

Assessment of genetically modified cotton GHB614 × LLCotton25 for renewal authorisation under regulation (EC) No 1829/2003 (dossier GMFF-2024-21890)

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The declarations of interest of all scientific experts active in EFSA's work are available at <https://open.efsa.europa.eu/experts>

Abstract

Following the submission of dossier GMFF-2024-21890 under Regulation (EC) No 1829/2003 from BASF Agricultural Solutions Seeds US LLC, the Panel on Genetically Modified Organisms of the European Food Safety Authority was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the herbicide-tolerant genetically modified cotton GHB614 × LLCotton25, for food and feed uses, excluding cultivation within the European Union. The data received in the context of this renewal application contained post-market environmental monitoring reports, an evaluation of the literature retrieved by a scoping review, a search for additional studies performed by or on behalf of the applicant and updated bioinformatics analyses. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. Under the assumption that the DNA sequences of the events in cotton GHB614 × LLCotton25 considered for renewal are identical to the sequences of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2024-21890 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton GHB614 × LLCotton25.

KEYWORDS

articles 11 and 23, cotton, GHB614 × LLCotton25, *Gossypium barbadense* L., *Gossypium hirsutum* L., regulation (EC) No 1829/2003, renewal

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SUMMARY

Following the submission of dossier GMFF-2024-21890 under Regulation (EC) No 1829/2003 from BASF Agricultural Solutions Seeds US LLC, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the herbicide-tolerant genetically modified cotton GHB614×LLCotton25. The scope of the renewal dossier GMFF-2024-21890 is for the renewal of the placing on the market of cotton GHB614×LLCotton25, for food and feed uses, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account dossier GMFF-2024-21890, additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications. The data received in the context of the renewal dossier GMFF-2024-21890 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a scoping review, a search for additional studies performed by or on behalf of the applicant and updated bioinformatics analyses. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

Under the assumption that the DNA sequences of the events in cotton GHB614 x LLCotton25 considered for renewal are identical to the sequences of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2024-21890 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton GHB614×LLCotton25.

1 | INTRODUCTION

1.1 | Background

On 22 March 2024 the European Food Safety Authority (EFSA) received from the European Commission (EC) dossier GMFF-2024-21890 for the renewal of the authorisation of cotton GHB614×LLCotton25 (Unique Identifier BCS-GHØØ2-5xACS-GHØØ1-3), submitted by BASF Agricultural Solutions Seeds US LLC (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003.¹

Following receipt of dossier GMFF-2024-21890, EFSA informed the Member States (MS) and made the summary of the application available to the public on the Open EFSA portal.²

EFSA checked the dossier for compliance with the relevant requirements of Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013³ and, when needed, asked the applicant to supplement the initial application. On 3 July 2024, EFSA declared the application valid and made the valid application available to the MS and the European Commission (EC).

Following the submission of applications EFSA-GMO-NL-2010-77 and the publication of the EFSA Scientific Opinion (EFSA GMO Panel, 2014), the placing on the market of cotton GHB614×LLCotton25 for products containing, consisting of, or produced from this GM cotton, excluding cultivation in the EU, was authorised by Commission Implementing Decision (EU) 2015/690 and 2019/1195.⁴ A copy of these authorisations was provided by the applicant.⁵

From the validity date, EFSA and its scientific Panel on Genetically Modified Organisms (hereafter referred to as 'the GMO Panel') endeavoured to respect a time limit of six months to issue a scientific opinion on dossier GMFF-2024-21890. This time limit was extended whenever EFSA and/or its GMO Panel requested supplementary information to the applicant. According to Regulation (EC) No 1829/2003, any supplementary information provided by the applicant during the risk assessment was made available to the MS and EC (for further details, see the Section 5).

In accordance with Regulation (EC) No 1829/2003, EFSA consulted the nominated risk assessment bodies of the MS, including national Competent Authorities within the meaning of Directive 2001/18/EC.⁶ The MS had three months to make their opinion known on dossier GMFF-2024-21890 as of date of validity.

