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SCIENTIFIC OPINION

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Assessment of genetically modified cotton T304-40 for renewal authorisation under Regulation (EC) No 1829/2003 (dossier GMFF-2024-23010)

EFSA Panel on Genetically Modified Organisms (GMO) | Josep Casacuberta | Francisco Barro | Albert Braeuning | Ruud de Maagd | Michelle M. Epstein | Thomas Frenzel | Jean-Luc Gallois | Frits Koning | Antoine Messéan | F. Javier Moreno | Fabien Nogué | Giovanni Savoini | Alan H. Schulman | Christoph Tebbe | Eve Veromann | Tilemachos Goumperis | Paolo Lenzi | Ana M. Camargo | Pietro Piffanelli | Tommaso Raffaello

Correspondence: nif@efsa.europa.eu

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-2024-23010 Regulation (EC) No 1829/2003 from BASF Agricultural Solutions Seed 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 insect resistant and herbicide tolerant genetically modified cotton T304-40, 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 sequence of the event in cotton T304-40 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2024-23010 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton T304-40.

KEY WORDS

articles 11 and 23, cotton, Regulation (EC) No 1829/2003, renewal, T304-40

CONTENTS

SUMMARY

Following the submission of dossier GMFF-2024-23010 under Regulation (EC) No 1829/2003 from BASF Agricultural Solutions Seed 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 insect-resistant and herbicide-tolerant genetically modified cotton T304-40. The scope of the renewal dossier GMFF-2024-23010 is for the renewal of the placing on the market of cotton T304-40 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-2024-23010, 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-2024-23010 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 sequence of the event in cotton T304-40 considered for renewal is identical to the sequence of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2024-23010 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton T304-40 (EFSA GMO Panel, 2013).

1 | INTRODUCTION

1.1 | Background

On 27 March 2024, the European Food Safety Authority (EFSA) received from the European Commission dossier GMFF-2024-23010 for the renewal of the authorisation of cotton T304-40 (Unique Identifier BCS-GHØØ4-7), submitted by BASF Agricultural Solutions Seed US LLC (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003.[1]

Following receipt of dossier GMFF-2024-23010, 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 503/2013[3] and, when needed, asked the applicant to supplement the initial application. On 24 July 2024, EFSA declared the application valid and made the valid application available to the MS and the European Commission.

Following the submission of application EFSA-GMO-NL-2011-97 and the publication of the EFSA scientific opinion (EFSA GMO Panel, 2013), the placing on the market of cotton T304-40 for products containing, consisting of or produced from this GM cotton, excluding cultivation in the EU, was authorised by Commission Implementing Decision (EU) 2015/699 and Commission Implementing Decision (EU) 2019/1195.[4,5] A copy of these authorisations was provided by the applicant.[6]

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 6 months to issue a scientific opinion on dossier GMFF-2024-23010. 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 European Commission (for further details, see 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.[7] The MS had 3 months to make their opinion known on dossier GMFF-2024-23010 as of the 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 T304-40 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.[8]

In addition to the present scientific opinion on cotton T304-40, 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,[9] 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 method(s), 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-2024-23010 following the 'EFSA guidelines for the submission of an application to comply with the specific provisions of Regulation (EU) No 503/2013' EFSA GMO Panel (2015) and of the 'Administrative guidance for the preparation of applications (EFSA, 2021).

[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.

[2]Available online: https://open.efsa.europa.eu/question/EFSA-Q-2024-00196.

[3]Commission 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.

[4]Commission Implementing Regulation (EU) 2015/699 of 24 April 2015 authorising the placing on the market of products containing, consisting of or produced from genetically modified cotton T304-40 (BCS-GHØØ4-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

[5]Commission Implementing Regulation (EU) 2019/1195 of 10 July 2019 amending Decisions 2008/730/EC, 2008/837/EC, 2009/184/EC, 2011/354/EU, Implementing Decisions 2012/81/EU, 2013/327/EU, (EU) 2015/690, (EU) 2015/697, (EU) 2015/699, (EU) 2016/1215, (EU) 2017/1208 and (EU) 2017/2451 as regards the authorisation holder and the representative for the placing on the market of genetically modified soybean, cotton, oilseed rape and maize.

[6]Dossier number: GMFF-2024-23,010. Technical dossier – Information to support the risk assessment – The authorisation for the placing of the GM food and/or feed onto the market in EU.

