Opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on application EFSA-GMO-UK-2004-01

Application for the placing on the market of glyphosate-tolerant insect-resistant genetically modified maize NK603 x MON810 for food and feed uses from Monsanto

(Question No EFSA-Q-2004-086)

31 March 2006

Summary

This document provides an overall opinion of the European Food Safety Authority on NK603 x MON810 maize in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application is genetically modified maize NK603 x MON810 for food and feed uses, food and feed containing, consisting of or produced from NK603 x MON810 maize. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms has carried out the scientific assessment of the genetically modified maize NK603 x MON810 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that this maize is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses.

The Community Reference Laboratory considers that the methods validated on the parental GM-lines show a comparable performance when applied to the material combining the two traits, which had already been the subject of validation studies. The certified reference materials of NK603 and MON810 can be accessed at the Joint Research Centre, 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 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 x MON810.

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Background

On 10 June 2004, the European Food Safety Authority (EFSA) received from the UK competent authority an application for authorisation of NK603 x MON810 maize (unique identifier MON-ØØ6Ø3-6 x MON-ØØ81Ø-6) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2004-01).

The scope of this application is genetically modified maize NK603 x MON810 for food and feed uses, food and feed containing, consisting of or produced from NK603 x MON810 maize. 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[1] on 23 June 2004. 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 15 October 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 application valid on 17 June 2005 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 6 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 subsequently consulted the nominated risk assessment bodies of the Member States, as well as the national competent authorities within the meaning of Directive 2001/18/EC, who had three months after the date of receipt of the valid application (*i.e.* until 17 September 2005) 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 26 July 2005 to 19 January 2006[2].

The overall opinion on application EFSA-GMO-UK-2004-01 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) 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 material can be accessed, and vii) the monitoring plan.

[1] http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html

[2] Request for additional information from CRL: requested on 26/07/2005, accepted on 19/01/2006

Applicant

The application was submitted by Monsanto Company, represented by Monsanto Europe S.A.

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Designation and specification of the product

The scope of this application is genetically modified maize NK603 x MON810 for food and feed uses, food and feed containing, consisting of or produced from NK603 x MON810 maize.

Genetically modified maize NK603 x MON810 is produced by crosses between maize lines containing NK603 and MON810 events and expresses the CP4 EPSPS protein which confers tolerance to glyphosate herbicides and the Cry1Ab protein which confers protection against certain lepidopteran insect pests (*Ostrinia nubilalis, Sesamia spp.)*.

Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified maize NK603 x MON810 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 13 October 2005. The GMO Panel considered all comments submitted by Member State bodies. The GMO Panel concludes that the information available for NK603 x MON810 maize addresses the scientific comments raised by the Member States and considers that NK603 x MON810 maize is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses (Annex A).

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 GMO Panel (Annex B).

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 GMO Panel that NK603 x MON810 maize is compositionally and phenotypically equivalent to its parental single-trait GM lines and 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).

Method for detection

The Joint Research Centre (JRC) as Community Reference Laboratory for the GM Food and Feed has carried out a verification study to assess the performance of two quantitative, event-specific methods, previously validated on the parental lines, to detect and quantify the NK603 and MON810 transformation events on seeds from the hybrid maize line combining the two thereof traits. The reports were published on 16 March 2006. The Community Reference Laboratory considers that the methods validated on the parental GM-lines show a comparable performance

when applied to the material combining the two traits, which had already been the subject of validation studies (Annexes D1, D2a, D2b).

Certified reference material

The certified reference materials of NK603 (ERM-BF415) and MON810 (ERM-BF413) can be accessed at the Joint Research Centre (JRC-IRMM) of the European Commission (Annex E).

Post market environmental monitoring

The GMO Panel evaluated the environmental monitoring plan proposed by the applicant. The GMO Panel considers that the monitoring plan provided by the applicant is in line with the intended uses for the GMO since the scope does not include cultivation (Annex F).

List of annexes:

Annex A:	Scientific opinion of the GMO Panel
Annex B:	Cartagena Protocol
Annex C:	Labelling
Annex D1:	Validation report (NK603xMON810)
Annex D2a:	Validated method (NK603)
Annex D2b:	Validated method (MON810)
Annex E:	Certified reference material
Annex F:	Monitoring plan