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-UK-2005-11) for the placing on the market of the genetically modified insect resistant maize MIR604 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta seeds S.A.S. on behalf of Syngenta Crop Protection AG[1]

Report of the GMO Unit

(Question No EFSA-Q-2005-046)

Issued on 21 July 2009

SUMMARY

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize MIR604 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-UK-2005-11 is for food and feed uses[2], food and feed containing, consisting of or produced from maize MIR604. 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 MIR604 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that the genetically modified maize MIR604 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 MIR604 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 MIR604.

[1] For citation purposes: Technical report of EFSA prepared by the GMO Unit on application EFSA-GMO-UK-2005-11 for the placing on the market of the genetically modified insect-resistant maize MIR604 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta seeds S.A.S. on behalf of Syngenta Crop Protection AG. ***EFSA Scientific Report*** (2009) 328, 1-8

[2] This does include GM maize MIR604 for import and processing as designated under part C of Directive 2001/18/EC.

Key words: overall opinion, GMO, maize, *Zea mays*, MIR604, insect tolerant, food and feed uses, food safety, feed safety, human and animal health, environment, Regulation (EC) No 1829/2003, Directive 2001/18/EC.

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BACKGROUND

On 12 January 2005, the European Food Safety Authority (EFSA) received from the Competent Authority of the United kingdom an application for authorisation of GM maize MIR604 (SYN-IR6Ø4-5) submitted by Syngenta Seeds S.A.S on behalf of Syngenta Crop Protection AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2005-11).

The scope of application EFSA-GMO-UK-2005-11 covers genetically modified maize MIR604 for food and feed uses, food and feed containing of or consisting from MIR604.

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 25 February 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 February 2005, 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 16 September 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 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 16 December 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 03 April 2006 to 22 June 2009[4].

The overall opinion on application EFSA-GMO-UK-2005-11 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] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2005-046

[4] Request for additional information from the JRC-CRL: requested (1) on 20/09/2005 – received on 18/11/2005, requested (2) on 17/03/2006 – received on 02/05/2006.
Request for additional information from the EFSA-GMO Panel: requested (1) on 03/04/2006 - received on 29/06/2006, requested (2) on 26/10/2006 - received on 30/01/2007, requested (3) on 14/03/2007 - received on 29/03/2007, requested (4) on 15/06/2007 - received on 04/07/2007, 23/08/2007, requested on (5) on 24/09/2007 - received on 21/10/2007, 14/11/2007, requested (6) on 26/11/2007 - received on 01/04/2008, 03/04/2008, requested (7) on 14/03/2008 - received on 15/05/2008, 03/04/2009 and clock restarted on 22/06/2009.

TERMS OF REFERENCE

The European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of GM maize MIR604 (SYN-IR6Ø4-5) submitted by Syngenta Seeds S.A.S on behalf of Syngenta Crop Protection AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2005-11). 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.

RESULTS

1. Applicant

The application was submitted by

Syngenta Seeds S.A.S.
12, Chemin de l'Hobit
BP27
F-31790 Saint-Sauveur

On behalf of
Syngenta Crop Protection AG,
Basel Switzerland and all affiliated companies
Schwarzwaldallee 215
CH 4058 Basle
Switzerland

2. Designation and specification of the product

The scope of application EFSA-GMO-UK-2005-11 covers genetically modified maize MIR604 for food and feed uses[5]. The scope does not include cultivation.

Maize MIR604 was engineered with a modified *cry3A* coding sequence *(mcry3A)* derived from *Bacillus thuringiensis* subsp. *tenebrionis* that encodes an insecticidally active mCry3A protein confering resistance to the Western Corn rootworm (WCR) *(Diabrotica virgifera virgifera)* and other related coleopteran pests of maize like the Northern Corn rootworm (NCR) (*Diabrotica barberi*). In addition maize MIR604 was engineered with the *pmi* (*manA*) gene from *Escherichia coli*, which encodes the enzyme PMI (PhosphoMannose Isomerase) as a selectable marker.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize MIR604 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 2[d] July 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 MIR604 addresses the scientific comments raised by the Member States and considers that the genetically modified maize MIR604 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] This does include GM maize MIR604 for import and processing as designated under part C of Directive 2001/18/EC.

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 MIR604 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 MIR604 transformation event in maize DNA. The reports were published on 03 April 2007. The validity of the method was verified and confirmed by the Community Reference Laboratory in 03 April 2007. 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 MIR604 (ERM-BF423) 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).

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 MIR604.

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