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-2007-48) for the placing on the market of the genetically modified insect resistant and herbicide tolerant maize MIR604 x GA21 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta[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 MIR604 x GA21 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-UK-2007-48 is for food and feed uses, food and feed containing, consisting of or produced from maize MIR604 x GA21, import and processing. 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 x GA21 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In conclusion, the EFSA GMO Panel considers that information available for maize MIR604 x GA21 addresses the scientific comments raised by Member States, and that the maize MIR604 x GA21, as described in this application, is as safe as its conventional counterpart and other appropriate comparators with respect to potential effects on human and animal health and the environment in the context of its intended uses. The EFSA GMO Panel concludes that maize MIR604 x GA21 is unlikely to have an adverse effect on human and animal health and 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 and maize GA21 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements and the American Oil Chemists' Society.

The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan is in line with Regulation (EC) No 1829/2003.

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1 On request from the Competent Authority of the United Kingdom for an application (EFSA-GMO-UK-2007-48) submitted by Syngenta, Questions No EFSA-Q-2010-00832 (EFSA overall opinion) and EFSA-Q-2007-196 (Scientific opinion of the EFSA GMO Panel), issued on 18 May 2010.

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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 x GA21.

KEY WORDS

Overall opinion, GMO, maize, *Zea mays*, MIR604 x GA21, insect resistance, glyphosate tolerance, food and feed uses, import and processing, food safety, feed safety, environmental safety, Regulation (EC) No 1829/2003.

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BACKGROUND

On 14 November 2007, the European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified maize MIR604 x GA21 (SYN-IR6Ø4-5 x MON-ØØØ21-9) submitted by Syngenta within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2007-48).

The scope of application EFSA-GMO-UK-2007-48 covers genetically modified maize MIR604 x GA21 for food and feed uses[3], food and feed containing, produced from or consisting of genetically modified maize MIR604 x GA21. 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[4] on 17 November 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 9 and 12 November 2007, the Community Reference Laboratory (CRL) received 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 12 March 2008 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 12 June 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 12 March 2008 to 24 June 2009 and from 5 October 2009 to 3 March 2010[5].

The overall opinion on application EFSA-GMO-UK-2007-48 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.

TERMS OF REFERENCE

The European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified maize MIR604 x GA21 (SYN-IR6Ø4-5 x MON-ØØØ21-9) submitted by Syngenta within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2007-48). EFSA was

[3]This does include genetically modified maize MIR604 x GA21 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-2010-00832

[5]Request for additional information from the EFSA GMO Panel: requested (1) on 12/03/2008 - received on 04/11/2008 and 07/04/2009, clock restarted on 24/06/2009; requested (2) on 05/10/2009 - received on 18/11/2009; requested (3) on 11/01/2010 - received on 08/02/2010; clock restarted on 03/03/2010.

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(s)

The application was submitted by

Syngenta Seeds S.A.S. 12, chemin de l'Hobit BP 27 F-31790 Saint-Sauveur France	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-2007-48 covers genetically modified maize MIR604 x GA21 for food and feed uses[6] and food and feed containing, consisting of or produced from maize MIR604 x GA21. The scope does not include cultivation.

Maize MIR604 x GA21 has been produced by conventional crossing methods between maize lines containing the single maize events MIR604 and GA21 to combine both the resistance trait against certain coleopteran target pests and the ability to use mannose as sole carbon source in maize MIR604 with tolerance to glyphosate-based herbicides in maize GA21.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize MIR604 x GA21 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 29 April 2010. 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. In conclusion, the EFSA GMO Panel considers that information available for maize MIR604 x GA21 addresses the scientific comments raised by Member States, and that the maize MIR604 x GA21, as described in this application, is as safe as its conventional counterpart and other appropriate comparators with respect to potential effects on human and animal health and the environment in the context of its intended uses. The EFSA GMO Panel concludes that maize MIR604 x GA21 is unlikely to have an adverse effect on human and animal health and 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, EFSA is of the opinion

[6] This does include genetically modified maize MIR604 x GA21 for import and processing as designated under part C of Directive 2001/18/EC.

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 genetically modified 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 MIR604 x GA21 which combines the MIR604 and GA21 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 issued on 30 March 2010 and 22 April 2010. 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. of Commission Regulation (EC) No 641/2004 (Annexes D1, D2a, D2b).

7. Certified reference materials

The certified reference materials of genetically modified maize MIR604 and maize GA21 (ERM - BF423) and (AOCS 0407-A and AOCS 0407-B) can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements and American Oil Chemists' Society (Annexes E1, 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 MIR604 x GA21.

LIST OF ANNEXES[7]

Annex A: Scientific opinion of the EFSA GMO Panel (maize MIR604 x GA21)
Annex B: Cartagena Protocol (maize MIR604 x GA21)
Annex C: Labelling (maize MIR604 x GA21)
Annex D1: Validation report (maize MIR604 x GA21)
Annex D2a: Validated method (maize MIR604)
Annex D2b: Validated method (maize GA21)
Annex E1: Certified reference materials report (maize MIR604)
Annex E2: Certified reference materials report (maize GA21)
Annex F: Post-market environmental monitoring plan (maize MIR604 x GA21)
Annex G: Member States' comments (maize MIR604 x GA21)

[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-2010-00832