TECHNICAL REPORT

APPROVED: 29 July 2016 PUBLISHED: 26 August 2016

Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on an application by Syngenta (EFSA-GMO-DE-2011-99) for the placing on the market of maize Bt11 × 59122 × MIR604 × 1507 × GA21 and twenty subcombinations, which have not been authorised previously independently of their origin, for food and feed uses, import and processing under Regulation (EC) No 1829/2003

European Food Safety Authority

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically maize Bt11 × 59122 × MIR604 × 1507 × GA21 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of application EFSA-GMO-DE-2011-99 for the placing on the market of maize Bt11 × 59122 × MIR604 × 1507 × GA21 subcombinations that have not been authorised previously (Table 1), independently of their origin, for food and feed uses, import and processing.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified (GM) maize Bt11 × 59122 × MIR604 × 1507 × GA21 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 the data available on the five-event stack maize and the 20 subcombinations, the scientific comments submitted by the Member States and the relevant scientific publications. The EFSA GMO Panel has previously assessed the five single events that are combined to produce this five-event stack maize Bt11 × 59122 × MIR604 × 1507 × GA21 and did not identify safety concerns. No new data on the single events, leading to a modification of the original conclusions on their safety, were identified. The molecular, agronomic, phenotypic and compositional data on the five-event stack maize did not give rise to safety concerns and there is no reason to expect interactions between the single events impacting on the food and feed safety of the five-event stack maize. Considering the scope of the application (no cultivation), routes of exposure and limited exposure levels, the Panel concludes that this five-event stack maize would not raise safety concerns in the event of accidental release of viable grains into the environment. The EFSA GMO Panel concludes that the five-event stack maize is as safe and as nutritious as its conventional counterpart in the context of its scope. For the 20 subcombinations, the EFSA GMO Panel followed a weight-of-evidence approach, and concluded that they are expected to be as safe as the five-event stack maize. No specific data were submitted for the subcombinations included in the scope of this application that could be produced by conventional crossing through targeted breeding approaches. In order to reduce the consequent uncertainties and to confirm assumptions made for their assessment, the EFSA GMO Panel considers that the applicant should provide relevant information, if these subcombinations were to be created via targeted breeding approaches and imported into the EU in the future. In this case, this information should focus on expression levels of the newly expressed proteins.

A minority opinion expressed by an EFSA GMO Panel member is presented in Annex to the opinion.

The European Union Reference Laboratory for GM Food and Feed (EURL-GMFF) considers the method validated as fit for the purpose of regulatory compliance. Institute for Reference Materials and Measurements (IRMM[1]).

The EFSA GMO Panel was not requested to give an opinion on information required under Anne× 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 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 Bt11 × 59122 × MIR604 × 1507 × GA21 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements and at the American Oil Chemists' Society (AOCS).

The GMO Panel considers that the scope of the PMEM provided by the applicant is consistent with the scope of the three-event stack maize and the already assessed two-event stack maize Bt11 × 59122 × MIR604 × 1507 × GA21. The GMO Panel agrees with the reporting intervals proposed by the applicant in the PMEM plans.

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 Bt11 × 59122 × MIR604 × 1507 × GA21.

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Key words: GMO overall opinion, GMO, maize (*Zea mays*), Bt11, 59122, MIR604, 1507, GA21, insect resistant and herbicide tolerant, Regulation (EC) 1829/2003

Requestor: Competent Authority of Germany

Question number: EFSA-Q-2011-00894

Correspondence: GMO@efsa.europa.eu

[1] Due to the re-organisation of the Joint Research Centre (JRC), the Institute for Reference Materials and Measurements (IRMM) has become Directorate F - Health, Consumers and Reference Materials

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1. Introduction

1.1. Background as provided by the Competent Authority of Germany

On 7 July 2011, the European Food Safety Authority (EFSA) received from the Competent Authority of Germany an application (reference EFSA-GMO-DE-2011-99) for authorisation of herbicide tolerant and insect resistant genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21 (referred to hereafter as 'five-event stack maize') and 20 subcombinations[2] (referred to as 'subcombinations *independently of their origin'* in the Commission implementing regulation (EU) No 503/2013[3]). The Unique Identifiers of the twenty-one maize events covered by the scope of the application EFSA-GMO-DE-2011-99 are listed in the table below.

