

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-2008-57) for the placing on the market of insect-resistant genetically modified cotton MON 15985 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 15985 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of application EFSA-GMO-UK-2008-57 is for food and feed uses; food and feed containing or consisting of cotton MON 15985; food produced from or containing ingredients produced from cotton MON 15985, feed produced from cotton MON 15985 and for import and processing³; it does not include cultivation in the EU. Thus, cotton MON 15985 will be imported into the EU for the above listed uses in the same way as any commercial cotton variety.

Since both EFSA-GMO-UK-2008-57 and EFSA-GMO-RX-MON15985 cover cotton MON 15985, the EFSA GMO Panel provides a single scientific opinion, valid for both applications.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified (GM) cotton MON 15985 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In delivering its Scientific Opinion, the EFSA GMO Panel considered applications EFSA-GMO-UK-2008-57 and EFSA-GMO-RX-MON15985, additional information submitted by the applicant on request of the Panel, the scientific comments submitted by Member States and relevant scientific publications. In accordance with its guidance document for renewal of authorisations of existing GMO products (EFSA, 2006), the EFSA GMO Panel took into account the new information, experience and data on cotton MON 15985 that became available during the authorisation period. The EFSA GMO Panel considers that the dossiers presented by the applicant had deficiency in the data set relative to agronomic and phenotypic trials, however the EFSA GMO Panel concludes that cotton MON 15985, as described in applications EFSA-GMO-UK-2008-57 and EFSA-GMO-RX-MON15985, is as safe as its conventional counterpart and non-GM cotton commercial varieties, and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of these applications. The European Union Reference Laboratory for GM Food and Feed

¹ On request from the Competent Authority of the United Kingdom for an application (EFSA-GMO-UK-2008-57) submitted by Monsanto, Questions No EFSA-Q-2014-00486 (EFSA overall opinion) and EFSA-Q-2008-385 (Scientific opinion of the EFSA GMO Panel), issued on 28 July 2014.

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³ This does include genetically modified cotton MON 15985 for import and processing as designated under part C of Directive 2001/18/EC

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Available online: www.efsa.europa.eu/publications

(EURL-GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of cotton MON 15985 can be accessed at the American Oil Chemists' Society (AOCS-USA). The information presented for the Cartagena Protocol 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 15985.

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KEY WORDS

Overall opinion, GMO, cotton, risk assessment, MON 15985, Genuity® Bollgard II®, insect resistance, Cry1Ac, Cry2Ab2, Regulation (EC) No 1829/2003

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BACKGROUND AS PROVIDED BY THE COMPETENT AUTHORITY OF THE UNITED KINGDOM

On 22 May 2008, the European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified cotton MON 15985 (unique identifier MON-15985-7) submitted by Monsanto Europe S.A./N.V. within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2008-57).

The scope of application EFSA-GMO-UK-2008-57 is for food and feed uses; food and feed containing or consisting of cotton MON 15985; food produced from or containing ingredients produced from cotton MON 15985 and feed produced from cotton MON 15985 and for import and processing⁴; it does not include cultivation in the EU. Thus, cotton MON 15985 will be imported into the EU for the above listed uses in the same way as any commercial cotton variety.

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 website⁵ on 9 June 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 11 February 2005, the European Union Reference Laboratory for Genetically modified Food and Feed (EU-RL – GMFF) 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 20 August 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 20 November 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 20 August 2008 to 21/09/2011 and from 5 December 2011 to 29 April 2014⁶.

The overall opinion on application EFSA-GMO-UK-2008-57 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

⁴ This does include genetically modified cotton MON 15985 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-2008-385>

Request for supplementary information from the EFSA GMO Panel: Requested (1) on 20/08/2008 – received on 02/09/2008; requested (2) on 24/11/2008 – received on 09/03/2009; requested (3) on 07/04/2009 – received on 18/05/2009; requested (4) on 28/05/2009 – received on 18/01/2010; requested (5) on 18/09/2009 – received on 08/06/2010; requested (6) on 15/03/2010 – received on 30/06/2010; requested (7) on 04/10/2010 – received on 02/12/2010; requested (8) on 31/01/2011 – received on 11/04/2011 and clock re-started on 21/09/2011. Requested (9) on 05/12/2011 – received on 14/09/2012; requested (10) on 06/07/2012 – received on 05/11/2012; requested (11) on 09/01/2013 – received on 12/03/2013; requested (12) on 03/06/2013 – received on 05/11/2013; requested (13) on 23/08/2013 – received on 11/11/2013 and clock re-started on 29/04/2014.