[7]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.

[8]Opinions 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.

[9]https://open.efsa.europa.eu/question/EFSA-Q-2024-00196.

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.[10] According to Art. 32c(2) of Regulation (EC) No 178/2002[11] and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[12] EFSA carried out a public consultation on the non-confidential version of the dossier from 17 January to 7 February 2025 for which no comments were received.

The GMO Panel based its scientific assessment of cotton T304-40 on the valid dossier GMFF-2024-23010, 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/2018/04 and OC/EFSA/GMO/2021/06, the contractor performed preparatory work and delivered reports on the methods applied by the applicant in performing literature search and updated bioinformatics analyses.

2.1.1 | Post-market monitoring and post-market environmental monitoring reports[13]

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 T304-40, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of cotton T304-40 (EFSA GMO Panel, 2013), 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 EuropaBio[14] 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 T304-40; (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 literature[15]

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed scoping reviews covering the period from April 2015 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, 2000 publications (including the updated search) were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, two peer-reviewed publications were identified as relevant for food and feed safety assessment. The relevant publications are listed in Appendix A.

2.1.3 | Updated bioinformatics analyses[16]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatics data set for cotton T304-40 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 the newly expressed proteins Cry1Ab and PAT regarding their capacity to trigger coeliac disease symptoms (EFSA GMO Panel, 2017). The outcome of the updated bioinformatics analyses is presented in Section 3.3.

[10] https://open.efsa.europa.eu/question/EFSA-Q-2024-00196.

[11] Regulation (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.

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

[13] Dossier number: GMFF-2024-23010. Technical dossier – Information to support the risk assessment – Post-market monitoring and post-market environmental monitoring reports; additional information: 20/11/2024.

[14] The 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 1 January 2021.

[15] Dossier number: GMFF-2024-23010. Technical dossier – Information to support the risk assessment – New information-Systematic search and evaluation of the literature; additional information: 20/11/2024, 16/01/2025, 28/03/2025.

[16] Dossier number: GMFF-2024-23010. Technical dossier – Information to support the risk assessment – New information – Updated bioinformatics; additional information: 16/01/2025, 13/06/2025.

2.1.4 | Additional documents or studies performed by or on behalf of the applicant[17]

In line with the renewal guidance requirements (EFSA, 2021; EFSA GMO Panel, 2015), the applicant provided an overview of the worldwide approvals of cotton T304-40 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 assessment[18]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of cotton T304-40 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA GMO Panel, 2013).

2.1.6 | Monitoring plan and proposal for improving the conditions of the original authorisation[19]

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 T304-40 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 T304-40, 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 assessed the applicant's literature searches on cotton T304-40 and the newly expressed proteins Cry1Ab and PAT. The overall quality of the performed literature searches is acceptable.

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 on cotton T304-40 was identified (EFSA GMO Panel, 2013).

3.3 | Evaluation of the updated bioinformatics analyses

Updated bioinformatics analyses to assess the potential interruption of cotton endogenous genes confirm previous results indicating that no endogenous genes were interrupted (EFSA GMO Panel, 2013, 2018).

[17]Dossier number: GMFF-2024-23010. Technical dossier – Information to support the risk assessment – New information-Additional documents or studies performed by or on behalf of the applicant; additional information: 28/03/2025.

[18]Dossier number: GMFF-2024-23010. Technical dossier – Information to support the risk assessment – New information- Overall assessment.

[19]Dossier number: GMFF-2024-23010. Technical dossier – Information to support the risk assessment – Post-market environmental monitoring plan; additional information: 20/11/2024.

The updated analyses of the amino acid sequence of the newly expressed Cry1Ab 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 indicated that the expression of an ORF showing significant similarities to allergens in cotton T304-40 is unlikely (EFSA GMO Panel, 2013, 2018).

The updated bioinformatic analyses for possible horizontal gene transfer for events T304-40 confirm previous conclusions (EFSA GMO Panel, 2013, 2018). Given the results of this analysis and that the recombinant DNA in cotton T304-40 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). Overall, the new additional documents or studies provided by the applicant do not raise any concerns for human and animal health and the environment, which would change the original risk assessment conclusions on cotton T304-40.

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 the renewal dossier GMFF-2024-23010 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on cotton T304-40.

