TECHNICAL REPORT

APPROVED: 6 October 2015 PUBLISHED: 8 October 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-2010-85) of soybean MON 87769 x MON 89788, genetically modified to contain stearidonic acid and be tolerant to glyphosate 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 genetically modified (GM) soybean MON 87769 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-2010-85 is for import, processing, and food and feed uses of soybean MON 87769 x MON 89788 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 GM soybean MON 87769 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-2010-85, 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 soybean MON 87769 x MON 89788 because of the lack of an appropriate nutritional assessment. The EFSA GMO Panel concludes that soybean MON 87769 x MON 89788 is unlikely to have any adverse effects on the environment, considering the scope of application EFSA-GMO-NL-2010-85. 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 87769 x MON 89788 can be accessed at the American Oil Chemists' Society (AOCS).

The EFSA GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol; the post-market environmental monitoring plan and reporting intervals are in line with the scope of this application.

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 87769 x MON 89788.

Key words: GMO overall opinion, soybean (*Glycine max* (L.) Merr.), CP4 EPSPS, herbicide tolerant, production of stearidonic acid, stack, Regulation (EC) No 1829/2003

Requestor: On request from the Competent Authority of the Netherlands for an application (EFSA-GMO-NL-2010-85) submitted by Monsanto

Question number: EFSA-Q-2010-01086

Correspondence: gmo@efsa.europa.eu

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1. Introduction

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

On 30 July 2010, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application (reference EFSA-GMO-NL-2010-85) for authorisation of genetically modified soybean MON 87769 x MON 89788 (Unique Identifier MON-87769-7 x MON-89788-1) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed.

The scope of application EFSA-GMO-NL-2010-85 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 14 September 2010. 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 23 July and on 3 September 2010, 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 26 November 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 21 August 2014[2]) 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 26 November 2010 to 10 April 2014, from 14 July 2014 to 2 March 2015 and from 30 March 2015 to 14 September 2015[3].

The overall opinion on application EFSA-GMO-NL-2010-85 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 87769 x MON 89788 (Unique Identifier MON-87769-7 x MON-89788-1) submitted by Monsanto within the framework of

[1] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question= EFSA-Q-2010-01086

[2] The Member States commenting period of application EFSA-GMO-NL-2010-85 was opened after its clock was re-started following the adoption of the Scientific Opinion of application EFSA-GMO-UK-2009-76 (authorisation of GM soybean MON 87769).

[3] Requests for supplementary information from the EFSA GMO Panel: Requested (1) on 25/07/2014 – received on 12/09/2014: requested (2) on 10/11/2014 – received on 28/01/2015 and clock re-started on 02/03/2015. Requested (3) on 30/03/2015 – received on 01/06/2015 and on 10/07/2015 and clock re-started on 14/09/2015.

Request for supplementary information from EFSA: Requested (1) on 14/07/2014 – received on 15/09/2014.

Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2010-85). 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

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B-1150 Brussels
Belgium

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
U.S.A.

2.2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2010-85 is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

Soybean MON 87769 x MON 89788 was developed to produce stearidonic acid (SDA) and to confer tolerance to glyphosate (*N*-(phosphonomethyl)glycine)-based herbicides. The production of stearidonic acid is achieved by the expression of a Δ6 desaturase protein from *Primula juliae* (PjΔ6D) and the Δ15 desaturase protein from *Neurospora crassa* (NcΔ15D). 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 87769 x MON 89788 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 17 September 2015. In delivering its Scientific Opinion, the EFSA GMO Panel considered application EFSA-GMO-NL-2010-85, 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 soybean MON 87769 x MON 89788 because of the lack of an appropriate nutritional assessment. The EFSA GMO Panel concludes that soybean MON 87769 x MON 89788 is unlikely to have any adverse effects on the environment, considering the scope of application EFSA-GMO-NL-2010-85 (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. 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

As a full assessment on possible health and nutritional impact of the MON 87769 x MON 89788 soybean oil was not made, the EFSA GMO Panel is not in the position to comment on the labelling (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 87769 x MON 89788-transformation event in soybean DNA. The reports were issued on 18 February 2008, 17 January 2012 and on 27 April 2015. 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 and D2b).

7. Certified reference materials

The certified reference materials of soybean MON 87769 x MON 89788 can be accessed at the American Oil Chemists' Society (AOCS) (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 scope of application EFSA-GMO-NL-2010-85. 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 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 87769 x MON 89788.

List of Annexes[4]

Annex A:	Scientific opinion of the EFSA GMO Panel (soybean MON 87769 x MON 89788)
Annex B:	Cartagena Protocol (soybean MON 87769 x MON 89788)
Annex C:	Labelling (soybean MON 87769 x MON 89788)
Annex D1:	Validation report (soybean MON 87769 x MON 89788)
Annex D2a:	Validated method (soybean MON 87769)
Annex D2b:	Validated method (soybean MON 89788)
Annex E1:	Certified reference materials (soybean MON 87769)
Annex E2:	Certified reference materials (soybean MON 89788)
Annex F:	Post-market environmental monitoring (soybean MON 87769 x MON 89788)
Annex G:	Member States' comments (soybean MON 87769 x MON 89788)

[4] 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-2015-00551