

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-NL-2011-97) for the placing on the market of insect resistance and herbicide tolerant genetically modified cotton T304-40 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience AG¹

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 T304-40 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-NL-2011-97 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 T304-40 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 T304-40 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 T304-40 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 cotton T304-40 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. 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 T304-40 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements.

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 the Netherlands for an application (EFSA-GMO-NL-2011-97) submitted by Bayer CropScience AG, Questions No EFSA-Q-2013-00525 (EFSA overall opinion) and EFSA-Q-2011-00312 (Scientific opinion of the EFSA GMO Panel), issued on 20 June 2013.

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 application (reference EFSA-GMO-NL-2011-97) for the placing on the market of insect resistance and herbicide tolerant genetically modified cotton T304-40 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience AG. Supporting Publications 2013:EN-447 [7 pp.]. Available online: www.efsa.europa.eu/publications

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 T304-40.

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KEY WORDS

Overall opinion, GMO, cotton T304-40, Regulation (EC) No 1829/2003, Cry1Ab, PAT, insect resistance, herbicide tolerance, risk assessment, food and feed uses, environment, import and processing.

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BACKGROUND

On 7 April 2011, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified cotton T304-40 (Unique Identifier BCS-GHØØ4-7) submitted by CropScience AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2011-97).

The scope of this application EFSA-GMO-NL-2011-97 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 2 May 2011. 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 September 2010, the 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 24 October 2011 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 24 January 2012) 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 5 December 2011 to 9 January 2013.⁵

The overall opinion on application EFSA-GMO-NL-2011-97 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 NETHERLANDS

The European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified cotton T304-40 (Unique Identifier BCS-GHØØ4-7) submitted by Bayer CropScience AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2011-97). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

³ This does include genetically modified cotton T304-40 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-2011-00312>.

⁵ Request for additional information from the EFSA GMO Panel: requested (1) on 05/12/2011 - received on 22/03/2012; requested (2) on 23/04/2012 - received on 06/06/2012 and clock re-started on 09/01/2013.

CONSIDERATIONS

1. Applicant

The application was submitted by

Bayer CropScience AG
Alfred-Nobel-Strasse
D-40789 Monheim am Rhein
Germany

Bayer BioScience NV
50 Technologiepark 38
B-9052 Gent
Belgium

represented by

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

The scope of this application EFSA-GMO-NL-2011-97 is for food and feed uses.⁶ The scope does not include cultivation.

The genetic modification in cotton T304-40 results in the expression of the Cry1Ab and PAT proteins, which confers tolerance to glufosinate-ammonium herbicide and resistance to certain lepidopteran insects.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified cotton T304-40 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 30 May 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 T304-40 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 T304-40 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 cotton T304-40 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 (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 T304-40 transformation event in maize DNA. The reports were issued on 14 March 2007 and 19 December 2012. 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 T304-40 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 T304-40 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (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 T304-40.

LIST OF ANNEXES⁷

Annex A:	Scientific opinion of the EFSA GMO Panel (cotton T304-40)
Annex B:	Cartagena Protocol (cotton T304-40)
Annex C:	Labelling (cotton T304-40)
Annex D1:	Validation report (cotton T304-40)
Annex D2:	Validated method (cotton T304-40)
Annex D3:	Sampling and extraction (cotton T304-40)
Annex E:	Certified reference materials report (cotton T304-40)
Annex F:	Post-market environmental monitoring plan (cotton T304-40)
Annex G:	Member States' comments (cotton T304-40)

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-2013-00525>