TECHNICAL REPORT

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Overall opinion of the European Food Safety Authority on genetically oilseed rape T45 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-012)

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-RX-012 for the continued placing on the market of genetically modified (GM) oilseed rape T45 according to Articles 11 and 23 of Regulation (EC) No 1829/2003.[1]

The scope of application EFSA-GMO-RX-012 is for the continued placing on the market of products containing or produced from oilseed rape T45 in the European Union (EU). Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel) on oilseed rape T45, 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 oilseed rape T45, and declared it fit for regulatory purpose. The certified reference materials of oilseed rape T45 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 is in line with the scope of application EFSA-GMO-RX-012. 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, Cartagena protocol are not considered by EFSA since they fall outside its remit.

Key words: oilseed rape, T45, EFSA-GMO-RX-012, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2019-00031

Correspondence: GMO_secretariat_applications@efsa.europa.eu

[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 1 March 2018, EFSA received from the European Commission an application (reference EFSA-GMO-RX-012), submitted by Bayer CropScience SA-NV under Articles 11 and 23 of Regulation (EC) No 1829/2003[2], to support the continued placing of products containing or produced from genetically modified (GM) oilseed rape T45 on the market in the European Union (EU). The unique identifier of oilseed rape T45 is ACS-BNØØ8-2.

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. The 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-012 valid on 5 June 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-012. 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 EU 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-012 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-012 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 three-month 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]http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00031
[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-012 was submitted by

Bayer CropScience LP *represented by*
2 T.W. Alexander Drive
P.O. Box 12014
Research Triangle Park
RTP, North Carolina 27709
USA

Bayer CropScience SA-NV
J.E. Mommaertslaan 14
B-1831 Diegem
Belgium

2.2. Designation and specification of the product

Oilseed rape T45 (unique identifier: ACS-BNØØ8-2) was developed to be tolerant to glufosinate-ammonium containing herbicides.

The scope of renewal application EFSA-GMO-RX-012 is for the continued placing on the market of products containing or produced from oilseed rape T45 in the EU.

2.3. Scientific opinion of the GMO Panel

On 23 January 2019, the GMO Panel adopted a scientific opinion on oilseed rape T45 (application EFSA-GMO-RX-012). 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 (Annex A).

The data received in the context of the renewal application EFSA-GMO-RX-012 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by two systematic searches, updated bioinformatics analyses, and additional 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.

Under the assumption that the DNA sequence of the event in oilseed rape T45 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-012 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape T45 (EFSA, 2008).

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 T45 transformation event in oilseed rape DNA. The reports were issued on 7 September 2016 and 15 January 2017. 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).

2.7. Certified reference materials

The certified reference materials of oilseed rape T45 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E).

2.8. Post-market environmental monitoring (PMEM)

The GMO Panel is of the opinion that the PMEM plan proposed by the applicant is in line with the scope of application EFSA-GMO-RX-012 (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).

[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 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-012 for the continued placing on the market of products containing or produced from oilseed rape T45 in the EU.

List of Annexes[6]

Annex A:	Scientific opinion of the 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 oilseed rape T45
Annex D2:	Validated detection method
Annex D3:	Sampling / DNA extraction
Annex E:	Certified reference materials
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: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00031