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Assessment of genetically modified LLCotton25 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-010)

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Abstract

Following the submission of application EFSA-GMO-RX-010 under Regulation (EC) No 1829/2003 from Bayer, 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 LLCotton25, for food and feed uses, import and processing, excluding cultivation within the EU. 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. In addition, the applicant provided sequence data on the LLCotton25 event using the material from a commercial variety that, according to the applicant, may be imported into the EU at the time of this renewal application. 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-010 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on LLCotton25.

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Summary

Following the submission of application EFSA-GMO-RX-010 under Regulation (EC) No 1829/2003 from Bayer CropScience N.V., 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 LLCotton25. The scope of renewal application EFSA-GMO-RX-010 is for placing on the market of products containing, consisting of, or produced from LLCotton25, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-010, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. The data received in the context of the renewal application EFSA-GMO-RX-010 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, updated bioinformatics analyses, and additional studies performed by or on behalf of the applicant. The applicant also provided sequence data on the LLCotton25 event using the material from a commercial variety that, according to the applicant, may be imported into the EU at the time of this renewal application. 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-010 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on LLCotton25 (EFSA, 2006).

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1. Introduction

1.1. Background

On 30 November 2017, the European Food Safety Authority (EFSA) received from the European Commission (DG SANTE) application EFSA-GMO-RX-010 by Bayer for the renewal of authorisation of genetically modified (GM) LLCotton25 (Unique Identifier ACS-GHØØ1-3) for the placing on the market of products containing, consisting of, or produced from this GM cotton submitted within the framework of Regulation (EC) No 1829/2003.¹ Before sending the application to EFSA, the European Commission confirmed whether the data submitted in the context of this renewal application were in line with the legal requirements laid down in Articles 11 and 23 of Regulation (EC) No 1829/2003.

After receiving application EFSA-GMO-RX-010, and in accordance with Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed Member States and made the summary of the application available to the public on the EFSA website.²

On 15 March 2018, EFSA declared the application valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003. EFSA made the valid application available to Member States and the European Commission, and consulted nominated risk assessment bodies of Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC following the requirements of Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, to request their scientific opinion. Member States had three months after the opening of the Member State commenting period (until 18 June 2018) to make their opinion known.

Following the submission of application EFSA-GMO-NL-2005-13 and the publication of the EFSA scientific opinion (EFSA, 2006), the placing on the market of LLCotton25 for products containing, consisting of, or produced from this GM cotton, excluding cultivation in the European Union (EU), was authorised by Commission Decision 2008/837/EC.³ A copy of this authorisation was provided by the applicant.⁴

EFSA requested additional information on 10 April 2018 and 29 August 2018. The applicant submitted its reply on 8 June 2018 and 24 September 2018, respectively.

In giving its scientific opinion to the European Commission, the Member States and the applicant, and in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, EFSA has endeavoured to respect a time limit of 6 months from the acknowledgement of the valid application. As additional information was requested by the GMO Panel, the time limit of six months was extended accordingly, in line with Articles 6(1), 6(2), 18(1) and 18(2) 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 and thus will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5).

1.2. Terms of Reference as provided by the requestor

The GMO Panel was requested to carry out a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the placing on the market of products containing, consisting of, or produced from GM LLCotton25, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003.

Where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of genetically modified organisms (GMOs) or food and feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas should be indicated in accordance with Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

The GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, the GMO Panel did not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in

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: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2017-00814>

³ COMMISSION DECISION of 29 October 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 299/36, 8.11.2008.

⁴ Dossier: LLCotton25 renewal – Annex 1.

the food and feed and/or food and feed produced from it), which are matters related to risk management.

2. Data and methodologies

2.1. Data

The data for application EFSA-GMO-RX-010 provided by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

The applicant submitted sequence data on LLCotton25 event⁵ and clarified that the material used to newly determine the LLCotton25 event sequence is representative of LLCotton25 varieties currently on the market, which may be imported into the EU.⁶ The applicant also clarified that this newly determined LLCotton25 event sequence is identical to the previously assessed LLCotton25 event sequence (submitted in application EFSA-GMO-NL-2010-77,⁷ EFSA GMO Panel, 2014) corrected for sequencing errors with respect to the originally provided sequence (application EFSA-GMO-NL-2005-13, EFSA, 2006).^{5,8}

2.1.1. Post-market monitoring reports⁹

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 post-market environmental monitoring (PMEM) plan, consisting of a general surveillance plan to check for any adverse effects on the environment arising from LLCotton25, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of LLCotton25 (EFSA, 2006), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided eight annual PMEM reports covering a reporting period from October 2008 to June 2016. The annual PMEM plans submitted by the applicant included (1) the description of a centralised system established by EuropaBio for the collection of information recorded by various operators (federations involved in cotton seeds import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of cotton possibly containing LLCotton25; (2) the reports of the surveillance activities conducted by such operators; and (3) the review of relevant scientific peer-reviewed studies retrieved from literature searches.

