

**Overall opinion of the European Food Safety Authority
on genetically modified cotton
GHB614 × LLCotton25 × MON 15985 for food and feed
uses, under Regulation (EC) No 1829/2003
(application EFSA-GMO-NL-2011-94)
European Food Safety Authority**

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-NL-2011-94 for the placing on the market of genetically modified (GM) cotton GHB614 × LLCotton25 × MON 15985 according to Articles 6 and 18 of Regulation (EC) No 1829/2003.¹

The scope of the application EFSA-GMO-NL-2011-94 is for import, processing, and food and feed uses of cotton GHB614 × LLCotton25 × MON 15985 within the European Union (EU), but excludes cultivation in the EU. Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel) on cotton GHB614 × LLCotton25 × MON 15985, EFSA reports on the particulars as laid down in Articles 6 and 18 of Regulation (EC) No 1829/2003.

Overall, the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF) validates, and declares fit for purpose, the detection methods for each single event applied for the detection and quantification of the respective events in cotton GHB614 × LLCotton25 × MON 15985. The certified reference materials of cotton GHB614 × LLCotton25 × MON 15985 can be accessed at the American Oil Chemists' Society (AOCS-USA). The post-market environmental monitoring plan is in line with the intended uses of cotton GHB614 × LLCotton25 × MON 15985. The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period.

The particulars regarding e.g. labelling, detection, Cartagena protocol are not considered by EFSA since they fall outside its remit.

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Key words: cotton, GHB614 × LLCotton25 × MON 15985, EFSA-GMO-NL-2011-94, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: Competent Authority of the Netherlands

Question number: EFSA-Q-2018-00147

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¹Regulation (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.

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1. Introduction

On 18 February 2011, EFSA received from the Competent Authority of the Netherlands an application (reference EFSA-GMO-NL-2011-94), submitted by Bayer CropScience under Articles 5 and 17 of Regulation (EC) No 1829/2003², to support the placing of genetically modified (GM) cotton GHB614 × LLCotton25 × MON 15985 on the market in the EU. The unique identifier of GHB614 × LLCotton25 × MON 15985 is BCS-GHØØ2-5 × ACS-GHØØ1-3 × MON-15985-7. The scope of the application EFSA-GMO-NL-2011-94 is for import, processing, and food and feed uses of cotton GHB614 × LLCotton25 × MON 15985 within the European Union (EU).

EFSA first checked the completeness of the application in accordance with the requirements laid down in Articles 5(3) and 17(3) of the above mentioned Regulation. On 30 November 2009, the EURL–GMFF received samples and control samples in accordance with the same Articles.

According to Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission of the application and made the summary of the application publicly available³.

At the end of a thorough completeness check, EFSA declared application EFSA-GMO-NL-2011-94 valid on 15 July 2015.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-NL-2011-94. Such time limit was extended whenever EFSA requested supplementary information to the applicant.

According to Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, EFSA consults the risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC⁴, of all EU Member States on each request for placing on the market of products consisting of or containing GMOs. The Member States were therefore given three months to comment the valid application EFSA-GMO-NL-2011-94 from 4 April 2016 till 4 July 2016.

1.1. Terms of Reference

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA is requested to issue an overall opinion on application EFSA-GMO-NL-2011-94 including: i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the scientific opinion of the GMO Panel, iv) the information required under Annex II to the Cartagena Protocol, v) the labelling proposal, vi) the method for detection, validated by the EURL–GMFF, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it, vii) an indication of where appropriate reference materials can be accessed, viii) the post-market environmental monitoring (PMEM) plan and ix) the Member States' comments submitted during the three-month consultation period.

² 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

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00134>

⁴ 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

2. Considerations

2.1. Name and address of the Applicant

Application EFSA-GMO-NL-2011-94 was submitted by

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

Bayer BioScience N.V.
J.E. Mommaertslaan 14
B-1831 Diegem
Belgium

2.2. Designation and specification of the product

Cotton GHB614 × LLCotton25 × MON 15985 (unique identifier BCS-GHØØ2-5 × ACS-GHØØ1-3 × MON-15985-7) was developed by conventional crossing of single lines GHB614 (expressing 2mEPSPS protein), LLCotton25 (expressing PAT protein) and MON 15985 (expressing Cry1Ac, Cry2Ab2, NPTII and GUS proteins) to confer resistance to certain lepidopteran pests and tolerance to glyphosate and glufosinate ammonium based herbicides.

