TECHNICAL REPORT

APPROVED: 17 October 2016 PUBLISHED: 21 October 2016

Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on application (EFSA-GMO-NL-2011-96) for the placing on the market of genetically modified insect-resistant and herbicide-tolerant cotton GHB119 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience AG

European Food Safety Authority

Summary

This document provides an overall opinion of the European Food Safety Authority (EFSA) on genetically modified (GM) cotton GHB119 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.[1]

The scope of application EFSA-GMO-NL-2011-96 is for food and feed uses, import and processing of cotton GHB119 within the European Union (EU) in the same way as any non-GM cotton but excludes cultivation in the EU.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of cotton GHB119 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In delivering its scientific opinion, the EFSA GMO Panel took into account the information presented in application EFSA-GMO-NL-2011-96, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. In conclusion, the EFSA GMO Panel considers that the information available for cotton GHB119 addresses the scientific comments raised by the Member States and that cotton GHB119, 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 the scope of this application.

The European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF) considers the method validated as fit for the purpose of regulatory compliance. The report on certified reference materials of cotton GHB119 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements.

The EFSA GMO Panel was not requested to give an opinion on the information required under Annex II to the Cartagena protocol. Furthermore, the EFSA GMO Panel did not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management.

The EFSA GMO Panel is of the opinion that the post-market environmental monitoring (PMEM) plan proposed by the applicant is in line with the scope of application EFSA-GMO-NL-2011-96. As no potential adverse environmental effects were identified, case-specific monitoring was not considered

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.

necessary. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan.

Under the terms of Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Articles 6 and 18 for the placing on the market of cotton GHB119.

Key words: GMO, overall opinion, cotton GHB119, Regulation (EC) No 1829/2003, Cry2Ae, PAT, insect resistance, herbicide tolerance, import and processing

Requestor: Competent Authority of the Netherlands

Question number: EFSA-Q-2011-00311

Correspondence: GMO@efsa.europa.eu

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Table of contents

1. Introduction

1.1. Background

On 7 April 2011, the European Food Safety Authority received from the Competent Authority of the Netherlands an application (reference EFSA-GMO-NL-2011-96) for authorisation of genetically modified insect-resistant and herbicide-tolerant cotton GHB119 (Unique Identifier BCS-GHØØ5-8), submitted by Bayer CropScience AG within the framework of Regulation (EC) No 1829/2003.

The scope of application EFSA-GMO-NL-2011-96 is for import, processing, and food and feed uses of cotton GHB119 within the EU but excludes cultivation in the EU.

In accordance with Articles 5(2)(b) and 17(2)(b) of the 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 website.[2] EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Articles 5(3) and 17(3) of the Regulation (EC) No 1829/2003. On 22 September 2010, the European Union Reference Laboratory for Genetically modified Food and Feed (EU-RL–GMFF) received samples and control samples in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. EFSA declared the application valid on 21 November 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[3], were given three months after the date of receipt of the valid application (*i.e.*, until 21 February 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 14 February 2012 to 9 January 2013, from 11 February 2013 to 4 April 2016, from 7 April 2016 to 29 June 2016 and from 3 August 2106 to 25 August 2016.[4]

The overall opinion on application EFSA-GMO-NL-2011-96 includes the scientific opinion of the EFSA GMO Panel together with the particulars required under Articles 6 and 18 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.

[2] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00311

[3] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 12.3.2001, p. 1–38.

[4] Requests for supplementary information from the EFSA GMO Panel: Requested(1) on 14/02/2012 – received on 04/07/2012; requested(2) on 17/04/2012 – received on 21/05/2012 and clock re-started on 09/01/2013. Requested(3) on 11/02/2013 – received on 13/03/2013; requested(4) on 22/02/2013 and on 28/02/2013 – received on 05/04/2013; requested(5) on 24/07/2013 – received on 02/03/2015; requested(6) on 24/06/2015 – received on 09/07/2015; requested(7) on 05/10/2015 – received on 11/11/2015; requested(8) on 12/10/2015 – received on 30/11/2015; requested(9) on 26/11/2015 – received on 23/12/2015; requested(10) on 16/02/2016 – received on 04/04/2016 and clock re-started on 04/04/2016. Requested(11) on 07/04/2016 – received on 16/06/2016; requested(12) on 13/06/2016 – received on 29/06/2016 and clock re-started on 29/06/2016. Requested(13) on 03/08/2016 – received on 25/08/2016 and clock re-started on 25/08/2016.

1.2. Terms of Reference as provided by the requestor

The European Food Safety Authority received from the Competent Authority of the Netherlands an application for authorisation of cotton GHB119 (Unique Identifier BCS-GHØØ5-8). The application (reference EFSA-GMO-NL-2011-96) was submitted by Bayer CropScience AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed. EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

2. Considerations

2.1. Applicant

The application was submitted by

Bayer CropScience AG Alfred-Nobel-Strasse 50 D–40789 Monheim am Rhein Germany	*represented by*	Bayer BioScience NV Technologiepark 38 B-9052 Gent Belgium

2.2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2011-96 is for import, processing, and food and feed uses of cotton GHB119 within the EU but excludes cultivation in the EU.

Cotton GHB119 was developed by *Agrobacterium tumefaciens* (also known as *Rhizobium radiobacter*)-mediated transformation. It expresses the Cry2Ae and PAT proteins which respectively confer resistance to certain lepidopteran species and tolerance to glufosinate ammonium-based herbicides.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel carried out the scientific assessment of cotton GHB119 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 21 September 2016. In delivering its scientific opinion, the EFSA GMO Panel took into account the information presented in application EFSA-GMO-NL-2011-96, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. In conclusion, the EFSA GMO Panel considers that the information available for cotton GHB119 addresses the scientific comments raised by the Member States and that cotton GHB119, 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 the scope of this application (Annex A).

4. Cartagena Protocol

The EFSA GMO Panel was not requested to give an opinion on the information required under Annex II to the Cartagena Protocol (Annex B).

5. Labelling

The EFSA GMO Panel did not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management (Annex C).

6. Method for detection

The EURL-GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the GHB119 transformation event in cotton DNA. The reports were published on 14 March 2007 and on 11 October 2012; on 21 November 2012, a corrected version of the Validation report was published. 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 the Commission Regulation (EC) No 641/2004[5] (Annexes D1, D2, D3).

[5] Regulation (EC) No 641/2004 of the Commission on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. OJ L 102/14, 7.4.2004, p. 1–12.

7. Certified reference materials

The report on certified reference materials of cotton GHB119 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 is of the opinion that the PMEM plan proposed by the applicant is in line with the scope of application EFSA-GMO-NL-2011-96. As no potential adverse environmental effects were identified, case-specific monitoring was not considered necessary. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan (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).

10. 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 cotton GHB119 for food and feed uses, import and processing.

List of Annexes[6]

Annex A:	Scientific opinion of the EFSA GMO Panel (cotton GHB119)
Annex B:	Cartagena protocol (cotton GHB119)
Annex C:	Labelling and Unique identifier (cotton GHB119)
Annex D1:	Validation report (cotton GHB119)
Annex D2:	Validated method (cotton GHB1191)
Annex D3:	Sampling and DNA extraction (cotton GHB119)
Annex E:	Certified reference materials (cotton GHB119)
Annex F:	Post-market environmental monitoring (cotton GHB119)
Annex G:	Member States comments (cotton GHB119)

[6]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-2016-00582