TECHNICAL REPORT

APPROVED: 14 November 2018 PUBLISHED: 15 November 2018

Overall opinion of the European Food Safety Authority on genetically modified LLCotton25 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-010)

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-RX-010 for the continued placing on the market of genetically modified (GM) LLCotton25 according to Articles 11 and 23 of Regulation (EC) No 1829/2003.[1] The scope of application EFSA-GMO-RX-010 is for food and feed uses, import and processing of LLCotton25 in the European Union (EU). Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) on LLCotton25, EFSA reports on the particulars as laid down in Articles 6 and 18 of Regulation (EC) No 1829/2003.

Overall, the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF) already validated the detection method of LLCotton25, and declared fit for regulatory purpose. The certified reference materials of LLCotton25 can be accessed at the American Oil Chemists' Society (AOCS-USA). The GMO Panel is of the opinion that the post-market environmental monitoring (PMEM) plan proposed by the applicant and reporting intervals are in line with the intended uses of LLCotton25. The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period.

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

Keywords: Cotton, LLCotton25, EFSA-GMO-RX-010, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2018-00814

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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.

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1. Introduction

On 30 November 2017, EFSA received from the European Commission an application (reference EFSA-GMO-RX-010), submitted by Bayer CropScience N.V. under Articles 11 and 23 of Regulation (EC) No 1829/2003[2], to support the continued placing of genetically modified (GM) LLCotton25 on the market in the European Union (EU). The unique identifier of LLCotton25 is ACS-GHØØ1-3.

The scope of renewal application EFSA-GMO-RX-010 is for placing on the market of products containing, consisting of, or produced from LLCotton25 within the EU.

EFSA first checked the completeness of the application in accordance with the requirements laid down in Articles 11(2) and 23(2) of the above mentioned Regulation. On 7 October 2004, EURL–GMFF received samples and control samples in accordance with the same Articles.
According to Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission of the application and made the summary of the application publicly available[3].

At the end of a thorough completeness check, EFSA declared application EFSA-GMO-RX-010 valid on 15 March 2018.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-RX-010. Such time limit was extended whenever EFSA requested supplementary information to the applicant.

According to Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, EFSA consults the risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC,[4] of all Member States on each request for placing on the market of products consisting of or containing GMOs.

The Member States were therefore given three months to comment the valid application EFSA-GMO-RX-010 from the date of its receipt.

1.1. Terms of Reference

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA is requested to issue an overall opinion on application EFSA-GMO-RX-010 including: i) the name and address of the applicant; ii) the designation of the food and its specification; iii) the scientific opinion of the GMO Panel; iv) the information required under Annex II to the Cartagena Protocol; v) the labelling proposal; vi) the method for detection, validated by the EURL-GMFF, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it; vii) an indication of where appropriate reference materials can be accessed; viii) the post-market environmental monitoring (PMEM) plan; and ix) the Member States' comments submitted during the consultation period.

[2] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.
[3] https://registrofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00814
[4] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 12.3.2001, p. 1–38.

2. Considerations

2.1. Name and address of the Applicant

Application EFSA-GMO-RX-010 was submitted by

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

Bayer CropScience N.V.
Square de Meeûs 40
B-1000 Brussels
Belgium

2.2. Designation and specification of the product

LLCotton25 (unique identifier: ACS-GHØØ1-3) was developed to be tolerant to glufosinate-ammonium containing herbicides.

The scope of renewal application EFSA-GMO-RX-010 is for placing on the market of products containing, consisting of, or produced from LLCotton25 in the EU.

2.3. Scientific opinion of the GMO Panel

On 17 October 2018, the GMO Panel adopted a scientific opinion on LLCotton25 (application EFSA-GMO-RX-010). During its safety evaluation, the GMO Panel considered the valid application as submitted by the applicant, any additional data provided by the applicant, the scientific comments submitted by the Member States and the relevant scientific literature.

The data received in the context of renewal application EFSA-GMO-RX-010 contained: annual PMEM 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 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) (Annex A).

2.4. Cartagena Protocol

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

2.5. Labelling

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

2.6. Methods for detection

The EURL-GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify cotton transformation event in crop DNA. The reports were issued on 14 March 2007. The EURL-GMFF considers that the method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2. to Commission Regulation (EC) No 641/2004[5] (Annexes D1, D2, D3).

[5] Regulation (EC) No 641/2004 of the Commission on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food

2.7. Certified reference materials

The certified reference materials of LLCotton25 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E).

2.8. Post-market environmental monitoring

The applicant indicated in the dossier that the PMEM plan is appropriate and does not need any changes (Annex F).

2.9. Member States Comments

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

and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. OJ L 102/14, 7.4.2004, p. 1–12.

3. Conclusions

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA issues an overall opinion on application EFSA-GMO-RX-010 for food and feed uses, import and processing of LLCotton25 in the EU.

List of Annexes[6]

Annex A: Scientific opinion of the EFSA GMO Panel
Annex B: Cartagena Protocol
Annex C: Labelling proposal
Annex D1: Validation report by EURL-GMFF of the event-specific detection methods for the quantification of LLCotton25
Annex D2: Validated detection method for LLCotton25
Annex D3: Sampling / DNA extraction
Annex E: Certified reference materials (LLCotton25)
Annex F: Post-market environmental monitoring plan
Annex G: Member States' comments and GMO Panel responses

[6] The annexes of the EFSA Overall opinion can be found in the Register of Questions (tab "Question documents") on the EFSA website under the following link:
https://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00814