TECHNICAL REPORT

Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on application (reference EFSA-GMO-UK-2006-34) for the placing on the market of the genetically modified maize 3272 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection 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 maize 3272 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-UK-2006-34 is for food and feed uses, import and processing. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified maize 3272 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. The EFSA GMO Panel considered that the information available for maize 3272 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, in the absence of an appropriately performed comparative assessment by the applicant, it is not in the position to complete its risk assessment on maize 3272 and therefore did not conclude on the safety of maize 3272 compared with its conventional counterpart with respect to potential effects on human and animal health. However, the EFSA GMO Panel concluded that maize event 3272 is unlikely to have any adverse effect on the environment in the context of its intended uses. The European Union Reference Laboratory for GM Food and Feed (EU-RL – GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize 3272 can be accessed at the Institute for Reference Materials and Measurements (IRMM).

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 placing on the market of genetically modified maize 3272.

[1] On request from the Competent Authority of the United Kingdom for an application (EFSA-GMO-UK-2006-34) submitted by Syngenta Crop Protection AG, Questions No EFSA-Q-2013-00526 (EFSA overall opinion) and EFSA-Q-2006-026 (Scientific opinion of the EFSA GMO Panel), issued on 20 June 2013

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

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KEY WORDS

Overall opinion, GMO, maize 3272, Regulation (EC) No 1829/2003, thermotolerant alpha-amylase, risk assessment, food and feed uses, environment, food and feed uses, import and processing.

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BACKGROUND

On 9 March 2006, the European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified maize 3272 (Unique Identifier SYN-E3272-5) submitted by Syngenta Crop Protection AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2006-34).

The scope of this application EFSA-GMO-UK-2006-34 is for food and feed uses.[3] 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[4] on 20 March 2006. 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 the detection method, samples and control samples in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. EFSA declared the application valid on 6 July 2007 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 6 October 2007) 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 11 July 2007 to 28 May 2013.[5]

The overall opinion on application EFSA-GMO-UK-2006-34 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.

TERMS OF REFERENCE AS PROVIDED BY THE COMPETENT AUTHORITY OF THE UNITED KINGDOM

The European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified maize 3272 (Unique Identifier SYN-E3272-5) submitted by Syngenta Crop Protection AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2006-34). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

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[3] This does include genetically modified maize 3272 for import and processing as designated under part C of Directive 2001/18/EC.

[4] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2006-026

[5] Request for additional information from the EFSA/EURL-GMFF: requested (1) on 11/07/2007 - received on 15/11/2007 and clock re-started on 06/12/2007.

Request for additional information from the EFSA/GMO Panel: requested (1) on 23/11/2007 - received on 07/01/2010; requested (2) on 14/04/2008 – received 07/01/2010; requested (3) on 06/05/2010 – received on 01/10/2010 and clock re-started on 28/05/2013.

The applicant requested clarifications on 01/07/2010; EFSA provided the clarifications requested on 26/07/2010.

CONSIDERATIONS

1. Applicant

The application was submitted by

Syngenta Seeds S.A.S.
12, chemin de l'Hobit
BP 27
F-31790 Saint-Sauveur
France

Syngenta Crop Protection AG,
Basel Switzerland and all affiliated companies
Schwarzwaldallee 215
CH-4058 Basel
Switzerland

on behalf of

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

The scope of this application EFSA-GMO-UK-2006-34 is for food and feed uses.[6] The scope does not include cultivation.

Maize 3272 has been developed to express a chimeric thermo tolerant alpha-amylase (AMY797E) and a phosphomannose isomerase (PMI) as a selectable marker.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize 3272 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 30 May 2013. The EFSA GMO Panel considered all comments submitted by Member State 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 3272 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, in the absence of an appropriately performed comparative assessment by the applicant, it is not in the position to complete its risk assessment on maize 3272 and therefore did not conclude on the safety of maize 3272 compared with its conventional counterpart with respect to potential effects on human and animal health. However, the EFSA GMO Panel concluded that maize event 3272 is unlikely to have any adverse effect on the environment in the context of its intended uses (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 Article 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 3272 transformation event in maize DNA. The reports were issued on 18 April 2007 and on 7 November 2008. The EU-RL – GMFF considers that the 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).

[6] This includes genetically modified maize 3272 for import and processing as designated under part C of Directive 2001/18/EC.

7. Certified reference materials

The certified reference materials of genetically modified maize 3272 can be accessed at the Institute for Reference Materials and Measurements (IRMM) (Annex E).

8. Post-market environmental monitoring (not applicable)

Due to the scope of the application, there are no requirements for a post-market environmental monitoring plan for maize 32772.

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 placing on the market of genetically modified maize 3272.

LIST OF ANNEXES[7]

Annex A: Scientific opinion of the EFSA GMO Panel (maize 3272)
Annex B: Cartagena Protocol (maize 3272)
Annex C: Labelling (maize 3272)
Annex D1: Validation report (maize 3272)
Annex D2: Validated method (maize 3272)
Annex D3: Sampling and extraction (maize 3272)
Annex E: Certified reference materials report (maize 3272)
Annex F: Not applicable
Annex G: Member States' comments (maize 3272)

[7] 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-2013-00526