TECHNICAL REPORT

APPROVED: 17 March 2017 PUBLISHED: 21 March 2017

Overall opinion of the European Food Safety Authority on application (EFSA-GMO-NL-2012-106) by Dow AgroSciences LLC for placing on the market of genetically modified herbicide-tolerant soybean DAS-44406-6 for food and feed uses, import and processing in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-NL-2012-106 for the placing on the market of genetically modified (GM) soybean DAS-44406-6 according to Articles 6 and 18 of Regulation (EC) No 1829/2003.[1] The scope of application EFSA-GMO-NL-2012-106 is for food and feed uses, import and processing of soybean DAS-44406-6 in the EU. Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel) on soybean DAS-44406-6, EFSA reports on the particulars as laid down in Articles 6 and 18 of Regulation (EC) No 1829/2003.

Overall, 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-44406-6 can be accessed at the Joint Research Centre of the European Commission and the Institute for Reference Materials and Measurements (IRMM). The 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-2012-106. The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period.

The particulars, regarding e.g. labelling, detection, Cartagena protocol are not considered by EFSA since they fall outside its remit.

Key words: soybean, DAS-44406-6, EFSA-GMO-NL-2012-106, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: Competent Authority of the Netherlands

Question number: EFSA-Q-2012-00368

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[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.

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1. Introduction

On 16 February 2012, EFSA received from the Competent Authority of the Netherlands an application (reference EFSA-GMO-NL-2012-106), submitted by Dow AgroSciences LLC under Articles 5 and 17 of Regulation (EC) No 1829/2003[2], to support the placing of genetically modified (GM) soybean DAS-44406-6 on the market in the European Union (EU). The Unique Identifier of soybean DAS-44406-6 is DAS-444Ø6-6. The scope of application EFSA-GMO-NL-2012-106 is for food and feed uses, import and processing of soybean DAS-44406-6 in the EU.

EFSA first checked the completeness of the application in accordance with the requirements laid down in Articles 5(3) and 17(3) of the above mentioned Regulation. On 11 January 2012, EURL–GMFF received samples and control samples in accordance with the same Articles.

According to Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission of the application and made the summary of the application publicly available[3].

At the end of a thorough completeness check, EFSA declared application EFSA-GMO-NL-2012-106 valid on 15 April 2013.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-NL-2012-106. Such time limit was extended whenever EFSA requested supplementary information to the applicant.

According to Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, EFSA consults the risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC[4], of all EU Member States on each request for placing on the market of products consisting of or containing GMOs. The Member States were therefore given three months to comment the valid application EFSA-GMO-NL-2012-106 from the date of its receipt.

1.1. Terms of Reference

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA is requested to issue an overall opinion on application EFSA-GMO-NL-2012-106 including : i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the scientific opinion of the GMO Panel, iv) the information required under Annex II to the Cartagena Protocol, v) the labelling proposal, vi) 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, vii) an indication of where appropriate reference materials can be accessed, viii) the post-market environmental monitoring (PMEM) plan and ix) the Member States' comments submitted during the three-month consultation period.

[2] 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.
[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00368
[4] 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.

2. Considerations

2.1. Name and address of the Applicant(s)

Application EFSA-GMO-NL-2012-106 was submitted by

Dow AgroScience LLC *represented by*
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Indianapolis, Indiana 46268-1054
USA
and
M.S. Technologies LLC
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103 Avenue D
USA

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United Kingdom

2.2. Designation and specification of the product

Soybean DAS-44406-6 (Unique Identifier: DAS-444Ø6-6) was developed to be herbicide-tolerant.

The scope of application EFSA-GMO-NL-2012-106 is for food and feed uses, import and processing and placing on the market of soybean DAS-44406-6 in the EU.

2.3. Scientific opinion of the GMO Panel

On 17 February 2017, the GMO Panel adopted a scientific opinion on soybean DAS-44406-6 (application EFSA-GMO-NL-2012-106). During its safety evaluation, the GMO Panel considered the valid application as submitted by the applicant, any additional data provided by the applicant, the scientific comments submitted by the Member States and the relevant scientific literature.

The molecular characterisation data and bioinformatics analyses did not identify issues requiring assessment for food/feed safety. The agronomic and phenotypic characteristics revealed no relevant differences between soybean DAS-44406-6 and its conventional counterpart, except for pod count, seed count and yield. The compositional analysis identified no differences requiring further assessment, except for an increase (up to 31%) in lectin activity in soybean DAS 44406-6. Such increase is unlikely to raise additional concerns for food/feed safety and nutrition of soybean DAS 44406-6 as compared to its conventional counterpart and non-GM reference varieties. There were no concerns regarding the potential toxicity and allergenicity of the three newly expressed proteins, and no evidence that the genetic modification might significantly change the overall allergenicity of soybean DAS-44406-6. Soybean DAS 44406-6 is as nutritious as its conventional counterpart and the non-GM soybean reference varieties tested. There are no indications of an increased likelihood of establishment and spread of occasional feral soybean DAS-44406-6 plants, unless exposed to the intended herbicides. The likelihood of environmental effects from the accidental release of viable seeds from soybean DAS-44406-6 into the environment is therefore very low. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of soybean DAS-44406-6. In conclusion, the GMO Panel considers that the information available for soybean DAS-44406-6 addresses the scientific comments raised by Member States and that soybean DAS-44406-6, as described in this application, is as safe as its conventional counterpart and 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).

2.4. Cartagena Protocol

The GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol (Annex B).

2.5. 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).

2.6. 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 DAS-44406-6 transformation event in crop DNA. The reports were published on 17 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 641/20045 (Annexes D1, D2, D3).

2.7. Certified reference materials

The certified reference materials of soybean DAS-44406-6 can be accessed at Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) (Annex E).

2.8. Post-market environmental monitoring (PMEM)

The 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-2012-106 (Annex F).

2.9. Member States Comments

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

[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.

3. Conclusions

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA issues an overall opinion on application EFSA-GMO-NL-2012-106 for food and feed uses, import and processing of soybean DAS-44406-6 in the EU.

List of Annexes[6]

Annex A:	Scientific opinion of the GMO Panel (soybean DAS-44406-6)
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-2012-00368