REPORT OF EFSA

Overall opinion of the European Food Safety Authority in accordance with Article 6 of Regulation (EC) No 1829/2003 on application (reference EFSA-GMO-NL-2012-107) for the placing on the market of food produced from or containing ingredients produced from maize MON 810, according to Article 3(1)(c) of Regulation (EC) No 1829/2003 (maize MON 810 pollen as or in food) (application EFSA-GMO-NL-2012-107) from Monsanto[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 pollen MON 810 in accordance with the requirements of Article 6 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-NL-2012-107 is for food produced from or containing ingredients produced from maize MON 810, according to Article 3(1)(c) of Regulation (EC) No 1829/2003 (maize MON 810 pollen as or in food). 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 pollen MON 810 in accordance with Article 6(6) of Regulation (EC) No 1829/2003. The EFSA GMO Panel considers that the information available for pollen MON 810 addresses the scientific comments raised by the Member States. While the EFSA GMO Panel is not in a position to conclude on the safety of maize pollen in or as food in general, it concludes that the genetic modification in maize MON 810 does not constitute an additional health risk if maize MON 810 pollen were to replace maize pollen from non-GM maize in or as food. The European Union Reference Laboratory for Genetically Modified Food and Feed (EU-RL–GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize MON 810 pollen can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements.

The information presented for the labelling proposal is in line with Regulation (EC) No 1829/2003.

[1] On request from the Competent Authority of the Netherlands for an application (EFSA-GMO-NL-2012-107) submitted by Monsanto, Questions No EFSA-Q-2012-00988 (EFSA overall opinion) and EFSA-Q-2012-00408 (Scientific opinion of the EFSA GMO Panel), issued on 18 December 2012.

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Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Article 6 or the placing on the market of genetically modified maize MON 810 pollen.

KEY WORDS

Overall opinion, GMO, maize, pollen, MON810, MON 810, honey, insect resistance, food uses, food ingredients, food safety, Regulation (EC) No 1829/2003.

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BACKGROUND

On 15 March 2012, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified pollen MON 810 (MON-ØØ81Ø-6) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2012-107).

The scope of application EFSA-GMO-NL-2012-107 covers food produced from or containing ingredients produced from maize MON 810, according to Article 3(1)(c) of Regulation (EC) No 1829/2003 (maize MON 810 pollen as or in food).[3] The scope does not include cultivation.

In accordance with Article 5 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 16 April 2012. EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Article 5 of Regulation (EC) No 1829/2003. On 18 May 1999, the EU-RL – GMFF 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 29 May 2012 and started the clock in accordance with Article 6 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 (Article 6(1)). EFSA made the valid application available to Member States and the European Commission. Following the procedure laid down in Article 6(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 August 2012) within which to make their opinion known.

EFSA did not request additional information from the applicant during the risk assessment of the application and, consequently, the clock of application EFSA-GMO-NL-2012-107 was not stopped.

The overall opinion on application EFSA-GMO-NL-2012-107 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms together with the particulars required under Article 6(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 labelling proposal, iv) the method for detection, validated by the EU-RL – GMFF, including sampling, identification of the transformation event in the food and/or foods produced from it, v) an indication of where appropriate reference materials can be accessed and vi) 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 Netherlands an application for authorisation of genetically modified maize MON 810 pollen (MON-ØØ81Ø-6) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2012-107). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Article 6).

[3] This does not include genetically modified maize MON 810 pollen 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-2012-00408

CONSIDERATIONS

1. Applicant

The application was submitted by

Monsanto Europe S.A.
Avenue de Tervueren 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 EFSA-GMO-NL-2012-107 is for food produced from or containing ingredients produced from maize MON 810, according to Article 3(1)(c) of Regulation (EC) No 1829/2003 (maize MON 810 pollen as or in food).[5] The scope does not include cultivation.

Maize MON 810 expresses the insecticidal protein Cry1Ab under the control of enhanced 35S promoter from *Cauliflower mosaic virus*. The Cry1Ab protein 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 the scientific assessment of the genetically modified maize MON 810 pollen in accordance with Article 6(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 6 December 2012. The EFSA GMO Panel considered all comments submitted by Member State bodies. The EFSA GMO Panel considers that the information available for pollen MON 810 addresses the scientific comments raised by the Member States. While the EFSA GMO Panel is not in a position to conclude on the safety of maize pollen in or as food in general, it concludes that the genetic modification in maize MON 810 does not constitute an additional health risk if maize MON 810 pollen were to replace maize pollen from non-GM maize in or as food (Annex A).

4. Cartagena Protocol (not applicable)

Due to the scope of the application, there are no requirements for a Cartagena Protocol for maize MON 810 pollen.

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).

[5] This does not include genetically modified maize MON 810 pollen for import and processing as designated under part C of Directive 2001/18/EC.

6. Method for detection

The EU-RL – GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the MON 810 transformation event in maize DNA. The reports were issued on 10 March 2006 and 28 May 2009. The EU-RL – GMFF 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).

7. Certified reference materials

The certified reference materials of pollen MON 810 (ERM-BF413) 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 (not applicable)

Due to the scope of the application, there are no requirements for a post-market environmental monitoring plan for maize MON 810 pollen.

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 Article 6 for the placing on the market of genetically modified maize MON 810 pollen.

LIST OF ANNEXES[6]

Annex A: Scientific opinion of the GMO Panel (maize MON 810 pollen)
Annex B: Cartagena protocol (Not applicable)
Annex C: Labelling (maize MON 810 pollen)
Annex D1: Validation report (maize MON 810)
Annex D2: Verification report (maize MON 810)
Annex E: Certified reference materials report (maize MON 810)
Annex F: Post-market environmental monitoring report (Not applicable)
Annex G: Member States' comments (maize MON 810 pollen)

[6] 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-2012-00988.