TECHNICAL REPORT

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Overall opinion of the European Food Safety Authority on genetically modified sugar beet H7-1 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-006)

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-RX-006 for the continued placing on the market of genetically modified (GM) sugar beet H7-1 according to Articles 11 and 23 of Regulation (EC) No 1829/2003.[1] The scope of application EFSA-GMO-RX-006 is for food and feed produced from or food containing ingredients produced from sugar beet H7-1 for import and processing in the European Union (EU). Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel) on sugar beet H7-1, 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 sugar beet H7-1, and declared fit for regulatory purpose. The certified reference materials of sugar beet H7-1 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM). A post-market monitoring plan (PMM) and post-market environmental monitoring plan (PMEM) plan were not required by the authorisation decision. The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period. The particulars regarding e.g. labelling proposal, detection, Cartagena protocol are not considered by EFSA since they fall outside its remit.

Key words: sugar beet, H7-1, EFSA-GMO-RX-006, labelling, detection, Member States comments, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2017-00714

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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 22 December 2016, EFSA received from the European Commission (DG SANTE) application EFSA-GMO-RX-006 submitted by KWS SAAT SE and Monsanto Company (referred to hereafter as the applicant) for the renewal of authorisation of GM sugar beet H7-1 for food and feed produced from or food containing ingredients produced from this GM sugar beet for import and processing submitted within the framework of Regulation (EC) No 1829/2003. The unique identifier of sugar beet H7-1 is KM-ØØØH71-4. The scope of the renewal application EFSA-GMO-RX-006 is for food and feed produced from or food containing ingredients produced from sugar beet H7-1 for import and processing, excluding cultivation within the EU.

EFSA first checked the completeness of the application in accordance with the requirements laid down in Articles 6(2) and 18(2) of the above mentioned Regulation. On 15 December 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[2].

At the end of a thorough completeness check, EFSA declared application EFSA-GMO-RX-006 valid on 18 April 2017.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-RX-006. 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[3], 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-006 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-006 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] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00026

[3] 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-006 was submitted by:

KWS SAAT SE
Grimsehlstrasse 31
D 37574, Einbeck
GERMANY

and

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
US

Represented by

Monsanto Europe S.A/N.V.
Avenue de Tervuren 270-272
B-1150 Brussels
BELGIUM

2.2. Designation and specification of the product

Sugar beet H7-1 (unique identifier: KM-ØØØH71-4) was developed to be herbicide-tolerant.

The scope of the renewal application EFSA-GMO-RX-006 is for food and feed produced from or food containing ingredients produced from sugar beet H7-1 for import and processing, excluding cultivation within the EU.

2.3. Scientific opinion of the GMO Panel

On 26 October 2017, the GMO Panel adopted a scientific opinion on sugar beet H7-1 (application EFSA-GMO-RX-006). 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 contained a systematic search 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 sugar beet H7-1 considered for renewal is identical to 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 sugar beet H7-1.

2.4. Cartagena Protocol

Not applicable. The scope of this application is for food produced from or containing ingredients produced from GM sugar beet H7-1 and feed produced from GM sugar beet H7-1. No information is therefore required under Annex II of the Cartagena Protocol.

2.5. Labelling

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

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 sugar beet transformation event in crop DNA. The reports were issued on 31 January 2006 and 19 May 2008. 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[4] (Annexes C1, C2, C3).

2.7. Certified reference materials

The certified reference materials of sugar beet H7-1 can be accessed at Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) (Annex D).

2.8. Post-market (environmental) monitoring

As a post-market plan and PMEM plan were not required by the authorisation decision, the applicant did not indicate any new proposal for monitoring. The GMO panel is of the opinion that a PMM and PMEM plan is still not needed.

2.9. Member States Comments

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

[4]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-006 for food and feed uses, import and processing of sugar beet H7-1 in the EU.

List of Annexes[5]

Annex A:	Scientific opinion of the GMO Panel
Annex B:	Labelling proposal
Annex C1:	Validation report by EURL-GMFF of the event-specific method for the quantification of sugar beet H7-1
Annex C2:	Validated detection method for sugar beet H7-1
Annex C3:	Sampling / DNA extraction
Annex D:	Certified reference materials
Annex E:	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-2017-00714