TECHNICAL REPORT

APPROVED: 13 March 2017 PUBLISHED: dd March 2017

Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on application (EFSA-GMO-NL-2011-91) by Dow AgroSciences for the placing on the market of genetically modified herbicide-tolerant soybean DAS-68416-4 for food and feed uses, import and processing

European Food Safety Authority

Summary

This document provides an overall opinion of the European Food Safety Authority (EFSA) on genetically modified (GM) soybean DAS-68416-4 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.[1]

The scope of application EFSA-GMO-NL-2011-91 is for import, processing, and food and feed uses of soybean DAS-68416-4 within the European Union (EU), but excludes cultivation in the EU.

The Scientific Panel on Genetically Modified Organisms (GMO Panel) has carried out the scientific assessment of GM soybean DAS-68416-4 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-2011-91, 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-68416-4 addresses the scientific comments raised by the Member States and that soybean DAS-68416-4, as described in this application, is as safe as its conventional counterpart and the tested non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of this 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-68416-4 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements.

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.

The GMO Panel considers that the scope of the post-market environmental monitoring plan provided by the applicant is consistent with the scope of application EFSA-GMO-NL-2001-91.

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-68416-4.

[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.

Key words: GMO, overall opinion, soybean (*Glycine max*), DAS-68416-4, herbicide tolerance, AAD-12, PAT, Regulation (EC) No 1829/2003

Requestor: Competent Authority of the Netherlands

Question number: EFSA-Q-2011-00052

Correspondence: GMO@efsa.europa.eu

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Table of contents

1. Introduction

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

On 25 January 2011, EFSA received from the Competent Authority of the Netherlands an application (reference EFSA-GMO-NL-2011-91) for authorisation of herbicide-tolerant soybean DAS-68416-4 (unique identifier DAS-68416-4), submitted by Dow AgroSciences within the framework of Regulation (EC) No 1829/2003, for food and feed uses, import and processing.

The scope of application EFSA-GMO-NL-2011-91 is for import, processing, and food and feed uses of soybean DAS-68416-4 within the European Union (EU), but it excludes cultivation in the 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 December 2010, the EURL–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 8 September 2011 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., until 8 December 2011) 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 5 December 2011 to 9 July 2012, from 7 September 2012 to 7 September 2016 and from 29 September 2016 to 26 October 2016.[4]

The overall opinion on application EFSA-GMO-NL-2011-91 includes the scientific opinion of the GMO Panel 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-feed and/or foods-feeds produced from it, vi) an indication of where appropriate reference materials can be accessed, vii) the

[2] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00052

[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 05/12/2011 – 13/04/2012; requested(2) on 30/01/2012 – received on 13/04/2012; requested(3) 07/09/2012 – received on 18/10/2013; requested(4) on 01/07/2014 – received on 02/09/2014; requested(5) on 28/11/2014 – received on 16/12/2014; requested(6) on 16/02/2015 – received on 19/02/2015; requested(7) on 19/02/2015 – received on 12/03/2015; requested(8) on 06/03/2015 – received on 16/03/2015; requested(9) on 01/04/2015 – received on 11/06/2015; requested(10) on 24/06/2015 – received on 22/07/2015; requested(11) on 15/09/2015 – received on 25/09/2015; requested(12) on 02/10/2015 – received on 23/11/2015 and 13/05/2016; requested(13) on 23/03/2016 – received on 29/04/2016; requested(14) on 26/05/2016 – received on 13/06/2016; Requested(15) on 29/09/2016 – received on 26/10/2016 and clock re-started on 26/10/2016.

Request for supplementary information from the EURL- GMFF: Requested(1) on 18/04/2011 – received on 17/04/2012 and clock re-started on 09/07/2012; requested(2) on 26/04/2016 – received on 27/06/2016 and clock re-started 07/09/2016.

The applicant provided additional information spontaneously on: 07/08/2012, 27/08/2012, 04/11/2014, 22/12/2015, 31/03/2016 and on 13/05/2016.

Letter from applicant to EFSA received on 07/12/2015 providing clarifications on information provided on 23/11/2015.

monitoring plan and viii) the Member States' comments submitted during the three-month consultation period.

1.2. Terms of Reference

EFSA received from the Competent Authority of the Netherlands an application for authorisation of soybean DAS-68416-4 (unique identifier DAS-68416-4). The application (reference EFSA-GMO-NL-2011-91) was submitted by Dow AgroSciences within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed. EFSA was requested to issue an overall opinion in line with the requirements of Regulation (EC) No 1829/2003 (Articles 6 and 18).

2. Considerations

2.1. Applicant

The application was submitted by

Dow AgroSciences Europe
European Development Center
2nd Floor, 3 Milton Park, Abingdon
Oxon OX14 4RN
United Kingdom

Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, Indiana 46268-1054
U.S.A.

2.2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2011-91 is for import, processing, and food and feed uses of soybean DAS-68416-4 within the EU, but it excludes cultivation in the EU.

Soybean DAS-68416-4 was developed to confer tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and glufosinate ammonium-based herbicides. Tolerance to 2,4-D and other related phenoxy herbicides is provided by the expression of the aryloxyalkanoate dioxygenase-12 (AAD-12) protein from *Delftia acidovorans*. Tolerance to glufosinate ammonium-based herbicides is provided by the expression of the phosphinothricin acetyltransferase (PAT) protein from *Streptomyces viridochromogenes*.

3. Scientific opinion of the GMO Panel

The GMO Panel carried out the scientific assessment of the soybean DAS-68416-4 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 26 January 2017. In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-NL-2011-91, 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-68416-4 addresses the scientific comments raised by the Member States and that soybean DAS-68416-4, as described in this application, is as safe as its conventional counterpart and the tested non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of this 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-68416-4 transformation event in crop DNA. The reports were published on 13 May 2014. 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 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.

7. Certified reference materials

The certified reference materials of soybean DAS-68416-4 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements. (Annex E)

8. Post-market environmental monitoring

The GMO panel considers that the scope of the post-market environmental monitoring plan provided by the applicant is consistent with the scope of application EFSA-GMO-NL-2011-91. (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)

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 genetically modified soybean herbicide-tolerant DAS-68416-4 for import, processing, and food and feed uses within the EU excluding cultivation in the EU.

List of Annexes[6]

Annex A:	Scientific opinion of the GMO Panel (soybean DAS-68416-4)
Annex B:	Cartagena Protocol
Annex C:	Labelling
Annex D1:	Validation report
Annex D2:	Validated method
Annex D3:	Sampling and DNA extraction
Annex E:	Certified reference materials
Annex F:	Post-market environmental monitoring
Annex G:	Member States' comments and GMO Panel responses

[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-2017-00067