

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 the application (reference EFSA-GMO-RX-MON1445) for renewal of the authorisation for continued marketing of existing food produced from cotton MON 1445 (cottonseed oil), food additives produced from cotton MON 1445 and feed produced from cotton MON 1445 (feed materials and feed additives) 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 1445 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-RX-MON1445 is for food produced from cotton MON 1445 (cottonseed oil), food additives produced from cotton MON 1445 and feed produced from cotton MON 1445 (feed materials and feed additives) which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. 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 1445 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In conclusion, the EFSA GMO Panel considers that information available for cotton MON 1445 addresses the questions raised by the Member States and that MON 1445-derived products are as safe as products derived from the conventional counterpart in the context of their 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 certified reference materials of cotton MON 1445 can be accessed at the American Oil Chemists' Society (AOCS-USA).

The information presented for the labelling proposal is in line with Regulation (EC) No 1829/2003.

¹ On request from the European Commission for an application (reference EFSA-GMO-RX-MON1445) submitted by Monsanto, Questions No EFSA-Q-2011-01179 (EFSA overall opinion) and EFSA-Q-2007-143 (Scientific opinion of the EFSA GMO Panel), issued on 16 December 2011.

² Correspondence: gmo@efsa.europa.eu

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 the application (reference EFSA-GMO-RX-MON1445) for renewal of the authorisation for continued marketing of existing food produced from cotton MON 1445 (cottonseed oil), food additives produced from cotton MON 1445 and feed produced from cotton MON 1445 (feed materials and feed additives) from Monsanto.

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 1445.

KEY WORDS

Overall opinion, GMO, cotton, MON 1445, herbicide tolerance, risk assessment, food and feed safety, environment, food and feed produced from, Regulation (EC) No 1829/2003, renewal, existing product.

TABLE OF CONTENTS

Summary	1
Table of contents	3
Background	4
Terms of reference.....	5
Considerations.....	6
1. Applicant	6
2. Designation and specification of the product	6
3. Scientific opinion of the EFSA GMO Panel.....	6
4. Cartagena Protocol (not applicable)	6
5. Labelling.....	6
6. Method for detection	7
7. Certified reference materials.....	7
8. Post-market environmental monitoring (not applicable).....	7
9. Member States' Comments.....	7
Conclusions	7
List of annexes	8

BACKGROUND

On 29 June 2007, the European Food Safety Authority (EFSA) received from the European Commission an application for renewal of the authorisation for continued marketing of existing products derived from GM cotton MON 1445 (MON-Ø1445-2) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-MON1445).

The scope of application EFSA-GMO-RX-MON1445 covers the continued marketing of existing food produced from cotton MON 1445 (cottonseed oil), food additives produced from cotton MON 1445 and feed produced from cotton MON 1445 (feed materials and feed additives) which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. After the date of entry into force of Regulation (EC) No 1829/2003 these products were notified to the European Commission according to Articles 8 and 20 of that Regulation and included in the Community Register of genetically modified food and feed.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 23 July 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 29 September 2004 and 1 October 2004, the European Union Reference Laboratory for GM Food and Feed confirmed receipt of 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 July 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 3 October 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 9 September 2008 to 16 September 2011 and from 21 September 2011 to 28 September 2011.⁵

The overall opinion on application EFSA-GMO-RX-MON1445 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 labelling proposal, iv) the method for detection, validated by the European Union Reference Laboratory for GM Food and Feed, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it, v) an indication of where appropriate reference materials can be accessed and vi) the Member States' comments submitted during the three-month consultation period.

³ http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=5

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-143>

⁵ Request for additional information from the EFSA GMO Panel: requested (1) on 09/09/2008 - received on 14/11/2008; requested (2) on 30/01/2009 - received on 03/06/2010; requested (3) on 27/04/2009 - received on 23/06/2009; requested (4) on 24/07/2009 - received on 03/02/2010; requested (5) on 17/09/2009 - received on 08/06/2010; requested (6) on 27/05/2010 - received on 14/09/2010; requested (7) on 02/08/2010 - received on 15/09/2010; requested (8) on 04/10/2010 - received on 02/12/2010; requested (9) on 31/01/2011 - received on 11/04/2011; requested (10) on 18/04/2011 - received on 26/07/2011 and clock restarted on 16/09/2011;

Request for additional information from EFSA: requested (1) on 21/09/2011 - received on 23/09/2011 and clock restarted on 28 September 2011.

TERMS OF REFERENCE

The European Food Safety Authority (EFSA) received from the European Commission an application for renewal of the authorisation for continued marketing of existing products derived from GM cotton MON 1445 (MON-Ø1445-2) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-MON1445). 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 this application EFSA-GMO-RX-MON1445 is for food produced from genetically modified cotton MON 1445 (cottonseed oil), food additives produced from cotton MON 1445 and feed produced from cotton MON 1445 (feed materials and feed additives). After the date of entry into force of Regulation (EC) No 1829/2003 these products were notified to the European Commission according to Articles 8 and 20 of that Regulation and included in the Community Register of genetically modified food and feed.⁶ The scope does not include cultivation.

Cotton MON 1445 has been developed for tolerance to glyphosate-based herbicides by the introduction, via *Agrobacterium tumefaciens*, of a gene coding for the 5-enolpyruvylshikimate-3-phosphate synthase from *Agrobacterium* sp. strain CP4 (CP4 *epsps*). MON 1445 also carries genes coding for neomycin phosphotransferase type II (NPTII) and 3'(9)-O-nucleotidyltransferase (AAD, not expressed in MON 1445), which were used as antibiotic-resistance marker genes during product development.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified cotton MON 1445 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 19 October 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. In conclusion, the EFSA GMO Panel considers that information available for cotton MON 1445 addresses the questions raised by the Member States and that MON 1445-derived products are as safe as products derived from the conventional counterpart in the context of their intended uses (Annex A).

4. Cartagena Protocol (not applicable)

Due to the scope of the application, there are no requirements for a Cartagena Protocol.

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 http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=5

6. Method for detection

The European Union Reference Laboratory for GM 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 1445 transformation event in cotton DNA. The reports were issued on 6 June 2008. The EURL-GMFF considers that the method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2. to Commission Regulation (EC) No 641/2004 (Annexes D1, D2, D3).

7. Certified reference materials

The certified reference materials of genetically modified cotton MON 1445 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E1).

8. Post-market environmental monitoring (not applicable)

Due to the scope of the application, there are no requirements for a post-market environmental monitoring plan for cotton MON 1445.

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 renewal of authorisation of genetically modified cotton MON 1445.

LIST OF ANNEXES⁷

Annex A:	Scientific opinion of the EFSA GMO Panel (cotton MON 1445)
Annex B:	Not applicable
Annex C:	Labelling (cotton MON 1445)
Annex D1:	Validation report (cotton MON 1445)
Annex D2:	Validated method (cotton MON 1445)
Annex D3:	Sampling and extraction (cotton MON 1445)
Annex E1:	Certified reference materials report (cotton MON 1445)
Annex F:	Not applicable
Annex G:	Member States' comments (cotton MON 1445)

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-2011-01179>