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 the application (reference EFSA-GMO-RX-MON863) for renewal of the authorisation of existing products produced from insect resistant genetically modified maize MON863 for food and feed uses 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 maize MON863 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-RX.MON863 is for food additives produced from and feed produced from maize MON863 (feed materials and feed additives) 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 not include cultivation.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified maize MON863 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that the genetically modified maize MON863 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 MON863 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.

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 MON863.

KEY WORDS

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[1] On request from the European Commission for an application (EFSA-GMO-RX-MON863) submitted by Monsanto, Questions No EFSA-Q- 2010-00175 (EFSA overall opinion) and EFSA-Q-2007-163 (Scientific opinion of the EFSA GMO Panel), issued on 30 March 2010.

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Overall opinion, GMO, maize, *Zea mays*, MON863, insect resistance, food and feed uses, import and processing, food safety, feed safety, environmental safety, Regulation (EC) No 1829/2003, renewal, existing product.

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BACKGROUND

On 29 June 2007, the European Food Safety Authority (EFSA) received from the European Commission an application for authorisation of GM maize MON863 (MON-ØØ863-5) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-MON863).

The scope of application EFSA-GMO-RX-MON863 covers the continued marketing of existing food additives produced from and feed produced from maize MON863 (feed materials and feed additives) which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No. 1829/2003. After the date of entry into force of Regulation (EC) No. 1829/2003 these products were notified to the European Commission according to Articles 8 and 20 of that Regulation and included in the Community Register of genetically modified food and feed[3]. 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 3 July 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 11 October 2004, 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 5 June 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 5 September 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 11 July 2009 to 21 January 2009 and from 12 February 2009 to 16 November 2009[5].

The overall opinion on application EFSA-GMO-RX-MON863 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) post-market environmental monitoring and, viii) the Member States' comments submitted during the three-month consultation period.

[3] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=12
[4] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-163

[5] Request for additional information from the EFSA GMO Panel: requested (1) on 11/07/2008 - received on 11/11/2008, clock restarted on 21/01/2009, requested (2) on 12/02/2009- received on 19/03/2009, requested (3) on 04/06/2009 – received on 01/10/2009, and clock restarted on 16/11/2009.

TERMS OF REFERENCE

The European Food Safety Authority (EFSA) received from the European Commission an application for authorisation of GM maize MON863 (MON-ØØ863-5) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-MON863). EFSA was 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

The application was submitted by

Monsanto Europe S.A.
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 application EFSA-GMO-RX-MON863 covers the continued marketing of existing food additives produced from and feed produced from maize MON863 (feed materials and feed additives). After the date of entry into force of Regulation (EC) No. 1829/2003 these products were notified to the European Commission according to Articles 8 and 20 of that Regulation and included in the Community Register of genetically modified food and feed[6]. The scope does not include cultivation.

Maize MON863 has been modified with a gene encoding the Cry3Bb1 protein which confers protection against coleopteran pests, principally the corn rootworm (*Diabrotica* spp.). In addition, a selectable marker gene *npt*II encoding neomycin phosphotransferase II has been introduced.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize MON863 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 10 March 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. The EFSA GMO Panel concludes that the information available for GM maize MON863 addresses the scientific comments raised by the Member States and considers that the genetically modified maize MON863 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 (not applicable)

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

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 MON863 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] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=12

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 MON863 transformation event in maize flour. The report was published on 31 January 2005. 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 MON863 (ERM-BF416) 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 MON863.

9. Member States' Comments

The EFSA GMO Panel has addressed in detail 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 renewal of authorisation of genetically modified maize MON863.

LIST OF ANNEXES[7]

Annex A: Scientific opinion of the EFSA GMO Panel (maize MON863)
Annex B: not applicable
Annex C: Labelling (maize MON863)
Annex D1: Validation report (maize MON863)
Annex D2: Validated method (maize MON863)
Annex E: Certified reference materials report (maize MON863)
Annex F: not applicable
Annex G: Member States' comments (maize MON863)

[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-2007-163