EFSA requested clarifications (1) on 03/08/2010; the applicant provided clarifications on 15/09/2010. EFSA requested clarifications (2-3) on 12/07/2012 and on 09/10/2012; the applicant provided clarifications on 20/08/2012.

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 APPLICANT

The European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified cotton MON 15985 (unique identifier MON-15985-7) submitted by Monsanto Europe S.A./N.V. within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2008-57). 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-UK-2008-57 is for food and feed uses; food and feed containing or consisting of cotton MON 15985; food produced from or containing ingredients produced from cotton MON 15985 and feed produced from cotton MON 15985 and for import and processing; it does not include cultivation in the EU. Thus, cotton MON 15985 will be imported into the EU for the above listed uses in the same way as any commercial cotton variety⁷.

Cotton MON 15985 was obtained by the transformation of genetically modified cotton MON 531 (unique identifier MON-ØØ531-6) with a DNA fragment carrying two expression cassettes: *cry2Ab2* and *uidA*. While expression of the Cry2Ab2 protein confers resistance to the major lepidopteran cotton pests including the cotton bollworm, tobacco budworm and the pink bollworm, the GUS E377K protein, produced by the *uidA* gene, was used as a histochemical marker during product development.

Cotton MON 531 has been developed to produce a synthetic variant of the Cry1Ac protein. In addition, cotton MON 531 contains a kanamycin resistance gene (*nptII*) under plant expression signals and the streptomycin/spectinomycin resistance gene *aadA* under the control of its bacterial promoter. Cotton MON 531 has been assessed previously (EFSA GMO Panel, 2011) on the basis of experimental data. No concerns were identified for human and animal health and the environment.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel carried out the scientific assessment of the genetically modified cotton MON 15985 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 2 July 2014. In delivering its Scientific Opinion, the EFSA GMO Panel considered applications EFSA-GMO-UK-2008-57 and EFSA-GMO-RX-MON15985, additional information submitted by the applicant on request of the Panel, the scientific comments submitted by Member States and relevant scientific publications. In accordance with its guidance document for renewal of authorisations of existing GMO products (EFSA, 2006), the EFSA GMO Panel took into account the new information, experience and data on cotton MON 15985 that became available during

⁷ This includes genetically modified cotton MON 15985 for import and processing as designated under part C of Directive 2001/18/EC.

the authorisation period. The EFSA GMO Panel considers that the dossiers presented by the applicant had deficiency in the data set relative to agronomic and phenotypic trials, however the EFSA GMO Panel concludes that cotton MON 15985, as described in applications EFSA-GMO-UK-2008-57 and EFSA-GMO-RX-MON15985, is as safe as its conventional counterpart and non-GM cotton commercial varieties, and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of these applications (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 Joint Research Centre (JRC) as Community Reference Laboratory for the Genetically Modified Food and Feed has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the cotton MON 15985-transformation event in cotton DNA. The reports were issued on 19 June 2008 and on 7 January 2009. The European Union Reference Laboratory considers that the method is 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, D2 and D3).

7. Certified reference materials

The certified reference materials of cotton MON 15985 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E).

8. Post-market environmental monitoring

The scope of the PMEM provided by the applicant is in line with the intended uses. As the ERA did not identify potential adverse environmental effects due to cotton MON 15985, no case-specific monitoring is required (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 15985.

LIST OF ANNEXES⁸

- Annex A: Scientific opinion of the EFSA GMO Panel (cotton MON 15985)
- Annex B: Cartagena Protocol (cotton MON 15985)
- Annex C: Labelling (cotton MON 15985)
- Annex D1: Validation report (cotton MON 15985)
- Annex D2: Validated method (cotton MON 15985)
- Annex D3: Sampling and extraction (cotton MON 15985)
- Annex E: Certified reference materials (cotton MON 15985)
- Annex F: Post-market environmental monitoring (cotton MON 15985)
- Annex G: Member States' comments (cotton MON 15985)

⁸ 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-2014-00486>