TECHNICAL REPORT

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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 Dow AgroSciences (EFSA-GMO-NL-2013-116) for the placing on the market of genetically modified insect-resistant soybean DAS-81419-2 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 modified soybean (GM) DAS-81419-2 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003[1].

The scope of application EFSA-GMO-NL-2013-116 is for import, processing, and food and feed uses of soybean DAS-81419-2 derived from grain and forage and does not include cultivation in the European Union (EU).

The Scientific Panel on Genetically Modified Organisms (GMO Panel) has carried out the scientific assessment of GM soybean DAS-81419-2 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-NL-2013-116, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. In conclusion, the GMO Panel considers that the information available for soybean DAS-81419-2 addresses the scientific comments raised by the Member States and that the soybean DAS-81419-2, as described in this application, is as safe and nutritious as its conventional counterpart and non-GM reference varieties tested with respect to potential effects on human and animal health and the environment in the context of the scope of the application.

The European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of soybean DAS-81419-2 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (JRC-IRMM).

The GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, 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. Post-market environmental monitoring (PMEM) is related to risk management, and thus a final adoption of the PMEM plan falls outside the mandate of EFSA. However, the GMO Panel gives its opinion on the scientific content of the PMEM plan provided by the applicant The GMO Panel considers that the scope of the PMEM plan provided by the applicant is consistent with the scope of soybean DAS-81419-2. As the ERA does not cover cultivation and did not identify potential adverse environmental effects from soybean DAS-81419-2, no case-specific monitoring is necessary. The GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan.

[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.

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 DAS-81419-2.

Key words: GMO, overall opinion, soybean (*Glycine max*), DAS-81419-2, Cry1F, Cry1Ac, PAT, Regulation (EC) No 1829/2003, import and processing

Requestor: Competent Authority of the Netherlands

Question number: EFSA-Q-2013-00527

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Panel members: Andrew Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Mikołaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Hanspeter Naegeli, Elsa Ebbesen Nielsen, Fabien Nogué Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli and Jean-Michel Wal.

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1. Introduction

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

On 13 May 2013, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application (reference EFSA-GMO-NL-2013-116) for authorisation of genetically modified insect-resistant soybean DAS-81419-2, submitted by Dow AgroSciences LLC within the framework of Regulation (EC) No 1829/2003, for food and feed uses, import and processing the European Union (EU). The Unique identifier of this event is DAS-81419-2.

The scope of application EFSA-GMO-NL-2013-116 is for import, processing, and food and feed uses of soybean DAS-81419-2 derived from grain and forage and does not include cultivation in the European Union (EU).

In accordance with Articles 5(2)(b) and 17(2)(b) 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[2]. EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Articles 5(3) and 17(3) of Regulation (EC) No 1829/2003. On 13 and 23 May 2013, 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 7 February 2014 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[3], were given three months after the date of receipt of the valid application (i.e., 27 May 2014) 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 12 February 2014 to 21 March 2014, from 8 April 2014 to 11 February 2016, from 17 February 2016 to 7 March 2016, from 15 March 2016 to 29 March 2016 and from 25 April 2016 to 08 September 2016.[4]

The overall opinion on application EFSA-GMO-NL-2013-116 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms together with the particulars required under Articles 6 and 18 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-

2http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00527

[3]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.

[4]Request for supplementary information from the GMO Panel: Requested(1) on 08/04/2014 – received on 18/06/2014; requested(2) on 28/05/2014 – received on 25/11/2014; requested(3) on 23/06/2014 - received on 27/08/2014; requested(4) on 09/09/2014 – received on 12/11/2014; requested(5) 01/10/2015 – received on 24/11/2015; requested(6) on 23/11/2015 – received on 18/01/2016 on and clock re-started on 11/02/2016. Requested(7) on 17/02/2016 – received on 07/03/2016 and clock re-started on 07/03/2016. Requested(8) on 15/03/2016 – received on 29/03/2016; requested(9) on 26/05/2016 – received on 13/06/2016; requested(10) on 10/06/2016 – received on 17/06/2016; requested (11) on 10/08/2016 – received on 01/09/2016. The last clock for this application re-started on 08/09/2016 (EURL re-start the clock letter sent by EFSA on 08/09/2016.

