TECHNICAL REPORT

Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on the application (reference EFSA-GMO-RX-T25) for renewal of the authorisation for continued marketing of existing food and food ingredients produced from maize T25 and feed containing, consisting of, or produced from maize T25 (feed materials and feed additives) from Bayer CropScience AG[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

This document provides an overall opinion of the European Food Safety Authority on genetically modified (GM) maize T25 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of the application EFSA-GMO-RX-T25 is for renewal of the authorisation for continued marketing of existing GM maize T25 for food and food ingredients produced from maize T25 and feed containing, consisting of, or produced from maize T25 (feed materials and feed additives), which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. The scope does not include cultivation.[3]

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified maize T25 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. The EFSA GMO Panel considers that the information available for maize T25 addresses the scientific issues indicated by the Guidance Document of the EFSA GMO Panel and the scientific comments raised by the Member States. In conclusion, the EFSA GMO Panel considered that maize T25, as described in applications EFSA-GMO-RX-T25 and EFSA-GMO-NL-2007-46, is as safe as its conventional counterpart with respect to potential effects on human and animal health or the environment in the context of its intended uses for food and feed, import and processing. The European Union Reference Laboratory for GM Food and Feed (EU-RL – GMFF)

[1] On request from the European Commission for an application (EFSA-GMO-RX-T25) submitted by Bayer CropScience AG, Questions No EFSA-Q-2013-00762 (EFSA overall opinion) and EFSA-Q-2007-157 (Scientific opinion of the EFSA GMO Panel), issued on 3 October 2013.

[2] Correspondence: gmo@efsa.europa.eu

[3] Application EFSA-GMO-NL-2007-46 was initially for food and feed uses, import and processing of maize T25 and all derived products, and cultivation of maize T25 in the European Union (EU). Following the applicant's request to modify the scope of applications EFSA-GMO-RX-T25 and EFSA-GMO-NL-2007-46 to no longer include cultivation of maize T25 in the EU, the EFSA GMO Panel provides a single scientific opinion, valid for both applications

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Available online: www.efsa.europa.eu/publications

considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize T25 can be accessed at the American Oil Chemists' Society (AOCS-USA).

The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan is in line with Regulation (EC) No 1829/2003.

Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Articles 6 and 18 for the renewal of authorisation of genetically modified maize T25.

KEY WORDS

Overall opinion, GM maize T25, herbicide tolerance, risk assessment, for food and food ingredients and feed materials and feed additives, import and processing, renewal existing product and Regulation (EC) No 1829/2003.

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BACKGROUND

On 29 June 2007, the European Food Safety Authority (EFSA) received from the European Commission an application for renewal of the authorisation for continued marketing of existing products derived from GM maize T25 (ACS-ZMØØ3-2), submitted by Bayer CropScience AG, within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-T25).

The scope of application EFSA-GMO-RX-T25 covers the continued marketing of existing food and food ingredients produced from maize T25 and feed containing, consisting of, or produced from maize T25 (feed materials and feed additives), which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. After the date of entry into force of Regulation (EC) No 1829/2003 these products were notified to the European Commission according to Articles 8 and 20 of that Regulation and included in the Community Register of genetically modified food and feed.[4] The scope does not include cultivation.

In accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission and made the summary of the application publicly available on the EFSA website[5] on 23 July 2007. EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Articles 5 and 17 of Regulation (EC) No 1829/2003. The EU-RL – GMFF received samples and control samples in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. EFSA declared the application valid on 10 June 2008 and started the clock in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003.

From that date, EFSA has endeavoured to respect a time limit of six months in giving its overall opinion (Articles 6(1) and 18(1)). EFSA made the valid application available to Member States and the European Commission. Following the procedure laid down in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, EFSA consulted the Member States. In this context, the Member States risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC, were given three months after the date of receipt of the valid application (i.e. until 10 September 2008) within which to make their opinion known.

Making use of the provisions under Articles 6(2) and 18(2), EFSA requested additional information from the applicant and the clock was stopped from 9 October 2008 to 24 June 2010; from 29 March 2012 to 18 October 2012 and from 4 February 2013 to 27 May 2013.[6]

The overall opinion on application EFSA-GMO-RX-T25 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms together with the particulars required under Articles 6(5)(a-g) and 18(5)(a-g) of Regulation (EC) No 1829/2003: i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the information required under Annex II to the Cartagena Protocol, iv) the labelling proposal, v) the method for detection, validated by the European Union Reference Laboratory, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it, vi) an indication of where appropriate reference materials can be accessed, vii) the monitoring plan and viii) the Member States' comments submitted during the three-month consultation period.

