TECHNICAL REPORT

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Overall opinion of the European Food Safety Authority on genetically modified oilseed rape MS8, RF3 and MS8×RF3 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-004)

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-RX-004 for the continued placing on the market of genetically modified (GM) oilseed rape MS8, RF3 and MS8×RF3 according to Articles 11 and 23 of Regulation (EC) No 1829/2003.[1] The scope of the renewal application EFSA-GMO-RX-004 covers feed containing or consisting of GM oilseed rape MS8, RF3 and MS8×RF3 and products other than food and feed containing or consisting of it.

Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel) on oilseed rape MS8, RF3 and MS8×RF3, 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) validates, and declares fit for purpose, the detection methods for each event MS8 and RF3 applied for the detection and quantification of the respective events in oilseed rape MS8×RF3. The certified reference materials of oilseed rape MS8, RF3 and MS8×RF3 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) and/or 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 consistent with the scope of oilseed rape MS8, RF3 and MS8×RF3. 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, MS8, RF3, MS8×RF3, EFSA-GMO-RX-004, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2016-00569

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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 9 September 2016, EFSA received from the European Commission an application (reference EFSA-GMO-RX-004), submitted by Bayer CropScience under Articles 11 and 23 of Regulation (EC) No 1829/2003[2], to support the continued placing of genetically modified (GM) oilseed rape MS8, RF3 and MS8×RF3 on the market in the EU. The unique identifiers of oilseed rape MS8, RF3 and MS8×RF3 are ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8xACS-BNØØ3-6. The scope of the renewal application EFSA-GMO-RX-004 covers feed containing or consisting of GM oilseed rape MS8, RF3 and MS8×RF3 and products other than food and feed containing or consisting of it.

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 3 September 2004 and on 22 March 2005, 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-004 valid on 21 October 2016.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-RX-004. 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-004 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-004 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 MS8, RF3 and MS8×RF3 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-2016-00569
[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(s)

Application EFSA-GMO-RX-004 was submitted by

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

Bayer BioScience NV
Technologiepark 38
B-9052 Gent
Belgium

2.2. Designation and specification of the product

Oilseed rape MS8, RF3 and MS8×RF3 (unique identifiers: ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8xACS-BNØØ3-6) was developed to be herbicide-tolerant.

The scope of the renewal application EFSA-GMO-RX-004 covers feed containing or consisting of GM oilseed rape MS8, RF3 and MS8×RF3 and products other than food and feed containing or consisting of it.

2.3. Scientific opinion of the GMO Panel

On 26 October 2017, the GMO Panel adopted a scientific opinion on oilseed rape MS8, RF3 and MS8×RF3 (application EFSA-GMO-RX-004). 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 this renewal application contain post-market environmental monitoring reports, systematic searches and evaluation of literature, updated bioinformatics 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. Under the assumption that the DNA sequence of the event in oilseed rape MS8, RF3 and MS8×RF3 considered for renewed authorisation is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in the context of this renewal application for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape MS8, RF3 and MS8×RF3 (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 previously validated individually, and declared fit for purpose, the detection methods for the events MS8 and RF3 (Annexes D2a, D2b, D3a, D3b).

In the context of application EFSA-GMO-RX-004, the EURL-GMFF has checked in-house the performance of each validated detection method when applied to genomic DNA extracted from oilseed rape MS8×RF3. The final validation report by the EURL-GMFF of the individual detection methods applied to DNA extracted from oilseed rape MS8×RF3 is provided in Annex D1.

2.7. Certified reference materials

The certified reference materials of oilseed rape MS8, RF3 and MS8×RF3 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 scope of the PMEM plan provided by the applicant is consistent with the scope of oilseed rape MS8, RF3 and MS8×RF3 (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).

3. Conclusions

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA issues an overall opinion on application EFSA-GMO-RX-004 for food and feed uses, import and processing of oilseed rape MS8, RF3 and MS8×RF3 in the EU.

List of Annexes[5]

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 MS8 and RF3 applied to oilseed rape MS8×RF3
Annex D2a:	Validated detection method for oilseed rape MS8
Annex D2b:	Validated detection method for oilseed rape RF3
Annex D3a:	Sampling / DNA extraction for oilseed rape MS8
Annex D3b:	Sampling / DNA extraction for oilseed rape RF3
Annex Ea:	Certified reference materials (oilseed rape MS8 and RF3)
Annex Eb:	Certified reference materials (oilseed rape MS8)
Annex F:	Post-market environmental monitoring plan
Annex G:	Member States' comments and GMO Panel responses

[5]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-2017-00713