TECHNICAL REPORT

APPROVED: 16 June 2015 PUBLISHED: 18 June 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-NL-2012-108) for the placing of the herbicide-tolerant genetically modified soybean MON 87708 x MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto

European Food Safety Authority

Summary

This document provides an overall opinion of the European Food Safety Authority on herbicide-tolerant genetically modified soybean MON 87708 x MON 89788 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of application EFSA-GMO-NL-2012-108 is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified (GM) soybean MON 87708 x MON 89788 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-NL-2012-108, 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 is of the opinion that the two-event stack soybean MON 87708 x MON 89788, as described in this application, is as safe as its non-GM comparator and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of its scope. It should be noted that the assessment of potential consumer health risks resulting from dicamba residues and its metabolites in soybean MON 87708 x MON 89788 is under the remit of the EFSA Pesticides Unit. 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 MON 87708 x MON 89788 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-NL-2012-108.

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 MON 87708 x MON 89788.

Key words: GMO overall opinion, soybean MON 87708 x MON 89788, food and feed safety, import and processing, herbicide tolerant soybean (*Glycine max* (L.) Merr), DMO and CP4 EPSPS, stack, Regulation (EC) No 1829/2003

Requestor: On request from the Competent Authority of The Netherlands for an application (EFSA-GMO-NL-2012-108) submitted by Monsanto S.A./N.V

Question number: EFSA-Q-2012-00442

Correspondence: gmo@efsa.europa.eu

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, Zoltán Divéki 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-NL-2012-108) for the placing on the market of the herbicide-tolerant genetically modified soybean MON 87708 x MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA supporting publication 2015:EN-826. 10 pp.

Table of contents

1. Introduction

1.1. Background as provided by the Competent Authority of The Netherlands

On 29 March 2012, the European Food Safety Authority (EFSA) received from the Competent Authority of The Netherlands an application (reference EFSA-GMO-NL-2012-108) for authorisation of genetically modified soybean MON 87708 x MON 89788 (Unique Identifier MON-877Ø8-9 x MON-89788-1) submitted by Monsanto S.A./N.V within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed.

The scope of application EFSA-GMO-NL-2012-108 is for food and feed uses, import and processing, but excludes cultivation within the European Union (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 16 April 2012. 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 9 December 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 20 July 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 20 October 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 24 July 2012 to 15 October 2014, from 13 April 2015 to 25 March 2015[2].

The overall opinion on application EFSA-GMO-NL-2012-108 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 the Netherlands an application for authorisation of genetically modified soybean MON 87708 x MON 89788 (Unique Identifier MON-877Ø8-9 x MON-89788-1) submitted by Monsanto S.A./N.V.] within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-

[1] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00442

[2] Request for supplementary information from the EFSA GMO Panel: Requested (1) on 24/07/2015 (Single event) – Requested (2) on 13/08/2013 – received on 02/09/2013; requested (3) on 06/12/2013 – received on 20/12/2013; requested (4) on 10/02/2014 – received on 19/02/2014; requested (5) on 05/06/2014 received on 20/06/2014 and clock re-started on 15/10/2014. Requested (6) on 09/01/2015 – received on 27/01/2015 and clock re-started on 25/03/2015

The applicant provided additional information spontaneously on 28/03/2014, 12/12/2014 and on 03/03/2015.

The applicant requested clarifications on 13/10/2014 – EFSA provided clarifications to the applicant on 07/11/2014. The applicant requested clarifications on 26/01/2015 – EFSA provided clarifications to the applicant on 16/04/2015.

GMO-NL-2012-108). 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

Monsanto Europe S.A.
Avenue de Tervuren 270-272
B-1150 Brussels
Belgium

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
USA

2.2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2012-108 is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

Soybean MON 87708 x MON 89788 was developed to confer tolerance to dicamba (3,6-dichloro-2-methoxybenzoic acid) and glyphosate (N-(phosphonomethyl)glycine)-based herbicides. Dicamba tolerance is achieved by the expression of dicamba mono-oxygenase (DMO) protein, which demethylate dicamba, producing 3,6-dichlorosalicylic acid and formaldehyde. For the same reasons as previously described in the EFSA scientific opinion on application EFSA-GMO-NL-2011-93 covering soybean MON 87708 (EFSA, 2013a), the assessment of potential consumer health risks resulting from dicamba residues and its metabolites in soybean MON 87708 x MON 89788 is under the remit of the EFSA Pesticides Unit. Tolerance to glyphosate is achieved by expression of the CP4 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS).

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel carried out the scientific assessment of the genetically modified soybean MON 87708 x MON 89788 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 27 May 2015. In delivering its Scientific Opinion, the EFSA GMO Panel considered application EFSA-GMO-NL-2012-108, 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 is of the opinion that the two-event stack soybean MON 87708 x MON 89788, as described in this application, is as safe as its non-GM comparator and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of its scope. It should be noted that the assessment of potential consumer health risks resulting from dicamba residues and its metabolites in soybean MON 87708 x MON 89788 is under the remit of the EFSA Pesticides Unit (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 event-specific method to detect and quantify the soybean MON 87708 x MON 89788-transformation event in maize DNA. The reports were issued on 18 February 2008, 6 May 2013 and on 14 March 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, D2a, D2b and D3).

7. Certified reference materials

The certified reference materials of soybean MON 87708 x MON 89788 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annexes E1 and E2).

8. Post-market environmental monitoring (PMEM)

The EFSA GMO Panel is of the opinion that the PMEM plan proposed by the applicant is in line with the scope of application EFSA-GMO-NL-2012-108 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 soybean MON 87708 x MON 89788.

List of Annexes[3]

Annex A:	Scientific Opinion of the EFSA GMO Panel (soybean MON 87708 x MON 89788)
Annex B:	Cartagena Protocol (soybean MON 87708 x MON 89788)
Annex C:	Labelling (soybean MON 87708 x MON 89788)
Annex D1:	Validation report (soybean MON 87708 x MON 89788)
Annex D2a:	Validated method (soybean MON 87708)
Annex D2b:	Validated method (soybean MON 89788)
Annex D3:	Sampling and extraction (soybean MON 87708 x MON 89788)
Annex E1:	Certified reference materials (soybean MON 87708)
Annex E2:	Certified reference materials (soybean MON 89788)
Annex F:	Post-market environmental monitoring (soybean MON 87708 x MON 89788)
Annex G:	Member States' comments (soybean MON 87708 x MON 89788)

[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-2015-00353