TECHNICAL REPORT

APPROVED: 4 May 2015 PUBLISHED: 5 May 2015

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-DE-2011-95) for the placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG

European Food Safety Authority

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize 5307 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of application EFSA-GMO-DE-2011-95 is for import, processing and food and feed uses of maize 5307 and does not include cultivation in the EU. Thus, maize 5307 will be imported into the EU for food or feed uses in the same way as any commercial maize variety. Possible food and feed products include starch, syrup, ethanol, maize oil, flakes, coarse and regular grits, coarse and dusted meal, flour, maize germ meal, maize gluten and maize gluten meal.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified (GM) maize 5307 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In delivering its Scientific Opinion, the EFSA GMO Panel considered application EFSA-GMO-DE-2011-95, additional information submitted by the applicant on request of the Panel, the scientific comments submitted by Member States and relevant scientific publications. In conclusion, the EFSA GMO Panel could not complete the food and feed safety assessment of maize 5307 due to the lack of an appropriate assessment of the eCry3.1Ab protein. However, the EFSA GMO Panel concludes that the maize event 5307 is unlikely to have any adverse effect on the environment in the context of the scope of application EFSA-GMO-DE-2011-95. The European Union Reference Laboratory for GM Food and Feed (EURL-GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize 5307 can be accessed at the American Oil Chemists' Society (AOCS-USA).

The EFSA GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, the EFSA GMO Panel did not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management; the post-market environmental monitoring plan and reporting intervals are in line with the scope of application EFSA-GMO-DE-2011-95.

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 5307.

Key words: GMO overall opinion, maize 5307, food and feed safety, environment import and processing, eCry 3.1Ab and PMI, Regulation (EC) No 1829/2003

Requestor: On request from the Competent Authority of Germany for an application (EFSA-GMO-DE-2011-95) submitted by Syngenta Crop Protection AG

Question number: EFSA-Q-2011-00310

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Acknowledgements: EFSA wishes to thank the GMO Panel members: Salvatore Arpaia, Andrew Nicholas Edmund Birch, Andrew Chesson, Patrick du Jardin, Achim Gathmann, Jürgen Gropp, Lieve Herman, Hilde-Gunn Hoen-Sorteberg, Huw Jones, József Kiss, Gijs Kleter, Martinus Løvik, Antoine Messéan, Hanspeter Naegeli, Kaare Magne Nielsen, Jaroslava Ovesná, Joe Perry, Nils Rostoks and Christoph Tebbe; the members of the Working Groups on Molecular Characterisation, Food and Feed Risk Assessment and Environment Risk Assessment for the preparatory work on this scientific opinion and EFSA staff members: Antonio Fernández Dumont, Matthew Ramon and Sylvie Mestdagh for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), 2015. 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-DE-2011-95) for the placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG. EFSA supporting publication 2015:D-EN-9232. 10 pp.

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1. Introduction

1.1. Background as provided by the Competent Authority of Germany

On 7 April 2011, the European Food Safety Authority (EFSA) received from the Competent Authority of Germany an application (reference EFSA-GMO-DE-2011-95) for authorisation of genetically modified maize 5307 (Unique Identifier SYN-Ø53Ø7-1) submitted by Syngenta Crop Protection AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed.

The scope of application EFSA-GMO-DE-2011-95 is for import, processing[1] and food and feed uses of maize 5307 and does not include cultivation in the EU. Thus, maize 5307 will be imported into the EU for food or feed uses in the same way as any commercial maize variety. Possible food and feed products include starch, syrup, ethanol, maize oil, flakes, coarse and regular grits, coarse and dusted meal, flour, maize germ meal, maize gluten and maize gluten meal.

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[2] on 26 June 2011. 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. On 15 April 2011, the European Union Reference Laboratory for Genetically modified Food and Feed (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 21 June 2011 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 21 September 2011) 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 17 July 2011 to 17 January 2014, from 27 May 2014 to 2 July 2014 and from 9 September 2014 to 14 April 2015[3].

The overall opinion on application EFSA-GMO-DE-2011-95 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-

[1]This does include genetically modified maize 5307 for import and processing as designated under part C of Directive 2001/18/EC.

[2]http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00310

[3]Request for supplementary information from the DG JRC/EURL-GMFF: Info requested(1) on 15/07/2011) – info provided on 05/09/2011; info requested(2) on 30/09/2011 – info provided on 31/05/2012; info requested(3) on 11/07/2012 – info provided on 25/07/2012; info requested(4) on 15/11/2012 – info provided on 22/08/2013 and clock re-started on 17/01/2014.

