

TECHNICAL REPORT

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-UK-2007-41) for the placing on the market of herbicide-tolerant genetically modified cotton MON 88913 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 cotton MON 88913 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-UK-2007-41 is for food and feed uses, 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 cotton MON 88913 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. The EFSA GMO Panel considers that the information available for cotton MON 88913 addresses the scientific issues indicated by the Guidance Document of the EFSA GMO Panel and the scientific comments raised by the Member States. In conclusion, the EFSA GMO Panel considers that the information available for cotton MON 88913 is not sufficient to reach a final overall conclusion due to partially outdated bioinformatic analyses. The European Union Reference Laboratory for GM Food and Feed (EU-RL – GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of cotton MON 88913 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 cotton MON 88913.

¹ On request from the Competent Authority of the United Kingdom for an application (EFSA-GMO-UK-2007-41) submitted by Monsanto, Questions No EFSA-Q-2013-00642 (EFSA overall opinion) and EFSA-Q-2007-085 (Scientific opinion of the EFSA GMO Panel), issued on 29 July 2013.

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KEY WORDS

GMO cotton MON 88913, Regulation (EC) No 1829/2003, CP4 EPSPS, risk assessment, food and feed safety, environment, import and processing.

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BACKGROUND AS PROVIDED BY THE APPLICANT

On 11 April 2007, the European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of herbicide-tolerant genetically modified cotton MON 88913 (Unique Identifier MON-88913-8) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2007-41).

The scope of this application EFSA-GMO-UK-2007-41 is for food and feed uses.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 website⁴ on 20 April 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 31 July and 16 November 2007 and on 3 April and 27 July 2008, the EU-RL – GMFF received 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 19 October 2007 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 19 January 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 30 October 2007 to 21 October 2008 and from 2 February 2009 to 11 April 2013.⁵

The overall opinion on application EFSA-GMO-UK-2007-41 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 AS PROVIDED BY THE COMPETENT AUTHORITY OF THE UNITED KINGDOM

The European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified cotton MON 88913 (Unique Identifier MON-88913-8) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2007-41). EFSA

³ This does include genetically modified cotton MON 88913 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-2013-00642>.

⁵ Request for additional information from the EU-RL – GMFF: Request (1) on 14/08/2007 – received on 27/06/2008, 31/07/2007, 01/08/2007, 16/10/2007, 28/11/2007 and on 16/11/2007; request (3) on 29/10/2007, 17/12/2007 and on 08/05/2008 – received on 24/07/2008 and clock re-started on 07/08/2008.

Request for additional information from EFSA: Request (1) on 20/12/2007 – received on 21/01/2008; request (2) on 27/02/2008 – received on 03/06/2008 and on 01/12/2010; request (3) on 24/06/2008 – received on 01/09/2008 and clock re-started on 21/10/2008. Request (4) on 02/02/2009 – received on 03/12/2012 and clock re-started on 11/04/2013.

On 15/09/2010 and on 01/07/2013 the applicant provided clarifications and modifications on the scope of the application.

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
B-1150 Brussels
Belgium

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

2. Designation and specification of the product as provided by the applicant

The scope of this application EFSA-GMO-UK-2007-41 is for food and feed uses.⁶ The scope does not include cultivation.

The genetic modification in cotton MON 88913 results in the expression of the CP4 EPSPS protein, which is intended to improve agronomic performance only and it is not intended to influence the nutritional properties, processing characteristics and overall use of cotton as a crop.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified cotton MON 88913 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 3 July 2013. 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 cotton MON 88913 addresses the scientific issues indicated by the Guidance Document of the EFSA GMO Panel and the scientific comments raised by the Member States. In conclusion, the EFSA GMO Panel considers that the information available for cotton MON 88913 is not sufficient to reach a final overall conclusion due to partially outdated bioinformatic analyses (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 Article 13(2)(a) and 25(2)(c) (Annex C).

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 cotton MON 88913-transformation event in cotton DNA. The reports were issued on 19 June 2008 and 5 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. of the Commission Regulation (EC) No 641/2004 (Annexes D1, D2, D3).

⁶ This includes genetically modified cotton MON 88913 for import and processing as designated under part C of Directive 2001/18/EC.

7. Certified reference materials

The certified reference materials of genetically modified cotton MON 88913 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 cotton MON 88913.

LIST OF ANNEXES⁷

- Annex A: Scientific opinion of the EFSA GMO Panel (cotton MON 88913)
- Annex B: Cartagena Protocol (cotton MON 88913)
- Annex C: Labelling (cotton MON 88913)
- Annex D1: Validation report (cotton MON 88913)
- Annex D2: Validated method (cotton MON 88913)
- Annex D3: Sampling and extraction (cotton MON 88913)
- Annex E: Certified reference materials report (cotton MON 88913)
- Annex F: Post-market environmental monitoring plan (cotton MON 88913)
- Annex G: Member States' comments (cotton MON 88913)

⁷ The annexes of the EFSA overall opinion can be found in the Register of Questions (tab “Question documents”) on the EFSA website under the following link:
<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00642>