Table 1: Twenty-one maize events covered by the scope of the application EFSA-GMO-DE-2011-99.

Degree of Stacking	Events	Unique Identifiers
Five-event stack maize	Bt11 × 59122 × MIR604 × 1507 × GA21	SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9
Four-event stack maize	Bt11 × MIR604 × 1507 × GA21	SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9
	Bt11 × 59122 × 1507 × GA21	SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1 × MON-ØØØ21-9
	Bt11 × 59122 × MIR604 × GA21	SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4- × MON-ØØØ21-9
	Bt11 × 59122 × MIR604 × 1507	SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1
	59122 × MIR604 × 1507 × GA21	DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9
Three-event stack maize	Bt11 × 59122 × MIR604	SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5
	Bt11 × 59122 × 1507	SYN-BTØ11-1 × DAS-59122-7 × Ø15Ø7-1
	Bt11 × 59122 × GA21	SYN-BTØ11-1 × DAS-59122-7 × MON-ØØØ21-9
	Bt11 × MIR604 × 1507	SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1
	Bt11 × 1507 × GA21	SYN-BTØ11-1 × DAS-Ø15Ø7-1 × MON-ØØØ21-9
	59122 × MIR604 × 1507	DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1
	59122 × MIR604 × GA21	DAS-59122-7 × SYN-IR6Ø4-5 × MON-ØØØ21-9
	59122 × 1507 × GA21	DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØØ21-9
	MIR604 × 1507 × GA21	SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9
Two-event stack maize	Bt11 × 59122	SYN-BTØ11-1 × DAS-59122-7
	Bt11 × 1507	SYN-BTØ11-1 × DAS-Ø15Ø7-1
	59122 × MIR604	DAS-59122-7 × SYN-IR6Ø4-5

[2] The specific subcombinations are listed in Table 1.
[3] Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. OJ L 157, 8.6.2013, p. 1–48.

59122 × GA21	DAS-59122-7 × MON-ØØØ21-9
MIR604 × 1507	SYN-IR6Ø4-5 × DAS-Ø15Ø7-1
1507 × GA21	DAS-Ø15Ø7-1 × MON-ØØØ21-9

The application was 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-2011-99 for the placing on the market of maize Bt11 × 59122 × MIR604 × 1507 × GA21 subcombinations that have not been authorised previously (Table 1), independently of their origin, for food and feed uses, import and processing.

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 25 July 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 1 July 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 14 June 2012 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 18 September 2012) 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 22 June 2012 to 29 August 2012, from 7 December 2012 to 7 December 2015 and from 20 December 2015 to 4 April 2016[5].

The overall opinion on application EFSA-GMO-DE-2011-99 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://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00894

[5] Request for supplementary information from the EURL-GMFF: Requested (1) on 22/06/2012 – received on 26/07/2012 and clock re-started on 29/08/2012; requested(2) on 02/04/2013 – received on 18/12/2013 and clock re-started on 06/03/2014.

Request for supplementary information from the EFSA GMO Panel: Requested(1) on 07/12/2012 – received on 03/05/2013; requested(2) on 05/02/2013 – received on 03/05/2013; requested(3) on – 23/09/2013 received on 23/06/2014; requested(4) on 12/03/2014 – received on 23/06/2014; requested(5) on 27/10/2014 – received on 21/11/2014 and on 27/07/2015; requested(6) on 18/09/2015 – received on 24/09/2015 and clock re-started on 07/12/2015. Requested(7) on 23/12/2015 – received on 04/03/2016 and clock re-started on 04/04/2016.

EFSA received spontaneous additional information from the applicant on 28/07/2014, 30/09/2014, 21/07/2015 and on 17/12/2015.

The applicant requested clarifications to EFSA on 26/05/2015 (letter received on 27/05/2015) – EFSA provided clarifications to the applicant on 18/06/2015.

