TECHNICAL REPORT

APPROVED: 10 July 2015 PUBLISHED:16 July 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-BE-2011-98) for the placing on the market of herbicide-tolerant genetically modified soybean FG72 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience

European Food Safety Authority

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified soybean FG72 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of application EFSA-GMO-BE-2011-98 is for import, processing, and food and feed uses of soybean FG72 within the European Union (EU) in the same way as any non-GM soybean, but excludes cultivation in the EU.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified (GM) soybean FG72 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-BE-2011-98, 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 considers that the soybean FG72, as described in this application, is as safe as its conventional counterpart and non-GM soybean commercial varieties, and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of this application. 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 soybean FG72 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-BE-2011-98 and the guidance document of the EFSA GMO Panel on PMEM of GM plants (EFSA 2011). The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan

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 soybean FG72.

Key words: GMO, overall opinion, soybean, (Glycine max L.), FG72, herbicide tolerance, HPPD W336, 2mEPSPS, Regulation (EC) No 1829/2003

Requestor: On request from the Competent Authority of Belgium for an application (EFSA-GMO-BE-2011-98) submitted by Bayer CropScience

Question number: EFSA-Q-2011-00848

Correspondence: gmo@efsa.europa.eu

Acknowledgements: EFSA wishes to thank the members of the Working Group on Molecular Characterisation: Fabien Nogue and Sirpa Kärenlampi; the member of the Working Group on Food and Feed Risk Assessment: Martinus Løvik; the members of the Working Group on Environmental Risk Assessment: Paolo Barberi and Joe Perry and EFSA staff members: Antonio Fernández-Dumont, Andrea Gennaro and Irina Olaru 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-BE-2011-98) for the placing on the market of herbicide-tolerant genetically modified soybean FG72 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. EFSA supporting publication 2015:EN-848. 10 pp.

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1. Introduction

1.1. Background as provided by the Competent Authority of Belgium

On 24 June 2011, the European Food Safety Authority (EFSA) received from the Competent Authority of Belgium an application (reference EFSA-GMO-BE-2011-98) for authorisation of genetically modified soybean FG72 (Unique Identifier MST-FGØ72-2) submitted by Bayer CropScience within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed.

The scope of application EFSA-GMO-BE-2011-98 is for import, processing, and food and feed uses of soybean FG72 within the European Union (EU) in the same way as any non-GM soybean, but excludes cultivation in the EU.

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[1] on 22 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 7 June 2010 and on 17 June 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 24 October 2010 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 24/01/2012) 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 8 February 2012 to 22 January 2015 and from 12 February 2015 to 23 June 2015[2].

The overall opinion on application EFSA-GMO-BE-2011-98 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.

1.2. Terms of Reference as provided by the Applicant

The European Food Safety Authority (EFSA) received from the Competent Authority of Belgium an application for authorisation of genetically modified soybean FG72 (Unique Identifier MST-FGØ72-2) submitted by Bayer CropScience within the framework of Regulation (EC) No 1829/2003 on genetically

[1]http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00848

[2]Request for supplementary information from the EFSA GMO Panel: Requested(1)on 08/02/2012 – info received on 13/06/2012; requested(2) on 04/04/2012 – info received on 08/05/2012; requested(3) on 06/12/2012 – received on 02/04/2013; requested(4) on 29/08/2013 – info received on 29/04/2014; requested(5) on 27/05/2014 – info received on 17/07/2014; requested(6) on 04/09/2014 – info received on 27/10/2014 and clock re-started on 22/01/2015. Requested(7) on 19/02/2015 – info received on 01/04/2015; requested(8) on 03/03/2015 – info received on 23/03/2015; requested(9) on 22/05/2015 – info received on 03/06/2015 and clock re-started on 23/06/2015.

The applicant provided supplementary information spontaneously on 29/04/2014.

The applicant requested clarifications on: (1) 28/08/2013; EFSA replied on 02/09/2013 – (2) 23/09/2013; EFSA replied on 25/10/2013 – (3) 09/01/2015; EFSA replied on 10/02/2015.

modified food and feed (reference EFSA-GMO-BE-2011-98). 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

Bayer CropScience AG
Alfred Nobelstrasse 50
D-40789 Monheim
Germany

Bayer BioScience N.V.
Technologiepark 38
B-9052 Gent
Belgium

2.2. Designation and specification of the product

The scope of application EFSA-GMO-BE-2011-98 is for import, processing, and food and feed uses of soybean FG72 within the European Union (EU) in the same way as any non-GM soybean, but excludes cultivation in the EU.

Soybean FG72 was developed by biolistic transformation of callus cells. It expresses HPPD W336, a modified version of the HPPD protein (4-hydroxyphenylpyruvate dioxygenase) and 2mEPSPS, a mutated version of soybean EPSPS (5-enolpyruvyl-shikimate-3-phosphate synthase) with an additional methionine in the N-terminus. These proteins confer tolerance to isoxaflutole- and glyphosate-based herbicides.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel carried out the scientific assessment of the genetically modified soybean FG72 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 25 June 2015. In delivering its Scientific Opinion, the EFSA GMO Panel considered application EFSA-GMO-BE-2011-98, 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 considers that the soybean FG72, as described in this application, is as safe as its conventional counterpart and non-GM soybean commercial varieties, and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of this application (Annex A).

4. Cartagena Protocol

The EFSA GMO Panel was not requested to give an opinion on information required under Annex II of the Cartagena Protocol. The information presented in the application EFSA-GMO-BE-2011-98 as required under Annex II of the Cartagena Protocol is in line with the scientific opinion of the EFSA GMO Panel on application EFSA-GMO-BE-2011-98 (Annex B).

5. Labelling

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 labelling proposal provided in the application is in line with the requirements of 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 event-specific method to detect and quantify the soybean FG72-transformation event in soybean DNA. The reports were issued on 14 May 2007 and on 16 July 2012. 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 soybean FG72 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 proposed by the applicant is in line with the scope of application EFSA-GMO-BE-2011-98 as the environmental risk assessment did not cover cultivation. The EFSA GMO Panel has not identified 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 soybean FG72.

List of Annexes[3]

Annex A:	Scientific opinion of the EFSA GMO Panel (soybean FG72)
Annex B:	Cartagena Protocol (soybean FG72)
Annex C:	Labelling (soybean FG72)
Annex D1:	Validation report (soybean FG72)
Annex D2:	Validated method (soybean FG72)
Annex D3:	DNA extraction (soybean FG72)
Annex E:	Certified reference materials (soybean FG72)
Annex F:	Post-Market Environmental Monitoring (soybean FG72)
Annex G:	Member States' comments (soybean FG72)

[3]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-2015-00392