2.1.2. Systematic search and evaluation of literature¹⁰

In addition to the eight separate literature searches provided as part of the annual PMEM reports, the applicant performed a systematic literature search covering the period from January 2007 till September 2014, in accordance with the recommendations on literature searching outlined in EFSA (2010, 2017a). However, search terms and electronic bibliographic databases were not consistent throughout the searches, as required in the renewal guidance (EFSA GMO Panel, 2015). As requested on 10 April 2018 by the GMO Panel, a new systematic literature search was performed for LLCotton25 and the newly expressed PAT/*bar* covering a reporting period from 1 January 2007 until 30 April 2018.

Searches against electronic bibliographic databases, screening of reference lists and internet searches to specialist databases were performed to identify relevant publications. Altogether, 1,704 publications were retrieved. After applying the eligibility/inclusion criteria defined *a priori* by the applicant, seven publications were identified as relevant for food and feed safety assessment, molecular characterisation and environmental safety assessment. The list of relevant publications is provided in Appendix A.

2.1.3. Updated bioinformatic data¹¹

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for LLCotton25 event (using the corrected sequence) including an analysis of the insert and

⁵ Study number M-585342-01-1 and study number M-600013-01-1.

⁶ Additional information: 24/09/2018.

⁷ Study number M-384916-01-1.

⁸ Available online: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2017-00803>

⁹ Dossier: LLCotton25 renewal – Annex 2.

¹⁰ Dossier: LLCotton25 renewal – Annex 3; additional information: 8/6/2018.

¹¹ Dossier: LLCotton25 renewal – Section 3b.

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, and an analysis of possible horizontal gene transfer (EFSA, 2017b). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

2.1.4. Additional documents or studies provided by the applicant¹²

In line with the renewal guidance requirements (EFSA GMO Panel, 2015), the applicant provided an overview on the worldwide approvals of LLCotton25 and a list containing the summaries of all 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.

On 10 April 2018, the GMO Panel requested the applicant to provide the full study reports of five of these studies considered potentially relevant for safety assessment. The applicant submitted the requested information on 8 June 2018.

2.1.5. Overall assessment as provided by the applicant¹³

In line with the requirements listed in the renewal guidance (EFSA GMO Panel, 2015), the applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of LLCotton25 for food and feed use and processing in the EU, does not change the outcome of the original risk assessment (EFSA, 2006).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation¹⁴

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

2.2. Methodologies

The GMO Panel assessed the application for renewal of authorisation of LLCotton25 for food and feed uses, import and processing 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 Member States are addressed in Annex G of EFSA's overall opinion¹⁵ and 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 LLCotton25, 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 LLCotton25. Although the overall quality of the performed literature searches is acceptable, the GMO Panel considers that future searches could be improved. 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);

¹² Dossier: LLCotton25 renewal – Section 3c; additional information: 8/6/2018.

¹³ Dossier: LLCotton25 renewal – Section 4.

¹⁴ Dossier: LLCotton25 renewal – Section 5.

¹⁵ Available online: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00814>

- use truncation consistently;
- include intended trait-specific search terms;
- include controlled vocabulary (subject indexing) in the searches when available, and where subject headings are available use both free-text terms and controlled vocabulary in the searches.

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 LLCotton25 (EFSA, 2006) have been identified by the applicant.

3.3. Evaluation of the updated bioinformatic data

The results of the updated bioinformatic analyses of LLCotton25 using the corrected event sequence confirm that no known endogenous genes were disrupted by the inserts. Analyses of the amino acid sequence of the newly expressed PAT protein reveal no significant similarities to toxins or allergens. In addition, bioinformatic analyses of the newly created ORFs within the insert or spanning the junctions with genomic DNA reveal no significant similarities to toxins and allergens.

The updated bioinformatic analyses confirm the previous conclusions on the likelihood of occurrence of horizontal gene transfer for LLCotton25 (e.g. EFSA GMO Panel, 2018). It was concluded that the unlikely, but theoretically possible, horizontal transfer of recombinant genes from LLCotton25 to bacteria did not raise any environmental safety concern.

3.4. Evaluation of the additional documents or studies provided by the applicant

The GMO Panel evaluated the summary and/or the full study reports of the additional studies provided (Appendix B). This new information does not raise any concern for human and animal health and the environment, which would change the original risk assessment conclusions on LLCotton25.

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-010 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on 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 cotton plant material, including LLCotton25. This general surveillance is coordinated by EuropaBio 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 LLCotton25 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

Based on the data provided, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-010 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on LLCotton25 (EFSA, 2006).

Documentation provided to EFSA

- 1) Letter from the European Commission to EFSA received on 30 November 2017 for the continued marketing of genetically modified cotton LLCotton25 in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Bayer (EFSA-GMO-RX-010).
- 2) Acknowledgement letter, dated 4 December 2017, from EFSA to the European Commission.
- 3) Letter from EFSA to applicant dated 22 January 2018 requesting additional information under completeness check.
- 4) Letter from applicant to EFSA received on 26 February 2018 providing additional information under completeness check.

