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Assessment of genetically modified cotton GHB614 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA–GMO–RX–018)

EFSA Panel on Genetically Modified Organisms (GMO),
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Abstract

Following the submission of application EFSA–GMO–RX–018 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 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, 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, a systematic search and evaluation of literature, updated bioinformatic analyses, and additional documents or studies performed by or on behalf of the applicant. 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. The GMO Panel concludes that there is no evidence in renewal application EFSA–GMO–RX–018 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton GHB614.

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Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2020-00420

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Panel members: Hanspeter Naegeli, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko, Francisco Javier Moreno, Ewen Mullins, Fabien Nogué, Nils Rostoks, Jose Juan Sánchez Serrano, Giovanni Savoini, Eve Veromann and Fabio Veronesi.

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

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Summary

Following the submission of application EFSA–GMO–RX–018 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 herbicide-tolerant genetically modified cotton GHB614. The scope of the renewal application EFSA–GMO–RX–018 is for the renewal of the placing on the market of products containing, consisting of, or produced from cotton GHB614, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA–GMO–RX–018, 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 application EFSA–GMO–RX–018 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, 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.

The GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-018 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton GHB614 (EFSA, 2009).

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1. Introduction

1.1. Background

On 2 June 2020, the European Food Safety Authority (EFSA) received from the European Commission application EFSA–GMO–RX–018 for the renewal of the authorisation of cotton GHB614 (Unique Identifier BCS-GHØØ2-5), 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 application EFSA–GMO–RX–018, EFSA informed the Member States (MS) and made the summary of the application available to the public on the EFSA website.[2]

EFSA checked the application 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 11 August 2020, 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-2008-51 and the publication of the EFSA scientific opinion (EFSA, 2009), the placing on the market of cotton GHB614 for products containing, consisting of, or produced from this GM cotton, excluding cultivation in the EU, was authorised by Commission Decision 2011/354/EU[4] and Commission Implementing Decision (EU) 2019/1195 amending Decision 2011/354/EU[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 application EFSA–GMO–RX–018. Such 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 the section 'Documentation', below).

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 application EFSA–GMO–RX–018 as of date of validity.

1.2. Terms of Reference as provided by the requestor

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA and its GMO Panel were requested to carry out a scientific risk assessment of cotton GHB614 for the renewal of authorisation for placing on the market of products containing, consisting of, or produced from GM cotton GHB614 in the context of its scope as defined in application EFSA–GMO–RX–018.

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 GHB614, 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.

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[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/questions/EFSA-Q-2020-00420

[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 Decision of 17 June 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB614 (BCS-GHØØ2-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 160/90, 18.6.2011.

[5] Commission Implementing Decision (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. Official Journal of the European Union L 187/43, 12.7.2019.

[6] Dossier: Cotton GHB614 – Annex I.

[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 EFSA Register of Questions, https://open.efsa.europa.eu/questions, querying the assigned Question Number.

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The relevant information is made available in the EFSA Register of Questions,[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 data for application EFSA–GMO–RX–018 submitted according to EFSA requirements (EFSA GMO Panel, 2015; EFSA, 2019) and provided by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

In the frame of the contracts OC/EFSA/GMO/2020/01 and OC/EFSA/GMO/2018/04, contractors performed preparatory work and delivered reports on the methods applied by the applicant in performing sequencing and literature search, respectively.

2.1.1. Post-market monitoring reports[10]

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, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of cotton GHB614 (EFSA, 2009), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided nine annual PMEM reports covering a reporting period from July 2010 till June 2019. 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 for the collection of information recorded by various operators (federations involved in cotton grains import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of cotton possibly containing cotton GHB614; (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[11]

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed two systematic literature searches covering the period from January 2009 till September 2020, in accordance with the recommendations on literature search outlined in EFSA (2010, 2017a).

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. Altogether 3162 publications were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, one publication was identified as relevant for food and feed safety assessment or molecular characterisation. The relevant publication is listed in Appendix A.

