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-CZ-2008-62) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Dow AgroSciences and 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 MON 89034 x 1507 x MON 88017 x 59122 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of application EFSA-GMO-CZ-2008-62 covers genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny for food and feed uses[3], food and feed containing, produced from or consisting of genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny. 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 MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny 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 MON 89034 x 1507 x MON 88017 x 59122 addresses the scientific comments raised by the Member States and that the maize MON 89034 x 1507 x MON 88017 x 59122, as described in this application, is as safe as its conventional

1 On request from the Competent Authority of the Czech Republic for an application (EFSA-GMO-CZ-2008-62) submitted by Dow AgroSciences and Monsanto, Questions No EFSA-Q-2010-00928 (EFSA overall opinion) and EFSA-Q-2008-764 (Scientific opinion of the EFSA GMO Panel), issued on 27 September 2010.

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3 This does include genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny for import and processing as designated under part C of Directive 2001/18/EC.

For citation purposes: European Food Safety Authority; 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-CZ-2008-62) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 on request from Dow AgroSciences and Monsanto.

counterpart and commercial maize varieties with respect to potential effects on human and animal health and the environment. In addition, the EFSA GMO Panel is of the opinion that crossing of single maize events MON 89034, 1507, MON 88017 and 59122 to produce maize MON 89034 x 1507 x MON 88017 x 59122 does not result in interactions between the events which would affect the safety of maize MON 89034 x 1507 x MON 88017 x 59122 with respect to potential effects on human and animal health and on the environment, in the context of its intended uses. Based on the data provided for maize stack MON 89034 x 1507 x MON 88017 x 59122, the single maize events and for the two double parental stacks 1507 x 59122 and MON 89034 x MON 88017, the EFSA GMO Panel is of the opinion that there is no biological reason to expect that any of the other sub-combinations of the individual events present in its segregating progeny would raise a safety concern. The EFSA GMO Panel concludes that maize MON 89034 x 1507 x MON 88017 x 59122 is unlikely to have adverse effects on human and animal health and 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 MON 89034, maize 1507, maize MON 88017 and maize 59122 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.

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 MON 89034 x 1507 x MON 88017 x 59122.

KEY WORDS

GMO, maize, stacked event, MON 89034 x 1507 x MON 88017 x 59122, insect resistant, herbicide tolerant, food and feed uses, import and processing, food safety, feed safety, environmental safety, Regulation (EC) No 1829/2003.

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BACKGROUND

On 28 October 2008, the European Food Safety Authority (EFSA) received from the Competent Authority of the Czech Republic an application for authorisation of genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 (MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7) submitted by Dow AgroSciences and Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-CZ-2008-62).

The scope of application EFSA-GMO-CZ-2008-62 covers genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny for food and feed uses[4], food and feed containing, produced from or consisting of genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny. 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[5] on 15 November 2008. 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 3 November 2008, 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 3 March 2009 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 3 June 2009) 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 20 May 2009 to 29 January 2010, from 11 March 2010 to 6 May 2010 and from 2 July 2010 to 19 August 2010[6].

The overall opinion on application EFSA-GMO-CZ-2008-62 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

[4]This does include genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny for import and processing as designated under part C of Directive 2001/18/EC.

[5]http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2008-764

[6]Request for additional information from the EFSA GMO Panel: requested (1) on 20/05/2009 - received on 23/06/2009; requested (2) on 11/09/2009 - received on 15/09/2009; information was submitted spontaneously on 25/09/2009; requested (3) on 05/10/2009 - received on 20/11/2009; requested (4) on 29/10/2009 - received on 23/12/2009; clock restarted on 29/01/2010; clarifications received on 02/02/2010; amendments on additional information received on 26/02/2010; requested (5) on 11/03/2010 - received on 31/03/2010; requested by e-mail (6) on 22/04/2010 - received on 03/05/2010; clock restarted on 06/05/2010; clarifications on the scope received on 16/06/2010; information was submitted spontaneously on 24/06/2010; requested (7) on 02/07/2010 – received on 19/07/2010; requested (8) on 26/07/2010 – received on 30/07/2010 and clock restarted on 19/08/2010.

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 Czech Republic an application for authorisation of genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 (MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7) submitted by Dow AgroSciences and Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-CZ-2008-62). 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(s)

The application was submitted by

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B-1150 Brussels
Belgium

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Oxon OX14 4RN
United Kingdom

Mycogen Seeds
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Abingdon 9330 Zionsville Road
Indianapolis
Indiana 46268-1054
U.S.A.

2. Designation and specification of the product

The scope of application EFSA-GMO-CZ-2008-62 covers genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny for food and feed uses[7] and food and feed containing, consisting of or produced from maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny. The scope does not include cultivation.

Maize MON 89034 x 1507 x MON 88017 x 59122 was produced by conventional crossing of inbred lines containing the maize stacks 1507 x 59122 and MON 89034 x MON 88017, to combine resistance against certain lepidopteran and coleopteran target pests and tolerance to glufosinate-ammonium and glyphosate-based herbicides.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 8 September 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 the information available for maize MON 89034 x 1507 x MON 88017 x 59122 addresses the scientific comments raised by the Member States and that maize MON 89034 x 1507 x MON 88017 x 59122, as described in this application, is as safe as its conventional counterpart and commercial maize varieties with respect to potential effects on human and animal health and the environment. In addition, the EFSA GMO Panel is of the opinion that crossing of

[7] This does include genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny for import and processing as designated under part C of Directive 2001/18/EC.

single maize events MON 89034, 1507, MON 88017 and 59122 to produce maize MON 89034 x 1507 x MON 88017 x 59122 does not result in interactions between the events which would affect the safety of maize MON 89034 x 1507 x MON 88017 x 59122 with respect to potential effects on human and animal health and on the environment, in the context of its intended uses. Based on the data provided for maize MON 89034 x 1507 x MON 88017 x 59122, the single maize events, and for two double stacks (1507 x 59122 and MON 89034 x MON 88017), the EFSA GMO Panel is of the opinion that there is no biological reason to expect that any of the other sub-combinations of the individual event as present in its segregating progeny would raise a safety concern. The EFSA GMO Panel concludes that maize MON 89034 x 1507 x MON 88017 x 59122 is unlikely to have adverse 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 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 four quantitative event specific methods on the hybrid maize line MON 89034 x 1507 x MON 88017 x 59122 which combines the maize MON 89034 x 1507 x MON 88017 x 59122 transformation events. The four methods have been validated individually on single-trait events, to detect and quantify each event in maize samples. The reports were issued on 21 February 2005, 8 June 2007, 21 October 2008, 30 March 2010 and 1 July 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, D2c, D2d).

7. Certified reference materials

The certified reference materials of genetically modified maize 1507 and genetically modified maize 59122 can be accessed at the Joint Research Centre of the European Commission (ERM-BF418 and ERM-BF424); the certified reference materials of genetically modified maize MON 88017 and genetically modified maize MON 89034 can be accessed at the Institute for Reference Materials and Measurements and American Oil Chemists' Society, (Annexes E1, E2, E3, E4).

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 MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny.

LIST OF ANNEXES[8]

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Annex B:	Cartagena Protocol (maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny)
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Annex F:	Post-market environmental monitoring plan (maize MON 89034 x 1507 x MON 88017 x 59122 and all sub-combinations of the individual events as present in its segregating progeny)
Annex G:	Member States' comments (maize MON 89034 x 1507 x MON 88017 x 59122)

[8] 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-2010-00928