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 T304-40. This general surveillance is coordinated by CropLife Europe and implemented by selected operators (federations involved in cottonseeds 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-2024-23010, but reminds that the final adoption and implementation of the PMEM plan fall outside the mandate of EFSA.

4 | CONCLUSIONS

Under the assumption that the DNA sequence of the event in cotton T304-40 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2024-23010 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton T304-40 (EFSA GMO Panel, 2013).

5 | DOCUMENTATION AS PROVIDED TO EFSA

- Letter from the European Commission to EFSA received on 27 March 2024 for the continued marketing of genetically modified cotton T304-40 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by BASF Agricultural Solutions Seed US LLC (GMFF-2024-23010).
- The application was made valid on 24 July 2024.
- Additional Information (Clock 1) was requested on 17 October 2024.
- Additional Information (Clock 1) was received on 20 November 2024.
- Additional Information (Clock 2) was requested on 17 December 2024.
- Additional Information (Clock 2) was received on 16 January 2025.
- Additional Information (Clock 3) was requested on 10 February 2025.
- Additional Information (Clock 3) was received on 28 March 2025.
- Additional Information (Clock 4) was requested on 10 April 2025.
- Additional Information (Clock 4) 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

EFSA-Q-2024-00196

PANEL MEMBERS

Josep Casacuberta, Francisco Barro, Albert Braeuning, Ruud de Maagd, Michelle M. Epstein, Thomas Frenzel, Jean-Luc Gallois, Frits Koning, Antoine Messéan, F. Javier Moreno, Fabien Nogué, Giovanni Savoini, Alan H. Schulman, Christoph Tebbe and Eve Veromann.

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EFSA (European Food Safety Authority), Gennaro, A., Gomes, A., Herman, L., Nogué, F., Papadopoulou, N., & Tebbe, C. (2017). Technical report on the explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms. *EFSA Supporting Publications*, *14*(7), EN-1273. https://doi.org/10.2903/sp.efsa.2017.EN-1273

EFSA (European Food Safety Authority), Devos, Y., Guajardo, I. M., Álvarez, F., & Glanville, J. (2019). Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market - note on literature searching to GMO risk assessment guidance. *EFSA Journal*, *16*(4), EN-1614. https://doi.org/10.2903/sp.efsa.2019.EN-1614

EFSA (European Food Safety Authority). (2021). Administrative guidance for the preparation of renewal applications on genetically modified food and feed. *EFSA Supporting Publications*, EN-6474. https://doi.org/10.2903/sp.efsa.2021.EN-6474

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2013). Scientific opinion on application EFSA-GMO-NL-2011-97 for the placing on the market of insect-resistant 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. *EFSA Journal*, *11*(6), 3251. https://doi.org/10.2903/j.efsa.2013.3251

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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 2015 to February 2025)

Reference
Asanuma, Y., Gondo, T., Ishigaki, G., Inoue, K., Zaita, N., Muguerza, M., and Akashi, R. (2017). Field trial of insect-resistant and herbicide tolerant genetically modified cotton (*Gossypium hirsutum* L.) for environmental risk assessment in Japan. *GM Crops & Food*, *8*(2), 106–116. https://doi.org/10.1080/21645698.2016.1272754
Wu, A. J., Chapman, K., Sathischandra, S., Massengill, J., Araujo, R., Soria, M., Bugas, M., Bishop, Z., Haas, C., Holliday, B., Cisneros, K., Lor, J., Canez, C., New, S., Mackie, S., Ghoshal, D., Privalle, L., Hunst, P., and Pallett, K. (2019). GHB614×T304-40×GHB119×COT102 Cotton: Protein expression analyses of field-grown samples. *Journal of Agricultural and Food Chemistry*, *67*(1), 275–281. https://doi.org/10.1021/acs.jafc.8b05395

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, animals or the environment from cotton T304-40

Study identification	Title
22-RSCT0519	Channel catfish feeding study with T304-40 toasted cottonseed meal
M-554703-01-1	The effect of temperature on PAT/bar as assessed by the PAT quantitative activity assay
M-557508-01-1	The effect of temperature on PAT/bar as assessed by ELISA
18-RSOS0041	Influence of ionic strength on PAT/bar functional activity
M-237258-01-1	Description of the amino acid sequence of Cry1Ab protein