2.1.3. Updated bioinformatic data[12]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic data set for cotton GHB614 event including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed protein and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer (EFSA, 2017b) and a safety assessment of the newly expressed protein 2mEPSPS regarding its capacity to trigger coeliac disease (EFSA GMO Panel, 2017). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

[9] https://open.efsa.europa.eu/questions/EFSA-Q-2020-00420
[10] Dossier: Cotton GHB614 – Annex II.
[11] Dossier: Cotton GHB614 – Annex III; additional information: 30/11/2020.
[12] Dossier: Cotton GHB614 – Annex III; additional information: 15/2/2021.

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2.1.4. Additional documents or studies provided by the applicant[13]

In line with the renewal guidance requirements (EFSA GMO Panel, 2015; EFSA, 2019), the applicant provided an overview on the worldwide approvals of cotton GHB614 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 as provided by the applicant[14]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of cotton GHB614 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA, 2009).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation[15]

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 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 comments 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 reports

During the general surveillance activities covering the authorisation period of cotton GHB614, no adverse effects were reported by the applicant.

3.2. Evaluation of the systematic search and evaluation of literature

The GMO Panel assessed the applicant's literature searches on cotton GHB614 and the newly expressed protein 2mEPSPS. The overall quality of the performed literature searches is acceptable; however, the GMO Panel considers that future searches could be fine-tuned. The GMO Panel therefore recommends the applicant for future searches to:

- ensure that enough search term variation is used (covering possible synonyms, related terms, acronyms, spelling variants, old and new terminology, brand and generic names, lay and scientific terminology, common typos, translation issues);
- adapt the search to the size of the retrieved publications (and thus not combine search sets when one of the search sets already yields only a small number of publications).

The GMO Panel acknowledges that no publications raising a safety concern for human and animal health and the environment which would change the original risk assessment conclusions on cotton GHB614 (EFSA, 2009) have been identified by the applicant.

[13] Dossier: Cotton GHB614 – Annex III; additional information: 31/3/2021, 4/5/2021.
[14] Dossier: Cotton GHB614 – Annex III.
[15] Dossier: Cotton GHB614 – Part III - Summary.

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3.3. Evaluation of the updated bioinformatic data[16]

The results of the updated bioinformatic analyses to assess the interruption of cotton endogenous genes confirm previous results indicating that no endogenous genes have been interrupted by event GHB614 (EFSA, 2009; EFSA GMO Panel, 2018a,b).

Analyses of the amino acid sequence of the newly expressed 2mEPSPS protein reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. The updated bioinformatic analyses of the newly created ORFs within the insert do not indicate sequence similarities to toxins or allergens in cotton GHB614. In addition, the updated bioinformatic analysis of the newly created ORFs spanning the junctions with genomic DNA confirms previous results which did not indicate sequence similarities to toxins or allergens in cotton GHB614 (EFSA, 2009; EFSA GMO Panel, 2018a,b).

The updated bioinformatic analysis for event GHB614 did not reveal any DNA sequence that could provide sufficient length and identity which could facilitate horizontal gene transfer (HGT) by double homologous recombination, confirming previous conclusions (EFSA, 2009; EFSA GMO Panel, 2018a,b). Given the results of this analysis and that the recombinant DNA in cotton GHB614 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 provided by the applicant

The GMO Panel evaluated the full study reports of the additional studies provided, including a new sequencing study (Appendix B). The sequencing data are compliant with the requirements laid down in the EFSA Technical Note on the quality of DNA sequencing for the molecular characterisation of genetically modified plants (EFSA GMO Panel, 2018c). The study confirms that the sequence of the event in recent plant material (year of collection 2019) is identical to the sequence of the event in the originally assessed application (EFSA, 2009).

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.

3.5. Evaluation of the overall assessment as provided by the applicant

The GMO Panel evaluated the overall assessment provided by the applicant and confirms that there is no evidence in renewal application EFSA–GMO–RX–018 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on cotton GHB614.

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. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in cotton grains 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 application EFSA–GMO–RX–018, but reminds that monitoring is related to risk management, and thus, the final adoption and implementation of the PMEM plan falls outside the mandate of EFSA.