The scope of the application EFSA-GMO-NL-2011-94 is for import, processing, and food and feed uses of cotton GHB614 × LLCotton25 × MON 15985 within the European Union (EU).

2.3. Scientific opinion of the EFSA GMO Panel

On 8 March 2018, the EFSA GMO Panel adopted a scientific opinion on cotton GHB614 × LLCotton25 × MON 15985 (application EFSA-GMO-NL-2011-94). During its safety evaluation, the GMO Panel considered the valid application as submitted by the applicant, any additional data provided by the applicant, the scientific comments submitted by the Member States and the relevant scientific literature.

No new data on the single cotton events GHB614, LLCotton25 and MON 15985 that would lead to a modification of the original conclusions on their safety were identified. Based on the molecular, agronomic/phenotypic and compositional characteristics, the combination of cotton events GHB614, LLCotton25 and MON 15985 in the three-event stack cotton did not give rise to issues regarding food and feed safety. The newly expressed proteins in the three-event stack cotton did not raise concerns for human and animal health. Food and feed from cotton GHB614 × LLCotton25 × MON 15985 are expected to have the same nutritional impact as those derived from the non-GM comparator.

The GMO Panel concluded that there is a very low likelihood of environmental effects resulting from the accidental release of viable seeds from cotton GHB614 × LLCotton25 × MON 15985 into the environment. No scientific information that could change the conclusions on this three-event stack was retrieved in a literature search covering the period since the time of validity of the application.

The GMO Panel concludes that cotton GHB614 × LLCotton25 × MON 15985, as described in this application, is as safe as the non-GM comparator with respect to potential effects on human and animal health and the environment (Annex A).

2.4. Cartagena Protocol

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

2.5. Labelling

The GMO Panel did not consider the proposal for labelling which is matter related to risk management (Annex C).

2.6. Methods for detection

The EURL-GMFF has previously validated individually, and declared fit for purpose, the detection methods for the single events GHB614, LLCotton25 and MON 15985 (Annexes D2a, D2b, D2c).

In the context of application EFSA-GMO-NL-2011-94, the EURL-GMFF has checked in-house the performance of each validated detection method when applied to genomic DNA extracted from cotton GHB614 × LLCotton25 × MON 15985. The final validation report by the EURL-GMFF of the individual detection methods applied to DNA extracted from the three cotton event stack is provided in Annexes D1 and D3.

2.7. Certified reference materials

The certified reference materials of cotton GHB614, LLCotton25 and MON 15985 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annexes E1, E2, E3).

2.8. Post-market environmental monitoring (PMEM)

The post-market environmental monitoring plan is in line with the intended uses of cotton GHB614 × LLCotton25 × MON 15985 (Annex F).

2.9. Member States Comments

The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period (Annex G).

3. Conclusions

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA issues an overall opinion on application EFSA-GMO-NL-2011-94 for food and feed uses, import and processing of cotton GHB614 × LLCotton25 × MON 15985 in the EU.

List of Annexes⁵

Annex A:	Scientific opinion of the EFSA GMO Panel
Annex B:	Cartagena Protocol
Annex C:	Labelling
Annex D1:	Validation report by EURL-GMFF of the event-specific method for the quantification of cotton GHB614 × LLCotton25 × MON 15985
Annex D2a:	Validated detection method for cotton GHB614
Annex D2b:	Validated detection method for cotton LLCotton25
Annex D2c:	Validated detection method for cotton MON 15985
Annex D3:	Sampling / DNA extraction
Annex E1:	Certified reference materials (GHB614)
Annex E2:	Certified reference materials (LLCotton25)
Annex E3:	Certified reference materials (MON 15985)
Annex F:	Post-market environmental monitoring plan
Annex G:	Member States' comments and EFSA GMO Panel responses

⁵ 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-2018-00417>