[4] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=20

[5] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-157

[6] Request for additional information from the EFSA/ERA Competent Authority: requested (1) on 09/10/2008 – received on 01/07/2009 and clock re-started on 24/06/2010.

Request for additional information from the EFSA GMO Panel: requested (1) on 29/03/2012 - received on 03/09/2012 and on 18/12/2012; requested (2) on 24/05/2012 - received on 03/09/2012 and on 18/12/2012, and clock re-started on 18/10/2012; requested (3) on 04/02/2013 – received on 19/02/2013 and clock re-started on 27/05/2013.

The applicant submitted additional information spontaneously on 07/10/2010 and on 26/06/2013.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The European Food Safety Authority (EFSA) received from the European Commission an application for renewal of the authorisation for continued marketing of existing products derived from GM maize T25 (ACS-ZMØØ3-2), submitted by Bayer CropScience AG, within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-T25). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

CONSIDERATIONS

1. Applicant

The application was submitted by

Bayer CropScience AG
Alfred-Nobel-Str.50
D-40789 Monheim am Rhein
Deutschland

2. Designation and specification of the product as provided by the applicant

The scope of the application EFSA-GMO-RX-T25 is for renewal of the authorisation for continued marketing of existing GM maize T25 for food and food ingredients produced from maize T25 and feed containing, consisting of, or produced from maize T25 (feed materials and feed additives). After the date of entry into force of Regulation (EC) No 1829/2003 these products were notified to the European Commission according to Articles 8 and 20 of that Regulation and included in the Community Register of genetically modified food and feed.[7] The scope does not include cultivation.

Maize T25 was developed to express the enzyme phosphinothricin acetyl-transferase (PAT), encoded by the *pat* gene from *Streptomyces viridochromogenes* codon-optimised for expression in plants. Expression of PAT confers tolerance to glufosinate-based herbicides.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize T25 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 11 September 2013. The EFSA GMO Panel considered all comments submitted by Member States' bodies and where deemed necessary, requested additional information from the applicant before finalising its scientific assessment. The EFSA GMO Panel considers that the information available for maize T25 addresses the scientific issues indicated by the Guidance Document of the EFSA GMO Panel and the scientific comments raised by the Member States. In conclusion, the EFSA GMO Panel considered that maize T25, as described in applications EFSA-GMO-RX-T25 and EFSA-GMO-NL-2007-46, is as safe as its conventional counterpart with respect to potential effects on human and animal health or the environment in the context of its intended uses for food and feed, import and processing (Annex A).

4. Cartagena Protocol

The information presented in the application and as required under Annex II of the Cartagena Protocol on Biosafety is in line with the scientific opinion of the EFSA GMO Panel (Annex B).

5. Labelling

The labelling proposal provided in the application is in line with the requirements in Regulation (EC) No 1829/2003. On the basis of the scientific opinion of the EFSA GMO Panel, EFSA is of the opinion that there is no need for a specific labelling in accordance with Articles 13(2)(a) and 25(2)(c) (Annex C).

6. Method for detection

The EU-RL – GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the maize T25 transformation event in maize DNA. The reports were issued on 14 June 2005 and 15 October 2008. The EU-RL – GMFF considers that the

[7] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=20

method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2. of the Commission Regulation (EC) No 641/2004 (Annexes D1, D2, D3).

7. Certified reference materials

The certified reference materials of genetically modified maize T25 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E).

8. Post-market environmental monitoring

The EFSA GMO Panel evaluated the post-market environmental monitoring plan proposed by the applicant. The EFSA GMO Panel considered that the monitoring plan provided by the applicant is in line with the intended uses for the GMO (Annex F).

9. Member States' Comments

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

CONCLUSIONS

Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Articles 6 and 18 for the renewal of authorisation of genetically modified maize T25.

LIST OF ANNEXES[8]

Annex A: Scientific opinion of the GMO Panel (maize T25)
Annex B: Cartagena Protocol (maize T25)
Annex C: Labelling proposal (maize T25)
Annex D1: Validation report (maize T25)
Annex D2: Validated method (maize T25)
Annex E: Certified reference materials report (maize T25)
Annex F: Post-market environmental monitoring plan (maize T25)
Annex G: Member States' comments (maize T25 in the context of application EFSA-GMO-RX-T25)

[8] The annexes of the EFSA overall opinion can be found in the Register of Questions ("Question documents") on the EFSA website under the following link:
http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00370