1.2 | Terms of Reference as provided by the requestor

EFSA and its GMO Panel were requested to carry out a scientific risk assessment of cotton GHB614 x LLCotton25 for the renewal of authorisation, according to Articles 11 and 23 of Regulation (EC) No 1829/2003.

According to Regulation (EC) No 1829/2003, this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation including the opinions of the nominated risk assessment bodies of the MS.⁷

In addition to the present scientific opinion on cotton GHB614×LLCotton25, EFSA and its GMO Panel were also asked to report on the particulars listed under Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003. The relevant information is made available in the OpenEFSA portal,⁸ including the information required under Annex II to the Cartagena Protocol, a labelling proposal, a post-market environmental monitoring (PMEM) plan as provided by the applicant; the methods, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it and the appropriate reference materials.

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a confidential and a non-confidential version of the dossier GMFF-2024-21890 following the EFSA requirements, as detailed in EFSA GMO Panel (2015) and EFSA (2021).

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.

²Available online: <https://open.efsa.europa.eu/questions/EFSA-Q-2024-00186>.

³Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. OJ L157, 8.6.2013, p. 1–48.

⁴Commission Implementing Decision (EU) 2015/690 authorising the placing on the market of products containing, consisting of, or produced from genetically modified GHB614 x LLCotton25 cotton (BCS-GHØØ2-5xACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Commission implementing Decision (EU) 2019/1195 amending Implementing Decision (EU) 2015/690 as regards the authorisation holder and the representative for the placing on the market of genetically modified GHB614 x LLCotton25 cotton.

⁵Dossier number: GMFF-2024-21,890. Technical dossier – Information to support the risk assessment – The authorization for the placing of the GM food and/or feed onto the market in EU.

⁶Directive 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.

⁷Opinions of the nominated risk assessment bodies of EU Member States can be found at the Open EFSA Portal <https://open.efsa.europa.eu/questions>, querying the assigned Question Number.

⁸<https://open.efsa.europa.eu/questions/EFSA-Q-2024-00186>.

In accordance with Art. 38 of the Regulation (EC) No 178/2002 and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, the non-confidential version of the dossier has been published on OpenEFSA.⁹ According to Art. 32c(2) of Regulation (EC) No 178/2002¹⁰ and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,¹¹ EFSA carried out a public consultation on the non-confidential version of the dossier from 3 January to 24 January 2024 for which no comments were received.

The GMO Panel based its scientific assessment of cotton GHB614×LLCotton25 on the valid dossier GMFF-2024-21890, additional information provided by the applicant during the risk assessment, relevant scientific comments submitted by EU MS and peer-reviewed scientific publications.

In the frame of the contracts OC/EFSA/GMO/2021/06, and OC/EFSA/MESE/2022/03-01-SC17, the contractor performed preparatory work and delivered reports on the methods applied by the applicant in performing updated bioinformatics analyses and literature search, respectively.

2.1.1 | Post-market monitoring and post-market environmental monitoring reports¹²

Based on the outcome of the initial food and feed risk assessment, a post-market monitoring plan for monitoring of GM food and feed was not required by the authorisation decision. The implementation of a PMEM plan, consisting of a general surveillance plan to check for any adverse effects on the environment arising from cotton GHB614 x LLCotton25, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of cotton GHB614 x LLCotton25 (EFSA GMO Panel, 2014), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided nine annual PMEM reports covering a reporting period from April 2015 to June 2023. The annual PMEM plans submitted by the applicant included (1) commodity crop (GM and non GM) imports into the EU by country of origin and destination; (2) the description of a centralised system established by EuropaBio¹³ for the collection of information recorded by various operators (federations involved in cotton import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of cotton possibly containing cotton GHB614×LLCotton25; (3) the reports of the surveillance activities conducted by such operators; and (4) the review of relevant scientific peer-reviewed studies retrieved from literature searches.

2.1.2 | Systematic search and evaluation of literature¹⁴

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed scoping reviews covering the period from April 2014 to February 2025, in accordance with the recommendations on literature search outlined in EFSA (2010, 2019).

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. Altogether, 398 publications (including the updated search) were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, two publications were identified as relevant for food and feed safety assessment. The relevant publications are listed in Appendix A.

