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-NL-2009-73) for the placing on the market of the genetically modified soybean MON 87701 x MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 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 soybean MON 87701 x MON 89788 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-NL-2009-73 is for food and feed uses, food and feed containing, consisting of or produced from soybean MON 87701 x MON 89788, 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 soybean MON 87701 x MON 89788 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 soybean MON 87701 × MON 89788 addresses the scientific issues indicated by the Guidance document of the EFSA GMO Panel and the scientific comments raised by the Member States, and that the soybean MON 87701 × MON 89788 is as safe as its comparator with respect to potential effects on human and animal health or the environment in the context of its intended uses. In addition, the EFSA GMO Panel is of the opinion that crossing of single soybean events MON 87701 and MON 89788 to produce soybean MON 87701 × MON 89788 does not result in interactions between the events which would affect the safety of soybean MON 87701 × MON 89788 with respect to potential effects on human and animal health and on 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

[1] On request from the Competent Authority of The Netherlands for an application (EFSA-GMO-NL-2009-73) submitted by Monsanto, Questions No EFSA-Q-2012-00123 (EFSA overall opinion) and EFSA-Q-2009-00761 (Scientific opinion of the EFSA GMO Panel), issued on 15 February 2012.

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certified reference materials of soybeans MON 87701 and MON 89788 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.

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 soybean MON 87701 x MON 89788.

KEY WORDS

Overall opinion, GMO, *Glycine max*, MON 87701, MON 89788, insect resistance, herbicide 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 1 September 2009, the European Food Safety Authority (EFSA) received from the Competent Authority of The Netherlands an application for authorisation of genetically modified soybean MON 87701 x MON 89788 (MON-877Ø1-2 x MON-89788-1) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2009-73).

The scope of application EFSA-GMO-NL-2009-73 covers genetically modified soybean MON 87701 x MON 89788 for food and feed uses[3] and food and feed containing, produced from or consisting of genetically modified soybean MON 87701 x MON 89788. 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 20 September 2009. 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 22 July 2009, 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 8 December 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 8 March 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 26 February 2010 to 8 July 2011 and from 26 August 2011 to 20 January 2012.[5]

The overall opinion on application EFSA-GMO-NL-2009-73 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 Competent Authority of The Netherlands an application for authorisation of genetically modified soybean MON 87701 x MON 89788 (MON-877Ø1-2 x MON-89788-1) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2009-73).

[3]This includes genetically modified soybean MON 87701 x MON 89788 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-20009-00761

[5]Request for additional information from the EFSA GMO Panel: requested (1) on 26/02/2010 - received on 09/04/2010; requested (2) on 21/06/2010 - received on 01/07/2010; requested (3) on 15/11/2010 - received on 03/01/2011; requested (4) on 04/03/2011 - received on 15/03/2011 and clock re-started on 08/07/2011; requested (5) on 26/08/2011 - received on 05/09/2011; requested (6) on 13/10/2011 - received on 03/11/2011; requested (7) on 02/12/2011 - received on 06/12/2011 and clock restarted on 20/01/2012.
The applicant sent additional information spontaneously on 18/05/2010.

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

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Avenue de Tervuren 270-272 800
B-1150 Brussels
Belgium

Monsanto Company
N. Lindbergh Boulevard
St. Louis, Missouri 63167
U.S.A.

2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2009-73 covers genetically modified soybean MON 87701 x MON 89788 for food and feed uses[6] and food and feed containing, consisting of or produced from soybean MON 87701 x MON 89788. The scope does not include cultivation.

Soybean MON 87701 x MON 89788 expresses the *cry1Ac* gene to confer resistance to specific lepidopteran insects and the CP4 *epsps* gene, conferring tolerance to glyphosate-containing herbicides.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified soybean MON 87701 x MON 89788 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 25 January 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 soybean MON 87701 × MON 89788 addresses the scientific issues indicated by the Guidance document of the EFSA GMO Panel and the scientific comments raised by the Member States, and that the soybean MON 87701 × MON 89788 is as safe as its comparator with respect to potential effects on human and animal health or the environment in the context of its intended uses. In addition, the EFSA GMO Panel is of the opinion that crossing of single soybean events MON 87701 and MON 89788 to produce soybean MON 87701 × MON 89788 does not result in interactions between the events which would affect the safety of soybean MON 87701 × MON 89788 with respect to potential effects on human and animal health and on 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

[6] This includes genetically modified soybean MON 87701 x MON 89788 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 European Union Reference Laboratory for GM Food and Feed has carried out an in-house verification study to assess the performance of two quantitative event specific methods on the hybrid soybean line MON 87701 x MON 89788 which combines the MON 87701 and MON 89788 transformation events. The two methods have been validated individually on single-trait events, to detect and quantify each event on soybean samples. The reports were issued on 27 February 2008, 15 July 2011 and 14 February 2012. The European Union Reference Laboratory considers that the methods are 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, D2a, D2b).

7. Certified reference materials

The certified reference materials of genetically modified soybean lines MON 87701 and MON 89788 can be accessed at the American Oil Chemists' Society (AOCS-USA) (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 of 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 soybean MON 87701 x MON 89788.

LIST OF ANNEXES[7]

Annex A:	Scientific opinion of the EFSA GMO Panel (soybean MON 87701 x MON 89788)
Annex B:	Cartagena Protocol (soybean MON 87701 x MON 89788)
Annex C:	Labelling (soybean MON 87701 x MON 89788)
Annex D1:	Validation report (soybean MON 87701 x MON 89788)
Annex D2a:	Validated method (soybean MON 87701)
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Annex E1:	Certified reference materials report (soybean MON 87701)
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Annex F:	Post-market environmental monitoring plan (soybean MON 87701 x MON 89788)
Annex G:	Member States' comments (soybean MON 87701 x MON 89788)

[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-2012-00123