

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-BE-2010-79) for the placing on the market of the insect resistant genetically modified soybean MON 87701 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto¹

European Food Safety Authority²

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 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-BE-2010-79 is for food and feed uses, food and feed containing, consisting of or produced from soybean MON 87701, 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 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 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 is as safe as its conventional counterpart with respect to potential effects on human and animal health or 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 soybean MON 87701 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.

¹ On request from the Competent Authority of Belgium for an application (EFSA-GMO-BE-2010-79) submitted by Monsanto, Questions No EFSA-Q-2011-00857 (EFSA overall opinion) and EFSA-Q-2010-00867 (Scientific opinion of the EFSA GMO Panel), issued on 26 July 2011.

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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 soybean MON 87701.

KEY WORDS

Overall opinion, GMO, soybean, *Glycine max*, insect resistance, food and feed uses, import and processing, food safety, feed safety, environmental safety, Regulation (EC) No 1829/2003.

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BACKGROUND

On 17 May 2010, the European Food Safety Authority (EFSA) received from the Competent Authority of Belgium an application for authorisation of genetically modified soybean MON 87701 (MON-877Ø1-2) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-BE-2010-79).

The scope of application EFSA-GMO-BE-2010-79 covers genetically modified soybean MON 87701 for food and feed uses³, food and feed containing, produced from or consisting of genetically modified soybean MON 87701. 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 website⁴ on 7 June 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 22 July 2009, 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 11 June 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 11 September 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 21 June 2010 to 31 May 2011⁵.

The overall opinion on application EFSA-GMO-BE-2010-79 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) 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 Belgium an application for authorisation of genetically modified soybean MON 87701 (MON-877Ø1-2) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-BE-2010-79). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

³This does include genetically modified soybean MON 87701 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-2011-00857>

⁵Request for additional information from the EFSA GMO Panel: requested (1) on 21/06/2010 - received on 01/07/2010; requested (2) on 15/11/2010 - received on 03/01/2011; requested (3) on 04/03/2011 - received on 15/03/2011 and clock restarted on 31/05/2011.

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-DE-2010-79 covers genetically modified soybean MON 87701 for food and feed uses⁶ and food and feed containing, consisting of or produced from soybean MON 87701. The scope does not include cultivation.

Soybean MON 87701 expresses the cry1Ac gene leading to the production of the Cry1Ac insecticidal crystal protein (δ -endotoxin). The Cry1Ac protein provides protection from feeding damage caused by specific lepidopteran pests in the soybean.

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 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 6 July 2011. 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 considers that the information available for soybean MON 87701 addresses the scientific comments raised by the Member States and that the soybean MON 87701, as described in this application, is as safe as its conventional counterpart 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 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

⁶ This does include genetically modified soybean MON 87701 for import and processing as designated under part C of Directive 2001/18/EC.

detect and quantify the soybean MON 87701 transformation event in soybean DNA. The reports were issued on 11 September 2007 and 13 July 2011. 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 the Commission Regulation (EC) No 641/2004 (Annexes D1, D2, D3).

7. Certified reference materials

The certified reference materials of genetically modified soybean MON 87701 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 soybean MON 87701.

LIST OF ANNEXES⁷

- Annex A: Scientific opinion of the EFSA GMO Panel (soybean MON 87701)
- Annex B: Cartagena Protocol (soybean MON 87701)
- Annex C: Labelling (soybean MON 87701)
- Annex D1: Validation report (soybean MON 87701)
- Annex D2: Validated method (soybean MON 87701)
- Annex D3: Sampling and extraction (soybean MON 87701)
- Annex E: Certified reference materials report (soybean MON 87701)
- Annex F: Post-market environmental monitoring plan (soybean MON 87701)
- Annex G: Member States' comments (soybean MON 87701)

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-2011-00857>