The applicant requested EC to modify the scope of the application on 21/02/2014 and on 17/05/2016.

1.2. Terms of Reference

The European Food Safety Authority (EFSA) received from the Competent Authority of Germany an application for authorisation of genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21. The Unique Identifiers of the twenty-one maize events covered by the scope of the application EFSA-GMO-DE-2011-99 are listed in Table 1. The application was 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-2011-99). 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-2011-99 for the placing on the market of maize Bt11 × 59122 × MIR604 × 1507 × GA21 subcombinations that have not been authorised previously (Table 1), independently of their origin, for food and feed uses, import and processing.

The five-event stack maize was developed to achieve insect resistance and herbicide tolerance to glyphosate- and glufosinate ammonium-based herbicides. The insect resistance confers protection against specific lepidopteran [e.g. *Ostrinia nubilalis* (European corn borer) and *Sesamia nonagrioides* (Mediterranean corn borer)] and coleopteran pests [*Diabrotica* spp. (corn rootworm larvae)].

3. Scientific opinion of the EFSA GMO Panel

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified (GM) maize Bt11 × 59122 × MIR604 × 1507 × GA21 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 the data available on the five-event stack maize and the 20 subcombinations, the scientific comments submitted by the Member States and the relevant scientific publications. The EFSA GMO Panel has previously assessed the five single events that are combined to produce this five-event stack maize Bt11 × 59122 × MIR604 × 1507 × GA21 and did not identify safety concerns. No new data on the single events, leading to a modification of the original conclusions on their safety, were identified. The molecular, agronomic, phenotypic and compositional data on the five-event stack maize did not give rise to safety concerns and there is no reason to expect interactions between the single events impacting on the food and feed safety of the five-event stack maize. Considering the scope of the application (no cultivation), routes of exposure and limited exposure levels, the Panel concludes that this five-event stack maize would not raise safety concerns in the event of accidental release of viable grains into the environment. The EFSA GMO Panel concludes that the five-event stack maize is as safe and as nutritious as its conventional counterpart in the context of its scope. For the 20 subcombinations, the EFSA GMO Panel followed a weight-of-evidence approach, and concluded that they are expected to be as safe as the five-event stack maize. No specific data were submitted for the subcombinations included in the scope of this application that could be produced by conventional crossing through targeted breeding approaches. In order to reduce the consequent uncertainties and to confirm assumptions made for their assessment, the EFSA GMO Panel considers that the applicant should provide relevant information, if these subcombinations were to be created via targeted breeding approaches and imported into the EU in the future. In this case, this information should focus on expression levels of the newly expressed proteins (Annex A).

4. Cartagena Protocol

The EFSA GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol (Annex B).

5. Labelling

The 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 (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 event-specific method to detect and quantify the maize Bt11 × 59122 × MIR604 × 1507 × GA21-transformation event in maize DNA. The reports were approved on 17 January 2005 (corrected version approved on 30 March 2010), 21 February 2005, 3 April 2007 (corrected version approved on 30 March 2010), 8 June 2007 and on 20 June 2008. 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, D2a, D2b, D2c, D2d, D2e).

7. Certified reference materials

The certified reference materials of maize Bt11 × 59122 × MIR604 × 1507 × GA21 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (Annexes E1a, E1b, E1d) and at the American Oil Chemists' Society (AOCS) (Annexes E1c and E1e).

8. Post-market monitoring

The EFSA GMO Panel is of the opinion that the PMEM plan proposed by the applicant is in line with the scope of the five-event stack maize. As no potential adverse environmental effects were identified, case-specific monitoring was not considered necessary. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plans (Annex G).

9. Member States' Comments

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

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 Bt11 × 59122 × MIR604 × 1507 × GA21.

A minority opinion expressed by an EFSA GMO Panel member is presented in Annex to the opinion.

List of Annexes[6]

Annex A:	Scientific opinion of the EFSA GMO Panel (maize Bt11 × 59122 × MIR604 × 1507 × GA21)
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Annex H:	Member States' comments (maize Bt11 × 59122 × MIR604 × 1507 × GA21)

[6]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-2016-00460