2.1.3 | Updated bioinformatics¹⁵

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatics dataset for cotton GHB614×LLCotton25 including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed proteins and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer (EFSA, 2017), and a safety assessment of

⁹<https://open.efsa.europa.eu/questions/EFSA-Q-2024-00186>.

¹⁰Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

¹¹Decision available at: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf.

¹²Dossier number: GMFF-2024-21890. Technical dossier – Information to support the risk assessment – Post-market monitoring and post-market environmental monitoring reports; additional information: 22/11/2024.

¹³The responsibilities of EuropaBio in coordinating activities of technology providers on the post-market environmental monitoring of GM crops were taken over by CroPLife Europe as of 1st January 2021.

¹⁴Dossier number: GMFF-2024-21890. Technical dossier – Information to support the risk assessment – New information-Systematic search and evaluation of the literature; additional information: 22/11/2024.

¹⁵Dossier number: GMFF-2024-21890. Technical dossier – Information to support the risk assessment – New information- Updated bioinformatics; additional information: 22/11/2024.

the newly expressed proteins 2mEPSPS and PAT regarding their capacity to trigger celiac disease symptoms (EFSA GMO Panel, 2017). The outcome of the updated bioinformatics analyses is presented in Section 3.3.

2.1.4 | Additional documents or studies performed by or on behalf of the applicant¹⁶

In line with the renewal guidance requirements (EFSA GMO Panel, 2015; EFSA, 2021), the applicant provided an overview on the worldwide approvals of cotton GHB614×LLCotton25 and searched for any available full reports of studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU (Appendix B).

The relevance of the listed studies for molecular characterisation, human and animal safety and the environment was assessed by the applicant.

2.1.5 | Overall assessment¹⁷

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of cotton GHB614×LLCotton25 for food and feed uses in the EU excluding cultivation does not change the outcome of the original risk assessment (EFSA GMO Panel, 2014).

2.1.6 | Monitoring plan and proposal for improving the conditions of the original authorisation¹⁸

The applicant indicated in the dossier that the environmental post-market monitoring plan is appropriate and does not need any changes.

2.2 | Methodologies

The GMO Panel assessed the application for renewal of the authorisation of cotton GHB614×LLCotton25 for food and feed uses in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003. The GMO Panel took into account the requirements described in its guideline for the risk assessment of renewal applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015). The opinions raised by the nominated risk assessment bodies of EU Member States were taken into consideration during the scientific risk assessment.

3 | ASSESSMENT

3.1 | Evaluation of the post-market monitoring and post-market environmental monitoring reports

The GMO Panel assessed the nine PMEM reports submitted by the applicant. During the general surveillance activities covering the authorisation period of cotton GHB614×LLCotton25, no adverse effects were reported by the applicant. This was confirmed by the evaluation of the results of the annual literature searches and the annual communications by the operators collating reports of adverse effects from their member organisations and companies. No safety concerns were identified by the GMO Panel.

3.2 | Evaluation of the systematic search and evaluation of literature

The GMO Panel reviewed the publications identified as relevant by the applicant. No new information raising safety concerns for human and animal health and the environment which would change the original risk assessment conclusions of cotton GHB614×LLCotton25 was identified.

¹⁶Dossier number: GMFF-2024-21890. Technical dossier – Information to support the risk assessment – New information-Additional documents or studies performed by or on behalf of the applicant.

¹⁷Dossier number: GMFF-2024-21890. Technical dossier – Information to support the risk assessment – New information – Overall assessment.

¹⁸Dossier number: GMFF-2024-21890. Technical dossier – Information to support the risk assessment – Post-market environmental monitoring plan; additional information: 22/11/2024.

3.3 | Evaluation of the updated bioinformatics analyses

Updated bioinformatics analyses to assess the interruption of cotton endogenous genes confirm previous results indicating that no known endogenous genes were interrupted by any of the two inserts (EFSA GMO Panel, 2009, 2014, 2018a, 2018b).

