TECHNICAL REPORT

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Overall opinion of the European Food Safety Authority on application EFSA-GMO-NL-2013-120 for authorisation of genetically modified soybean FG72 × A5547-127 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Bayer CropScience LP and M.S. Technologies LLC

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-NL-2013-120 for the placing on the market of genetically modified (GM) soybean FG72 × A5547-127 according to Articles 6 and 18 of Regulation (EC) No 1829/2003.[1]
The scope of application EFSA-GMO-NL-2013-120 is for food and feed uses, import and processing of soybean FG72 × A5547-127 in the European Union (EU).
Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) on soybean FG72 × A5547-127, 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 FG72 × A5547-127 can be accessed at the American Oil Chemists' Society (AOCS-USA).
The EFSA 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-2013-120.
The EFSA 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, FG72 × A5547-127, EFSA-GMO-NL-2013-120, 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-2017-00209

Correspondence: GMO@efsa.europa.eu

[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 10 December 2013, EFSA received from the Competent Authority of the Netherlands an application (reference EFSA-GMO-NL-2013-120), submitted by Bayer CropScience LP and M.S. Technologies, LLC under Articles 5 and 17 of Regulation (EC) No 1829/2003[2], to support the placing of genetically modified (GM) soybean FG72 × A5547-127 on the market in the European Union (EU). The unique identifier of soybean FG72 × A5547-127 is MST-FGØ72-2 × ACS-GMØØ6-4.

The scope of application EFSA-GMO-NL-2013-120 is for food and feed uses, import and processing of soybean FG72 × A5547-127 in the European Union (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 25 October 2015, 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-2013-120 valid on 23 February 2015.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-NL-2013-120. 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-2013-120 from 19 August 2015[5] till 26 November 2015.

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-2013-120 including: i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the scientific opinion of the EFSA 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/questionDocumentsLoader?question=EFSA-Q-2013-01032
[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.
[5] The 3-month commenting period on application EFSA-GMO-NL-2013-120 started following the adoption by the EFSA GMO Panel of application EFSA-GMO-BE-2011-98 (on soybean FG72).

2. Considerations

2.1. Name and address of the Applicants

Application EFSA-GMO-NL-2013-120 was submitted by

Bayer CropScience LP
2 T.W. Alexander Drive
P.O. Box 12014
Research Triangle Park
RTP, North Carolina 27709
USA

M.S. Technologies, LLC
103 Avenue D
West Point, Iowa 52656
USA

Represented by

Bayer CropScience N.V.
J.E. Mommaertslaan 14
1831 Diegem
Belgium

2.2. Designation and specification of the product

Soybean FG72 × A5547-127 (unique identifier: MST-FGØ72-2 × ACS-GMØØ6-4) was developed to confer tolerance to isoxaflutole- (5-cyclopropylisoxazol-4-yl 2-mesyl-4-trifluoromethylphenyl ketone), glyphosate- (*N*-(phosphonomethyl) glycine) and glufosinate ($_L$-phosphinothricin) ammonium-based herbicides. Tolerance to these herbicides is achieved by expression of the HPPD W336 (4-hydroxyl phenyl-pyruvate-dioxygenase), 2mEPSPS (5-enolpyruvylshikimate-3-phosphate synthase) and PAT (phosphinothricin acetyl-transferase) proteins, respectively.

The scope of application EFSA-GMO-NL-2013-120 is for food and feed uses, import and processing of soybean FG72 × A5547-127 in the EU.

2.3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel previously assessed the two single events combined to produce the two-event stack soybean FG72 × A5547-127 and did not identify safety concerns. No new data on the single events, leading to modification of the original conclusions on their safety, were identified. The molecular, agronomic, phenotypic and compositional data on soybean FG72 × A5547-127 did not give rise to safety concerns and no reason to expect interactions between the single events impacting on the food and feed safety of the two-event stack soybean was identified. Although the EFSA GMO Panel cannot conclude on forage composition, soybean forage is not expected to be imported in a significant amount for use as feed. Considering the routes of exposure and limited exposure levels, the EFSA GMO Panel concludes that soybean FG72 × A5547-127 would not give rise to safety concerns in the event of accidental release of viable seeds into the environment. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of soybean FG72 × A5547-127. The EFSA GMO Panel concludes that soybean FG72 × A5547-127 is as safe as the non-genetically modified (GM) comparator and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment.

2.4. Cartagena Protocol

The EFSA 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 EFSA 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 an in-house verification study to assess the performance of two quantitative event specific methods on the hybrid soybean line FG72 × A5547-127 which combines the FG72 and A5547-127 transformation events. The two methods have been validated individually on single-trait events, to detect and quantify each event in soybean samples. The reports were issued on 16 July 2012 and 20 January 2009. The EURL-GMFF considers that the methods are applicable to the control samples provided in accordance with the requirements of Annex I-2.C.2. to the Commission Regulation (EC) No 641/2004[6] (Annexes D1, D2a, D2b).

2.7. Certified reference materials

The certified reference materials of FG72 and A5547-127 can be accessed at the AOCS-USA (Annex E1, E2).

2.8. 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 the scope of application EFSA-GMO-NL-2013-120 (Annex F).

2.9. Member States Comments

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

[6] 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-2013-120 for food and feed uses, import and processing of soybean FG72 × A5547-127 in the EU.

List of Annexes[7]

Annex A:	Scientific opinion of the EFSA GMO Panel (soybean FG72 × A5547-127 - EFSA-GMO-NL-2013-120)
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Annex C:	Labelling
Annex D1:	Validation report
Annex D2a:	Validated method (soybean FG72)
Annex D2b:	Validated method (soybean A5547-127)
Annex D3:	Sampling and DNA Extraction
Annex E1:	Certified reference materials (soybean FG72)
Annex E2:	Certified reference materials (soybean A5547-127)
Annex F:	Post-market environmental monitoring
Annex G:	Member States' comments and EFSA GMO Panel responses

[7]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-2017-00209