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-DE-2010-82) for the placing on the market of the genetically modified maize MIR162 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 MIR162 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-DE-2010-82 is for food and feed uses, food and feed containing, consisting of or produced from maize MIR162, 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 MIR162 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In conclusion, the EFSA GMO Panel considers that the information available for maize MIR162 addresses scientific comments raised by Member States and that the maize MIR162, as described in this application, is as safe as its conventional counterpart and non-GM commercial varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses. The European Union Reference Laboratory for GM Food and Feed (EURL-GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize MIR162 can be accessed at the American Oil Chemists' Society (AOCS-USA).

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 German Competent Authority for an application (EFSA-GMO-DE-2010-82) submitted by Syngenta, Questions No EFSA-Q-2012-00624 (EFSA overall opinion) and EFSA-Q-2010-00972 (Scientific opinion of the EFSA GMO Panel), issued on 21 June 2012.

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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 MIR162.

KEY WORDS

Overall opinion, GMO, maize (*Zea mays*), MIR162, insect resistance, Vip3Aa20, PMI, human and animal health, import and processing, Regulation (EC) No 1829/2003.

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BACKGROUND

On 12 July 2010, the European Food Safety Authority (EFSA) received from the German Competent Authority an application for authorisation of genetically modified maize MIR162 (SYN-IR162-4) submitted by Syngenta within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-DE-2010-82).

The scope of application EFSA-GMO-DE-2010-82 covers genetically modified maize MIR162 for food and feed uses[3], food and feed containing, produced from or consisting of genetically modified maize MIR162. 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 26 July 2010. 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 12 and 17 December 2008, the European Union Reference Laboratory 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 24 August 2010 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 24 November 2010) 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 August 2010 to 17 April 2012.[5]

The overall opinion on application EFSA-GMO-DE-2010-82 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 European Union 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 German Competent Authority an application for authorisation of genetically modified maize MIR162 (SYN-IR162-4) submitted by Syngenta within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-DE-2010-82). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

[3]This does include genetically modified maize MIR162 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-2010-00972

[5]Request for additional information from the EFSA GMO Panel: requested (1) on 24/08/2010 - received on 05/10/2010; requested (2) on 21/01/2011 - received on 01/02/2012 and clock restarted on 17/04/2012.

CONSIDERATIONS

1. Applicant

The application was submitted by

Syngenta Crop Protection AG
Schwarzwaldallee 215
4058 Basel
Switzerland

2. Designation and specification of the product

The scope of application EFSA-GMO-DE-2010-82 covers genetically modified maize MIR162 for food and feed uses[6] and food and feed containing, consisting of or produced from maize MIR162. The scope does not include cultivation.

Maize MIR162 expresses the Vip3Aa protein for resistance against certain lepidopteran target pests. As a selectable marker, it also expresses a phosphomannose isomerase (PMI) protein.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize MIR162 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 31 May 2012. 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 the information available for maize MIR162 addresses scientific comments raised by Member States and that the maize MIR162, as described in this application, is as safe as its conventional counterpart and non-GM commercial varieties with respect to potential effects on human and animal health and 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. 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 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 European Union 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 maize MIR162 transformation event in maize DNA. The reports were issued on 3 April 2007 and 31

[6] This does include genetically modified maize MIR162 for import and processing as designated under part C of Directive 2001/18/EC.

January 2011. The European Union 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 the Commission Regulation (EC) No 641/2004 (Annexes D1, D2, D3).

7. Certified reference materials

The certified reference materials of genetically modified maize MIR162 can be accessed at the American Oil Chemists' Society (AOCS-USA) (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 MIR162.

LIST OF ANNEXES[7]

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Annex B: Cartagena Protocol (maize MIR162)
Annex C: Labelling (maize MIR162)
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Annex F: Post-market environmental monitoring plan (maize MIR162)
Annex G: Member States' comments (maize MIR162)

[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-2012-00624