TECHNICAL REPORT OF EFSA

Overall opinion of the European Food Safety Authority in accordance with Article 18 of Regulation (EC) No 1829/2003 on application EFSA-GMO-RX-MON810$_{[20\text{-}1a]}$ for renewal of the authorisation of existing products produced from insect resistant genetically modified maize MON810$_{[20\text{-}1a]}$, and seeds for cultivation under Regulation (EC) No 1829/2003 from Monsanto [1]

Report of the GMO Unit

(Question No EFSA-Q-2007-153)

Issued on 22 June 2009

SUMMARY

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize MON810$_{[20\text{-}1a]}$ in accordance with the requirements of Article 18 of Regulation (EC) No 1829/2003.

The scope of this application covers the continued marketing of existing feed containing or consisting of maize MON810 and seeds for cultivation 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 include cultivation.

The Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out one scientific assessment of genetically modified maize MON810 covering all scopes (MON810 $_{[8\text{-}1a]\ [20\text{-}1a]\ [8\text{-}1b/20\text{-}1b]}$) in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that the genetically modified maize MON810 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses. This also applies to the products which are the subject of the present application. For the scope cultivation, the EFSA GMO Panel also concludes that maize MON810 is unlikely to have any adverse effect on the environment in the context of its intended uses, especially if appropriate management measures are put in place in order to mitigate possible exposure of non-target Lepidoptera. Moreover, the EFSA GMO Panel advises that pest resistance management strategies continue to be employed.

The Community Reference Laboratory considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize MON810 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements.

[1] For citation purposes: Technical report of EFSA prepared by the GMO Unit on application EFSA-GMO-RX-MON810$_{[20\text{-}1a]}$ for renewal of the authorisation of existing products produced from insect resistant genetically modified maize MON810$_{[20\text{-}1a]}$, and seeds for cultivation under Regulation (EC) No 1829/2003 from Monsanto. ***EFSA Scientific Report*** (2009) 312, 1-8.

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 Article 18 for the renewal of authorisation of genetically modified maize MON810[20-1a].

Key words: overall opinion, GMO, maize (*Zea mays*), MON810, insect resistant, Cry1Ab, food safety, feed safety, human and animal health, environment, Regulation (EC) No 1829/2003, Directive 2001/18/EC, Directive 90/220/EEC, renewal, existing products

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BACKGROUND

On 29 June 2007, the European Food Safety Authority (EFSA) received from the European Commission an application for renewal of the authorisation of existing products produced from insect-resistant genetically modified maize MON810[20-1a] (MON-ØØ81Ø-6) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-MON810[20-1a]).

The scope of this application covers the continued marketing of existing feed containing or consisting of maize MON810 and seeds for cultivation 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 include cultivation.

In accordance with Article 17 of Regulation (EC) No 1829/2003, EFSA informed the Member States and made the summary of the application publicly available on the EFSA website[2] on 3 July 2007. EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Article 17 of Regulation (EC) No 1829/2003. On 18 May 1999, the Community Reference Laboratory (CRL) confirmed receipt of samples and control samples in accordance with Article 17 of Regulation (EC) No 1829/2003. EFSA declared the application valid on 29 January 2008 and started the clock in accordance with Article 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 (Article 18(1)). EFSA made the valid application available to Member States and the European Commission. Following the procedure laid down in Articles 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 29 April 2008) 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 24 April 2008 to 7 April 2009[3].

The EFSA overall opinion on application EFSA-GMO-RX-MON810[20-1a] includes one scientific opinion of the Panel on Genetically Modified Organisms (EFSA GMO Panel) covering all scopes (MON810 [8-1a] [20-1a] [8-1b/20-1b]) 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) post-market environmental monitoring, viii) the Member States' comments on MON810[20-1a] submitted during the three-month consultation period and ix) the environmental risk assessment report from the National Competent Authority.

[2] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-153

[3] Request for additional information from the Spanish competent Authority: (1) on 13/05/2008 – received on 09/06/2008, requested (2) on 22/07/2008 – received on 20/08/2008 and 30/09/2008,

Request for additional information from EFSA-GMO Panel: requested (3) on 24/04/2008 - received on 15/05/2008, requested (4) on 12/11/2008 – received on 02/12/2008 and 05/12/2008, requested (5) on 11/02/2009 - received on 27/02/2009, and clock restarted on 07/04/2009.

TERMS OF REFERENCE

EFSA received from the European Commission an application, submitted by Monsanto under Article 20(4) of Regulation (EC) No 1829/2003, for the renewal of authorisation of existing feed containing or consisting of maize MON810 and seeds for cultivation which were notified according to Article 20(1)(a) of 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 (Article 18).

ACKNOWLEDGEMENTS

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RESULTS

1. Applicant

The application was submitted by

Monsanto Europe S.A./N.V.
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 this application covers the continued marketing of existing feed containing or consisting of maize MON810 and seeds for cultivation 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 include cultivation.

Genetically modified maize MON810[20-1a] expresses a Cry1Ab insecticidal protein which confers protection against lepidopteran target pests such as the European corn borer (*Ostrinia nubilalis*) and species belonging to the genus *Sesamia*.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out one scientific assessment of the genetically modified maize MON810 covering all scopes (MON810 [8-1a] [20-1a] [8-1b/20-1b]) in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 15 June 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 MON810 addresses the scientific comments raised by the Member States and considers that GM maize MON810 is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses. For the scope cultivation, the EFSA GMO Panel also concludes that GM maize MON810 is unlikely to have any adverse effect on the environment in the context of its intended uses, especially if appropriate management measures are put in place in order to mitigate possible exposure of non-target Lepidoptera. Moreover, the EFSA GMO Panel advises that pest resistance management strategies continue to be employed (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 MON810 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 Article 25(2)(c) (Annex C).

6. Method for detection

The Joint Research Centre (JRC) as Community Reference Laboratory for 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 MON810 transformation event in maize DNA. The summary of the report was published on 10 March 2006. The validity of the method was verified and confirmed by the Community Reference Laboratory in June 2009. 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).

7. Certified reference materials

The certified reference materials of maize MON810 (ERM-AD413) 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 on GM maize MON810$_{[20\text{-}1a]}$ 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 Article 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-RX-MON810$_{[20\text{-}1a]}$ concerning the continued marketing of existing feed containing or consisting of maize MON810 and seeds for cultivation. The report was submitted on 11 November 2008 (Annex H).

CONCLUSIONS

Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Article 18 for the renewal of authorisation of genetically modified maize MON810$_{[20\text{-}1a]}$.

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