4. Conclusions

The GMO Panel concludes that there is no evidence in renewal application EFSA–GMO–RX–018 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton GHB614 (EFSA, 2009).

5. Documentation as provided to EFSA

1) Letter from the European Commission to EFSA received on 2 June 2020 for the continued marketing of genetically modified cotton GHB614 submitted in accordance with articles 11

[16] The GMO Panel considered the bioinformatic databases and the analyses satisfactory at the Plenary Meeting of January 27th, 2021.

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and 23 of Regulation (EC) No 1829/2003 by BASF Agricultural Solutions Seed US LLC (EFSA–GMO–RX–018).

2) Application EFSA–GMO–RX–018 validated by EFSA, 11 August 2020.
3) Request for supplementary information to the applicant, 1 October 2020.
4) Receipt of supplementary information from the applicant, 30 November 2020.
5) Request for supplementary information to the applicant, 17 December 2020
6) Receipt of supplementary information from the applicant, 15 February 2021.
7) Request for supplementary information to the applicant, 22 February 2021.
8) Receipt of supplementary information from the applicant, 31 March 2021.
9) Receipt of spontaneous information from applicant, 09 April 2021.
10) Request for supplementary information to the applicant, 28 April 2021.
11) Receipt of spontaneous information from applicant, 04 May 2021.

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Abbreviations

EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
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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Appendix A – List of relevant publications identified by the applicant through systematic literature searches (January 2009–September 2020)

Reference
Loureiro I, García-Ruiz E, Gutiérrez E, Gómez P, Escorial M-C and Chueca M-C, 2016. Pollen-mediated gene flow in the cultivation of transgenic cotton under experimental field conditions in Spain. Industrial Crops and Products, 85, 22–28. https://doi.org/10.1016/j.indcrop.2016.02.045

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Appendix B – 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 GHB614

Study identification	Title
19-RSCT0199	Sequencing of the GHB614 cotton transgenic locus in a commercial variety
M-412368-01-1	Comparative assessment of the plant morphology, agronomic performance, disease susceptibility and fiber characteristics of glyphosate-tolerant cotton (transformation event GHB614) compared to its non-transgenic comparator, Spain 2007 and 2008
M-416280-01-1	Stability of 2mEPSPS protein expression over several generations of the glyphosate tolerant cotton event GHB614: Comparison between plant growth and analysis in the Southeastern US and Europe
M-472156-02-1	GlyTol event GHB614 cotton: Non-Target Arthropod Testing in Field Grown Crop. - Spain, 2012
M-472176-01-1	Cotton pollen from GlyTol event GHB614: Effects of an exposure to spiked diet on honey bee larvae (Apis mellifera carnica) during a semi-chronic feeding period in an in vitro laboratory testing design - Cotton Pollen from GlyTol event GHB614
M-473543-01-1	GHB614 cotton - production and protein expression analyses in pollen from field grown samples
M-497125-01-1	Influence of the use of GHB614 cotton on the soil microbial community
M-497630-01-1	2mEPSPS protein - Acute toxicity study by oral gavage in mice
M-500886-01-1	The effect of temperature on microbially-produced 2mEPSPS as assessed by ELISA
M-509359-01-1	Structural and functional equivalence of 2mEPSPS protein produced in Escherichia coli and GHB614, Gossypium hirsutum - Supplement
M-528381-01-1	Quantitation of 2mEPSPS herbicide tolerant protein in tissues of GlyTol cotton hybrids tested in BRL-1 (1st season) during Kharif 2012 at Rajkot in Central zone
M-528383-01-1	Quantitation of 2mEPSPS herbicide tolerant protein in tissues of GlyTol cotton hybrids tested in BRL-1 (1st season) during Kharif 2012 at Sirsa in North zone
M-535666-01-1	Compositional analyses of cottonseed samples from field grown GHB614 (GlyTol) cotton - BRL-1-I and BRL-1-II trials (North zone and Central zone)

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