Request for supplementary information from the EFSA GMO Panel: Info requested(1) on 13/09/2011 – info received on 03/10/2011; info requested(2) on 14/10/2011 – info received on 29/01/2013; info requested(3) on 25/06/2013 – info received on 08/08/2013 and clock re-started on 17/10/2013.
Info requested(4) on 27/05/2014 – info received on 12/06/2014 and clock re-started on 02/07/2014.
Info requested(5) on 09/09/2014 – info received on 18/09/2014; info requested(6) on 29/10/2014 – info received on 11/12/2014; info requested(7) on 16/02/2015 – info provided on 24/03/2015; info requested(8) on 27/02/2015 – info received on 24/03/2015 and clock re-started on 14/04/2015.

The applicant provided additional information spontaneously on 28/07/2014.

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.

1.2. Terms of Reference as provided by the Applicant

The European Food Safety Authority (EFSA) received from the Competent Authority of Germany an application for authorisation of genetically modified maize 5307 (Unique Identifier SYN-Ø53Ø7-1) submitted by Syngenta Crop Protection AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-DE-2011-95). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

2. Considerations

2.1. Applicant

The application was submitted by

Syngenta Crop Protection AG
Schwarzwaldallee 215
CH 4058 Basel
Switzerland

2.2. Designation and specification of the product

The scope of application EFSA-GMO-DE-2011-95 is for import, processing[4] and food and feed uses of maize 5307 and does not include cultivation in the EU. Thus, maize 5307 will be imported into the EU for food or feed uses in the same way as any commercial maize variety. Possible food and feed products include starch, syrup, ethanol, maize oil, flakes, coarse and regular grits, coarse and dusted meal, flour, maize germ meal, maize gluten and maize gluten meal.

Maize 5307 expresses a chimeric Cry protein, designated eCry3.1Ab, which is based on a modified Cry3A protein (mCry3A) derived from B. *thuringiensis* subsp. *tenebrionis* and the Cry1Ab from *B. thuringiensis* subsp. *kurstaki* strain HD-1. The protein confers resistance to certain coleopteran pests. The expression of the phosphomannose isomerase (PMI) protein is used as a marker for the selection of transformants.

The genetic modification in maize 5307 is intended to improve agronomic performance only and is not intended to influence the nutritional properties, the processing characteristics, or the overall use of maize as a crop.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel carried out the scientific assessment of the genetically modified maize 5307 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 16 April 2015. In delivering its Scientific Opinion, the EFSA GMO Panel considered application EFSA-GMO-DE-2011-95, additional information submitted by the applicant on request of the Panel, the scientific comments submitted by Member States and relevant scientific publications. In conclusion, the EFSA GMO Panel could not complete the food and feed safety assessment of maize 5307 due to the lack of an appropriate assessment of the eCry3.1Ab protein. However, the EFSA GMO Panel concludes that the maize event 5307 is unlikely to have any adverse effect on the environment in the context of the scope of application EFSA-GMO-DE-2011-95 (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 Joint Research Centre (JRC) as Community Reference Laboratory for the Genetically Modified Food and Feed has carried out a collaborative study to assess the performance of a quantitative

[4] This includes genetically modified maize 5307 for import and processing as designated under part C of Directive 2001/18/EC.

event-specific method to detect and quantify the maize 5307-transformation event in maize DNA. The reports were issued on 3 April 2007 and on 5 December 2014. The European Union Reference Laboratory 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 and D3).

7. Certified reference materials

The certified reference materials of maize 5307 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E).

8. Post-market environmental monitoring (PMEM)

The EFSA GMO Panel is of the opinion that the scope of the PMEM plan provided by the applicant, including the reporting intervals, is in line with the intended uses of maize 5307 as the ERA did not cover cultivation and identified no potential adverse environmental effects. No case-specific monitoring is necessary. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan (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).

10. 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 5307.

List of Annexes[5]

Annex A:	Scientific opinion of the EFSA GMO Panel (maize 5307)
Annex B:	Cartagena Protocol (maize 5307)
Annex C:	Labelling (maize 5307)
Annex D1:	Validation report (maize 5307)
Annex D2:	Validated method (maize 5307)
Annex D3:	Sampling and extraction (maize 5307)
Annex E:	Certified reference materials (maize 5307)
Annex F:	Post-market environmental monitoring (maize 5307)
Annex G:	Member States' comments (maize 5307)

[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-2015-00241