The updated analyses of the amino acid sequence of the newly expressed 2mEPSPS and PAT proteins reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. Moreover, the updated bioinformatics analyses of the newly created ORFs within the insert and spanning the junctions between the insert and genomic DNA confirm previous results which did not indicate sequence similarities to toxins or allergens in cotton GHB614×LLCotton25 (EFSA GMO Panel, 2009, 2014, 2018a, 2018b).

The updated bioinformatics analyses for possible horizontal gene transfer for events GHB614 and LLCotton25 confirm previous conclusions (EFSA GMO Panel, 2009, 2014, 2018a, 2018b). Given the results of this analysis and that the recombinant DNA in cotton GHB614×LLCotton25 does not confer selective advantages to microorganisms, the GMO Panel identified no safety concern linked to an unlikely but theoretically possible HGT.

3.4 | Evaluation of the additional documents or studies performed by or on behalf of the applicant

The GMO Panel evaluated the reports of the additional studies provided (Appendix B). The applicant provided new information on the sequences of the events and suggested that no changes occurred. However, as it was not submitted in accordance with the EFSA Technical Note (2018), the GMO Panel could not derive any conclusions from the study. Overall, the new additional documents or studies provided by the applicant do not raise any concern for human and animal health and the environment, which would change the original risk assessment conclusions on cotton GHB614×LLCotton25.

3.5 | Evaluation of the overall assessment

The GMO Panel evaluated the overall assessment provided by the applicant and confirms that there is no evidence in renewal dossier GMFF-2024-21890 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on cotton GHB614×LLCotton25.

3.6 | Evaluation of the monitoring plan and proposal for improving the conditions of the original authorisation

The PMEM plan covers general surveillance of imported GM plant material, including cotton GHB614×LLCotton25. This general surveillance is coordinated by CropLife Europe and implemented by selected operators (federations involved in cotton seeds import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. The GMO Panel is of the opinion that the scope of the plan provided by the applicant is consistent with the scope of dossier GMFF-2024-21890 but reminds that the final adoption and implementation of the PMEM plan falls outside the mandate of EFSA.

4 | CONCLUSIONS

Under the assumption that the DNA sequences of the events in cotton GHB614×LLCotton25 considered for renewal are identical to the sequences of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2024-21890 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton GHB614×LLCotton25 (EFSA GMO Panel, 2014).

5 | DOCUMENTATION AS PROVIDED TO EFSA

- Letter from the European Commission to EFSA received on 22 March 2024 for the continued marketing of genetically modified cotton GHB614×LLCotton25 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by BASF Agricultural Solutions Seeds US LLC (GMFF-2024-21890).
- The application was made valid on 3 July 2024.
- Additional Information (Clock 1) was requested on 28 October 2024.
- Additional Information (Clock 1) was received on 22 November 2024.
- Additional Information (Clock 2) was requested on 29 January 2025.
- Additional Information (Clock 2) was received on 28 March 2025.

- Additional Information (Clock 3) was requested on 4 April 2025.
- Additional Information (Clock 3) was received on 13 June 2025.

ABBREVIATIONS

GM	genetically modified
GMO	genetically modified organism
GMO Panel	EFSA Panel on Genetically Modified Organisms
HGT	horizontal gene transfer
ORFs	open reading frames
PMEM	post-market environmental monitoring

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REQUESTOR

European Commission

QUESTION NUMBER

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

List of relevant publications identified by the applicant through literature searches (April 2014–February 2025)

References

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APPENDIX B

List of additional studies

List of additional studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU with regard to the evaluation of the safety of the food and feed for humans, animal or the environment from cotton GHB614x LLCotton25.

Study identification	Title
19-RSCT0344	DNA sequence determination of the GHB614 and LLCotton25 transgenic loci in GHB614 x LLCotton25 cotton
18-RSOS0041	Influence of ionic strength on PAT/bar functional activity
15-RSKBS010	The effect of temperature on 2mEPSPS as assessed by SDS-PAGE and western blot
15-RSKBS006	The effect of temperature on 2mEPSPS as assessed by the EPSPS quantitative activity assay
16-RSTPS004	The effect of temperature on PAT/bar as assessed by the PAT quantitative activity assay
16-RSTPS003	The effect of temperature on PAT/bar as assessed by ELISA