring plan (maize NK603)
Annex G: Member States' comments (maize NK603)
Annex H1: Report of the Spanish Competent Authority and its Biosafety Commission (maize NK603)
Annex H2: Annex 1 of report of the Spanish Competent Authority and its Biosafety Commission (maize NK603)