TECHNICAL REPORT

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Overall opinion on genetically modified maize Bt11 × MIR162 × 1507 × GA21 and three subcombinations independently of their origin, for food and feed uses under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2010-86)

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-DE-2010-86 submitted by Syngenta Crop Protection AG according to Articles 6 and 18 of Regulation (EC) No 1829/2003[1]. The scope of application EFSA-GMO-DE-2010-86 was limited to maize Bt11 × MIR162 × 1507 × GA21 and three of its subcombinations, independently of their origin, for food and feed uses, import and processing in the European Union.

Alongside with the related scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel), EFSA reports on the particulars as laid down in Articles 6 and 18 of Regulation (EC) No 1829/2003. A minority opinion expressed by a GMO Panel member is presented in the Annex to the scientific opinion.

Overall, the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF) validates, and declares fit for purpose, the detection methods for each single event applied for the detection and quantification of the respective events in maize Bt11 × MIR162 × 1507 × GA21.

The certified reference materials of maize Bt11 × MIR162 × 1507 × GA21 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) and at the American Oil Chemists' Society (AOCS-USA). The GMO Panel considers that the scope of the PMEM plan provided by the applicant is consistent with the intended uses of maize Bt11 × MIR162 × 1507 × GA21. 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 fall outside the remit of EFSA.

Key words: maize, Bt11, MIR162, 1507, GA21, EFSA-GMO-DE-2010-86, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: Competent Authority of Germany

Question number: EFSA-Q-2018-00467

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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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Table of contents

1. Introduction

On 10 August 2010, EFSA received from the Competent Authority of Germany application EFSA-GMO-DE-2010-86 submitted by Syngenta under Articles 5 and 17 of Regulation (EC) No 1829/2003[2]. The scope of application EFSA-GMO-DE-2010-86 as assessed in this Scientific Opinion is for the placing on the market of maize Bt11 × MIR162 × 1507 × GA21 and three subcombinations (Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507), independently of their origin, for food and feed uses, import and processing.

The unique identifiers are SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9, SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1, SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9, SYN-IR162-4 x DAS-Ø15Ø7-1 respectively.

EFSA first checked the completeness of the application in accordance with the requirements laid down in Articles 5(3) and 17(3) of the above mentioned Regulation. On 5 November 2010, 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[3].

At the end of a thorough completeness check, EFSA declared application EFSA-GMO-DE-2010-86 valid on 14 June 2012. From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-DE-2010-86. 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[4], 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-DE-2010-86 from 14 June 2012 until 18 September 2012.

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-DE-2010-86 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] 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.
[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2010-01087
[4] 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-DE-2010-86 was submitted by:

Syngenta Crop Protection AG
Schwarzwaldallee 215
CH 4058 Basel
Switzerland

2.2. Designation and specification of the product

Maize Bt11 × MIR162 × 1507 × GA21 was developed to be herbicide-tolerant and insect-resistant. The scope of application EFSA-GMO-DE-2010-86 was subsequently limited to the placing on the EU market of maize Bt11 × MIR162 × 1507 × GA21 and three of its subcombinations, independently of their origin, for food and feed uses, import and processing. The unique identifiers are SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9, SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1, SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9, SYN-IR162-4 x DAS-Ø15Ø7-1 respectively.

2.3. Scientific opinion of the GMO Panel

On 31 May 2018, the GMO Panel adopted a scientific opinion on application EFSA-GMO-DE-2010-86 (Annex A). 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.

In this opinion, the GMO Panel assessed the four-event stack maize Bt11 × MIR162 × 1507 × GA21 and three of its subcombinations, independently of their origin. The GMO Panel previously assessed the four single events and seven of their combinations and did not identify safety concerns. No new data on the single events or the seven subcombinations leading to modification of the original conclusions were identified. Based on the molecular, agronomic, phenotypic and compositional characteristics, the combination of the single events in the four-event stack maize did not give rise to food/feed safety issues. Based on the nutritional assessment of the compositional characteristics of maize Bt11 × MIR162 × 1507 × GA21, foods and feeds derived from the GM maize are expected to have the same nutritional impact as those derived from non-GM maize varieties. In the case of accidental release of viable grains of maize Bt11 × MIR162 × 1507 × GA21 into the environment, this would not raise environmental safety concerns. The GMO Panel concludes that maize Bt11 × MIR162 × 1507 × GA21 is nutritionally equivalent to and as safe as its non-GM comparator in the context of the scope of this application. For the three subcombinations included in the scope, for which no experimental data were provided, the GMO Panel assessed the likelihood of interactions among the single events, and concluded that their combinations would not raise safety concerns. These maize subcombinations are therefore expected to be as safe as the single events, the previously assessed subcombinations and the four-event stack maize. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of maize Bt11 × MIR162 × 1507 × GA21 and its subcombinations.

A minority opinion expressed by a GMO Panel member is presented in the Annex to the scientific opinion.

2.4. Cartagena Protocol

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

2.5. Labelling

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

2.6. Methods for detection

The EURL-GMFF has previously validated individually, and declared fit for purpose, the detection methods for the single events Bt11, MIR162, 1507 and GA21 (Annexes D2a-d).

In the context of application EFSA-GMO-DE-2010-86 on maize Bt11 × MIR162 × 1507 × GA21, the EURL-GMFF has checked in-house the performance of each validated detection method when applied to genomic DNA extracted from maize Bt11 × MIR162 × 1507 × GA21. The final validation report by the EURL-GMFF of the individual detection methods applied to DNA extracted from maize Bt11 × MIR162 × 1507 × GA21 is provided in Annexes D1 and D3.

2.7. Certified reference materials

The certified reference materials of single maize events Bt11 and 1507 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM, Annexes E1 and E3) and the certified reference materials of single maize events MIR162 and GA21 can be accessed at the American Oil Chemists' Society (AOCS-USA, Annexes E2 and E4).

2.8. Post-market environmental monitoring (PMEM)

The GMO Panel considers that the scope of the PMEM plan provided by the applicant is consistent with the intended uses of maize Bt11 × MIR162 × 1507 × GA21. (Annex F).

2.9. Member States Comments

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

3. Conclusions

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA issues an overall opinion on application EFSA-GMO-DE-2010-86 for food and feed uses, import and processing of maize Bt11 × MIR162 × 1507 × GA21 and three of its subcombinations in the EU.

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

List of Annexes[5]

Annex A:	Scientific opinion of the GMO Panel
Annex B:	Cartagena Protocol
Annex C:	Labelling proposal
Annex D1:	Validation report by EURL-GMFF of the event-specific method for the quantification of maize Bt11 x MIR162 x 1507 x GA21
Annex D2a:	Validated detection method for maize Bt11
Annex D2b:	Validated detection method for maize MIR162
Annex D2c:	Validated detection method for maize 1507
Annex D2d:	Validated detection method for maize GA21
Annex D3:	Sampling / DNA extraction
Annex E1:	Certified reference materials (Bt11)
Annex E2:	Certified reference materials (MIR162)
Annex E3:	Certified reference materials (1507)
Annex E4:	Certified reference materials (GA21)
Annex F:	Post-market environmental monitoring plan
Annex G:	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/questionDocumentsLoader?question=EFSA-Q-2018-00467