[4]Request for supplementary information from the EURL-GMFF: Requested(1) on 12/02/2014 – received on 14/02/2014 and clock re-started on 21/03/2014. Requested(2) on 25/04/2016 – received on 16/08/2016 and clock re-started on 08/09/2016.

The applicant provided additional information spontaneously on 16/12/2014.

The applicant provided clarifications on the scope of the application on 22/01/2016.

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

The European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified soybean DAS-81419-2. The Unique identifier of this event is DAS-81419-2. The application was submitted by Dow AgroSciences LLC within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2013-116). 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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European Development Centre
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Milton Park, Abingdon
Oxon OX14 4RN
United Kingdom

Dow AgroSciences LLC
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U.S.A.

2.2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2013-116 is for import, processing, and food and feed use of soybean DAS-81419-2 derived from grain and forage and does not include cultivation in the EU.

Soybean DAS-81419-2 was developed by *Agrobacterium tumefaciens* (also known as *Rhizobium radiobacter*)-mediated transformation of cotyledonary nodes derived from germinated soybean (*G. max*) cv. Maverick seeds. It expresses the Cry1F and Cry1Ac proteins which confer resistance to lepidopteran insect pests. Soybean DAS-81419-2 also produces the PAT protein which confers tolerance to glufosinate ammonium-based herbicides and was used as a selectable marker during product development.

3. Scientific opinion of the GMO Panel

The GMO Panel carried out the scientific assessment of the genetically modified soybean DAS-81419-2 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 26 October 2016. In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-NL-2013-116, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. In conclusion, the GMO Panel considers that the information available for soybean DAS-81419-2 addresses the scientific comments raised by the Member States and that the soybean DAS-81419-2, as described in this application, is as safe and nutritious as its conventional counterpart and non-GM reference varieties tested with respect to potential effects on human and animal health and the environment in the context of the scope of the application (Annex A).

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).

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 EURL-GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the DAS-81419-2 transformation event in crop DNA. The reports were issued on 13 May 2014 and on 13 March 2015. The EURL-GMFF considers that the method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2. to Commission Regulation (EC) No 641/2004[5] (Annexes D1, D2, D3).

[5]Regulation (EC) No 641/2004 of the Commission on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food

7. Certified reference materials

The certified reference materials of GM event DAS-81419-2 can be accessed at JRC-IRMM (Annex E).

8. Post-market environmental monitoring

The scope of the PMEM plan provided by the applicant and the reporting intervals are in line with the intended uses of soybean DAS-81419-2 and the GMO Panel guidelines on the PMEM of GM plants (EFSA GMO Panel, 2011b) (Annex F).

9. Member States Comments

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

and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. OJ L 102/14, 7.4.2004, p. 1–12.

10. Conclusions

Under the terms of Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Articles 6 and 18 for the placing on the market of soybean DAS-81419-2 for import, processing, and food and feed use of soybean within the EU excluding cultivation.

List of Annexes[6]

Annex A:	Scientific Opinion of the GMO Panel (soybean DAS-81419-2)
Annex B:	Cartagena protocol (soybean DAS-81419-2)
Annex C:	Labelling and Unique identifier (soybean DAS-81419-2)
Annex D1:	Validation report (soybean DAS-81419-2)
Annex D2:	Validated method (soybean DAS-81419-2)
Annex D3:	Sampling and DNA Extraction (soybean DAS-81419-2)
Annex E:	Post-market environmental monitoring (soybean DAS-81419-2)
Annex G:	Member States comments (soybean DAS-81419-2)

[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-2016-00701