

## 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-2010-77) for the placing on the market of genetically modified cotton GHB614 x LLCotton25 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience<sup>1</sup>**

**European Food Safety Authority<sup>2</sup>**

European Food Safety Authority (EFSA), Parma, Italy

### SUMMARY

This document provides an overall opinion of the European Food Safety Authority on genetically modified cotton GHB614 x LLCotton25 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of application EFSA-GMO-NL-2010-77 is for food and feed uses, import and processing of all derived products of cotton GHB614 x LLCotton25 such as the production of refined oil from seeds, production of cellulose from linters as food or food ingredients and use of cottonseed meal and hulls in animal feed. 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 GHB614 x LLCotton25 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In conclusion, the EFSA GMO Panel considers that the information available for cotton GHB614 x LLCotton25 addresses the scientific comments raised by Member States. The EFSA GMO Panel is of the opinion that crossing cotton GHB614 and cotton LLCotton25 to produce cotton GHB614 x LLCotton25 results in no interactions affecting the safety of cotton GHB614 x LLCotton25 with respect to potential effects on human and animal health, or on the environment, in the context of its intended uses. The EFSA GMO Panel concludes that cotton GHB614 x LLCotton25 is as safe as its conventional counterpart and commercial cotton varieties and that it is unlikely to have any adverse effect on human and animal health, or on the environment, in the context of its 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 GHB614 x LLCotton25 can be accessed at the American Oil Chemists' Society.

The EFSA GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, the EFSA GMO Panel did not consider proposals for labelling and methods of

<sup>1</sup> On request from the Competent Authority of the Netherlands for an application (EFSA-GMO-NL-2010-77) submitted by Bayer CropScience, Questions No EFSA-Q-2014-00304 (EFSA overall opinion) and EFSA-Q-2010-00106 (Scientific opinion of the EFSA GMO Panel), issued on 16 May 2014.

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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.

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 GHB614 x LLCotton25.

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#### **KEY WORDS**

Overall opinion, GMO, cotton (*Gossypium hirsutum* L. and *Gossypium barbadense* L.), GHB614 x LLCotton25, herbicide tolerant, stack, Regulation (EC) No 1829/2003

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## BACKGROUND AS PROVIDED BY THE COMPETENT AUTHORITY OF THE NETHERLANDS

On 4 February 2010, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified cotton GHB614 x LLCotton25 (BCS-GHØØ2-5 x ACS-GHØØ1-3) submitted by Bayer CropScience within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2010-77).

The scope of application EFSA-GMO-NL-2010-77 is for food and feed uses, import and processing of all derived products of cotton GHB614 x LLCotton25 such as the production of refined oil from seeds, production of cellulose from linters as food or food ingredients and use of cottonseed meal and hulls in animal feed. 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 website<sup>3</sup> on 19 February 2010. 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 28 January 2010, the European Union Reference Laboratory 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 26 January 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 26 April 2011) 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 15 April 2011 to 3 October 2013 and from 25 November 2013 to 25 February 2014.<sup>4</sup>

The overall opinion on application EFSA-GMO-NL-2010-77 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 and vii) 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 Netherlands an application for authorisation of genetically modified cotton GHB614 x LLCotton25 (BCS-GHØØ2-5 x ACS-GHØØ1-3) submitted by Bayer CropScience within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2010-77). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

<sup>3</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-00106>

<sup>4</sup> Request for additional information from the EFSA GMO Panel: requested (1) on 15/04/2011 – received on 13/05/2011; requested (2) on 16/09/2011 – received on 18/03/2013 and clock re-started on 03/10/2013; requested (3) on 25/11/2013 – received on 23/12/2013; and clock re-started on 25/02/2014.

## CONSIDERATIONS

### 1. Applicant

The application was submitted by

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Alfred-Nobel-Strasse 50  
D - 40789 Monheim am Rhein  
Germany  
*represented by*

Bayer BioScience N.V.  
Technologiepark 38  
B-9052 Gent  
Belgium

### 2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2010-77 is for food and feed uses, import and processing of all derived products of cotton GHB614 x LLCotton25 such as the production of refined oil from seeds, production of cellulose from linters as food or food ingredients and use of cottonseed meal and hulls in animal feed. The scope does not include cultivation.

Cotton GHB614 x LLCotton25 was produced by conventional crossing of inbred lines of cotton GHB614 and cotton event LLCotton25, combining tolerances to glyphosate and glufosinate-ammonium herbicides. The newly expressed proteins 2mEPSPS (expressed in cotton GHB614) and phosphinothricin acetyltransferase (PAT) (expressed in cotton LLCotton25) were assessed previously and no concerns were identified.

### 3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel carried out the scientific assessment of the genetically modified cotton GHB614 x LLCotton25 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 11 April 2014. 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 the information available for cotton GHB614 x LLCotton25 addresses the scientific comments raised by Member States. The EFSA GMO Panel is of the opinion that crossing cotton GHB614 and cotton LLCotton25 to produce cotton GHB614 x LLCotton25 results in no interactions affecting the safety of cotton GHB614 x LLCotton25 with respect to potential effects on human and animal health, or on the environment, in the context of its intended uses. The EFSA GMO Panel concludes that cotton GHB614 x LLCotton25 is as safe as its conventional counterpart and commercial cotton varieties and that it is unlikely to have any adverse effect on human and animal health, or on the environment, in the context of its intended uses (Annex A).

### 4. Cartagena Protocol

The EFSA GMO Panel was not requested to give an opinion on 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 (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 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 GHB614 x LLCotton25 transformation event in cotton DNA. The reports were issued on 14 June 2005, 14 March 2007 and 5 September 2008. 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. to the Commission Regulation (EC) No 641/2004 (Annexes D1, D2a, D2b, D3).

## **7. Certified reference materials**

The certified reference materials of cotton GHB614 and LLCotton25 can be accessed at the American Oil Chemists' Society (Annexes E1 and E2).

## **8. Post-market environmental monitoring**

The EFSA GMO Panel is of the opinion that the scope of the PMEM plan proposed by the applicant is in line with the intended uses of cotton GHB614 x LLCotton25 since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. No case-specific monitoring is necessary. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan.

## **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 GHB614 x LLCotton25.

**LIST OF ANNEXES<sup>5</sup>**

- Annex A: Scientific opinion of the EFSA GMO Panel (cotton GHB614 x LLCotton25)
- Annex B: Cartagena Protocol (cotton GHB614 x LLCotton25)
- Annex C: Labelling (cotton GHB614 x LLCotton25)
- Annex D1: Validation report (cotton GHB614 x LLCotton25)
- Annex D2a: Validated method (cotton GHB614)
- Annex D2b: Validated method (cotton LLCotton25)
- Annex D3: Sampling and extraction (cotton GHB614 x LLCotton25)
- Annex E1: Certified reference materials report (cotton GHB614)
- Annex E2: Certified reference materials (cotton LLCotton25)
- Annex F: Not applicable
- Annex G: Member States' comments (cotton GHB614 x LLCotton25)

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<sup>5</sup> 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-2014-00304>