- 5) Letter from EFSA to applicant dated 15 March 2018 delivering the 'Statement of Validity' for application EFSA-GMO-RX-010.
- 6) Letter from EFSA to applicant dated 10 April 2018 requesting additional information and stopping the clock.
- 7) Letter from applicant to EFSA received on 8 June 2018 providing additional information.
- 8) Letter from EFSA to applicant dated 15 June 2018 re-starting the clock from 8 June 2018.
- 9) Letter from EFSA to applicant dated 29 August 2018 requesting additional information and stopping the clock.
- 10) Letter from applicant to EFSA received on 24 September 2018 providing additional information.
- 11) Letter from EFSA to applicant dated 24 September 2018 re-starting the clock from 24 September 2018.

References

- EFSA (European Food Safety Authority), 2006. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-NL-2005-13) for the placing on the market of glufosinate-tolerant genetically modified LLCotton25, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. EFSA Journal 2006;4(12):429, 19 pp. <https://doi.org/10.2903/j.efsa.2006.429>
- EFSA (European Food Safety Authority), 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010;8(6):1637, 90 pp. <https://doi.org/10.2903/j.efsa.2010.1637>
- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on application (EFSA-GMO-NL-2010-77) for the placing on the market of herbicide-tolerant genetically modified cotton GHB614 LLCotton25 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. EFSA Journal 2014;12(5):3680, 26 pp. <https://doi.org/10.2903/j.efsa.2014.3680>
- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. EFSA Journal 2015;13(6):4129, 8 pp. <https://doi.org/10.2903/j.efsa.2015.4129>
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- EFSA (European Food Safety Authority), Devos Y, Guajardo IM, Glanville J and Waigmann E, 2017a. 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. EFSA supporting publications 2017:EN-1207, 48 pp. <https://doi.org/10.2903/sp.efsa.2017.en-1207>
- EFSA (European Food Safety Authority), Gennaro A, Gomes A, Herman L, Nogue F, Papadopoulou N and Tebbe C, 2017b. 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 2017:14(7):EN-1273, 11 pp. <https://doi.org/10.2903/sp.efsa.2017.en-1273>

Abbreviations

GM	genetically modified
GMO	genetically modified organisms
GMO Panel	EFSA Panel on Genetically Modified Organisms
ORFs	open reading frames
PMEM	post-market environmental monitoring

Appendix A – List of relevant publications identified by the applicant through the systematic literature search

Reference

Fard NA et al., 2013. *In silico* allergenicity assessment of novel proteins derived from GMHR crops. Ortuno F and Rojas I [Editors]. 2013 pp. 275. Proceedings IWBBIO 2013: International Work-Conference on Bioinformatics and Biomedical Engineering. 978-84-15814-13-9(S).

Fard NA et al., 2013. Allergenicity study of genetically modified herbicide resistant crops (bioinformatics assessment). Bulletin of Environment, Pharmacology and Life Sciences, 2, 24-32.

Llewellyn D et al., 2007. Containment of regulated genetically modified cotton in the field. Agriculture, Ecosystems and Environment, 121, 419-429.

Oh J et al., 2009. Evaluation for allergenicity for genetically modified organic foods. Journal of Allergy and Clinical Immunology, 123, S244.

Siruguri V et al., 2015. Evaluation of Bar, Barnase, and Barstar recombinant proteins expressed in genetically engineered *Brassica juncea* (Indian mustard) for potential risks of food allergy using bioinformatics and literature searches. Food and Chemical Toxicology, 83, 93-102.

Sun H-J et al., 2010. Assessment of phosphinothricin acetyltransferase (PAT) degradation from transgenic zoysiagrass digested with simulated gastric fluid (SGF). Journal of Plant Biology, 53, 113-120.

Verma AK et al., 2011. Computational allergenicity prediction of transgenic proteins expressed in genetically modified crops. Immunopharmacology and Immunotoxicology, 33, 410-422.

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 LLCotton25

Study identification	Title
M-487218-01-1 ^(a)	Avaliação a campo do algodão libertylink – Field assessment of LibertyLink cotton
M-384718-01-1 ^{(b),(c)}	LLCotton25: 90-Day toxicity study in the rat by dietary administration of toasted meal
M-509357-01-1	Structural and functional equivalence of PAT/bar protein produced in <i>Escherichia coli</i> and LLCotton25, <i>Gossypium hirsutum</i> – Supplement
M-557508-01-1 ^(b)	The effect of temperature on PAT/bar as assessed by ELISA
M-554703-01-1 ^(b)	The effect of temperature on PAT/bar as assessed by the PAT quantitative activity assay
M-461494-01-1 ^(b)	Recombinant PAT/bar protein: Acute toxicity by oral gavage in female mice
M-475319-01-1 ^(b)	PAT/bar protein - Acute toxicity by oral gavage in mice

(a): Report in Portuguese.

(b): Studies for which the full report was requested by the GMO Panel.

(c): The GMO Panel notes that this study did not adhere to EFSA guidance documents relevant for the conduction of 90-day feeding studies. However, the study was evaluated to exclude any documented adverse effect.