TECHNICAL REPORT

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-2009-64) for the placing on the market of the genetically modified herbicide tolerant soybean BPS-CV127-9 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from BASF Plant Science GmbH [1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

This document provides an overall opinion of the European Food Safety Authority on genetically modified soybean BPS-CV127-9 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-NL-2009-64 is for food and feed uses, import and processing. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified soybean BPS-CV127-9 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. The EFSA GMO Panel considers that the information available for soybean BPS-CV127-9 addresses scientific comments raised by Member States and that the soybean BPS-CV127-9, as described in this application, is as safe and nutritious as its conventional counterpart and commercial soybean varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses. The European Union Reference Laboratory for GM Food and Feed (EU-RL – GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of soybean BPS-CV127-9 can be accessed at the Institute of Reference Materials and Measurements (IRMM).

The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan is in line with Regulation (EC) No 1829/2003.

[1] On request from the Competent Authority of the Netherlands for an application (reference EFSA-GMO-NL-2009-64) submitted by BASF Plant Science GmbH, Questions No EFSA-Q-2013-00999 (EFSA overall opinion) and Question No EFSA-Q-2009-360 (Scientific opinion of the EFSA GMO Panel), issued on 17 January 2014.

[2] Correspondence: GMO@efsa.europa.eu

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KEY WORDS

GMO soybean (*Glycine max* (L). Merr.), BPS-CV127-9, herbicide tolerance, risk assessment, food and feed safety and environmental safety, food and feed uses and import and processing, Regulation (EC) No 1829/2003

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BACKGROUND AS PROVIDED BY THE APPLICANT

On 15 January 2009, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified soybean BPS-CV127-9 (Unique Identifier BPS-CV127-9) submitted by BASF Plant Science GmbH within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2009-64).

The scope of this application EFSA-GMO-NL-2009-64 is for food and feed uses.[3] The scope does not include cultivation.

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[4] on 9 February 2009. 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.

The EU-RL – GMFF received the detection method, samples and control samples in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 on 20 February 2009. EFSA declared the application valid on 13 July 2009 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 10 September 2008) 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 21 September 2009 to 6 July 2011 and from 2 August 2011 to 29 November 2013.[5]

The overall opinion on application EFSA-GMO-NL-2009-64 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.

[3] This does include genetically modified soybean BPS-CV127-9 for import and processing as designated under part C of Directive 2001/18/EC.

[4] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-360

[5] Request for additional information from the EFSA GMO Panel: requested (1) on 21/09/2009 – received on 26/11/2010; requested (2) on 18/02/2011 – received on 26/05/2011 and clock re-started on 06/07/2011. Requested (3-4) on 02/08/2011 and on 24/08/2011 – received on 03/11/2011; requested (5) on 17/02/2012 – received on 25/07/2012; requested (6) on 13/06/2012 – received on 09/08/2012; requested (7) on 13/02/2013 – received on 26/03/2013; requested (8) on 27/03/2013 – received on 16/04/2013; requested (9) on 11/04/2013 – received on 13/05/2013; requested (10) on 18/11/2013) – received on 26/11/2013 and clock re-started on 29/11/2013.

The applicant asked for clarifications on 23/03/2012 and on 19/10/2012; EFSA provided clarifications to the applicant on 18/06/2012 and on 16/11/2012, respectively.

The applicant submitted additional information spontaneously on 13/11/2012, on 04/02/2013 and on 26/03/2013.

TERMS OF REFERENCE AS PROVIDED BY THE COMPETENT AUTHORITY OF THE NETHERLANDS

The European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified soybean BPS-CV127-9 (Unique Identifier BPS-CV127-9) submitted by BASF Plant Science GmbH within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2009-64). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

CONSIDERATIONS

1. Applicant

The application was submitted by

BASF Plant Science GmbH
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67056 Ludwigshafen
Germany
Representing

BASF Agrochemical Products B.V.
Groningensingel 1
6835 EA Arnhem
The Netherlands

2. Designation and specification of the product as provided by the applicant

The scope of this application EFSA-GMO-NL-2009-64 is for food and feed uses.[6] The scope does not include cultivation.

Soybean (*Glycine max* (L). Merr.) event BPS-CV127-9 expresses a mutant acetohydroxyacid synthase large subunit of *Arabidopsis thaliana* (L.) Heynh. The mutant ahasl allele (S653N, referred as *csr1-2* in the literature) confers tolerance to the imidazolinone class of herbicides. The genetic modification in soybean BPS-CV127-9 is intended to improve agronomic performance only and it is not intended to influence the nutritional properties, the processing characteristics, and overall use of soybean as a crop.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified soybean BPS-CV127-9 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 5 December 2013. The EFSA GMO Panel considered all comments submitted by Member States bodies and where deemed necessary, requested additional information from the applicant before finalising its scientific assessment. EFSA GMO Panel considers that the information available for soybean BPS-CV127-9 addresses scientific comments raised by Member States and that the soybean BPS-CV127-9, as described in this application, is as safe and nutritious as its conventional counterpart and commercial soybean varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses.

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 EU-RL – GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the soybean BPS-CV127-9 transformation event in soybean DNA. The reports were issued on 20 September 2009. The EU-RL – GMFF considers that the

[6] This includes genetically modified soybean BPS-CV127-9 for import and processing as designated under part C of Directive 2001/18/EC.

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, D2, D3).

7. Certified reference materials

The certified reference materials of genetically modified soybean BPS-CV127-9 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E).

8. Post-market environmental monitoring

The EFSA GMO Panel considered that the monitoring plan provided by the applicant is in line with the intended uses for the GMO (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).

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 BPS-CV127-9.

LIST OF ANNEXES[7]

Annex A: Scientific opinion of the EFSA GMO Panel (soybean BPS-CV127-9)
Annex B: Cartagena Protocol (soybean BPS-CV127-9)
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Annex F: Post-market environmental monitoring plan (soybean BPS-CV127-9)
Annex G: Member States' comments (soybean BPS-CV127-9)

[7] The annexes of the EFSA overall opinion can be found in the Register of Questions ("Question documents") on the EFSA website under the following link: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00999