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Assessment of genetically modified soybean A5547-127 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-020)

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Abstract

Following the submission of application EFSA-GMO-RX-020 under Regulation (EC) No 1829/2003 from BASF Agricultural Solutions Seed US LLC, the Panel on Genetically Modified Organisms of the EFSA was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the herbicide-tolerant genetically modified soybean A5547-127, for food and feed uses, excluding cultivation within the European Union. The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. The GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-020 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean A5547-127.

Keywords: Soybean, A5547-127, renewal, Articles 11 and 23, Regulation (EC) No 1829/2003

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Summary

Following the submission of application EFSA-GMO-RX-020 under Regulation (EC) No 1829/2003 from BASF Agricultural Solutions Seed US LLC, the Panel on genetically modified organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the herbicide-tolerant genetically modified soybean A5547-127. The scope of the renewal application EFSA-GMO-RX-020 is for the renewal of the placing on the market of products containing, consisting of, or produced from soybean A5547-127, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-020, additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications. The data received in the context of the renewal application EFSA-GMO-RX-020 contained post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, additional studies performed by or on behalf of the applicant and updated bioinformatics analyses. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

The GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-020 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean A5547-127 (EFSA GMO Panel, 2011).

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1. Introduction

1.1. Background

On 4 January 2021, the European Food Safety Authority (EFSA) received from the European Commission (EC) application EFSA-GMO-RX-020 for the renewal of the authorisation of soybean A5547-127 (Unique Identifier ACS-GMØØ6-4), submitted by BASF Agricultural Solutions Seed US LLC (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003[1].

Following receipt of application EFSA-GMO-RX-020, EFSA informed the Member States (MS) and made the summary of the application available to the public on the EFSA website.[2]

EFSA checked the application for compliance with the relevant requirements of Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013[3] and, when needed, asked the applicant to supplement the initial application. On 7 May 2021, EFSA declared the application valid and made the valid application available to the MS and the EC.

Following the submission of application EFSA-GMO-NL-2008-52 and the publication of the EFSA scientific opinion (EFSA GMO Panel, 2011), the placing on the market of soybean A5547-127 for products containing, consisting of, or produced from this GM soybean, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2012/81/EU[4] and Commission Implementing Decision (EU) 2019/1195 amending Decision 2012/81/EU[5]. A copy of these authorisations was provided by the applicant.[6]

From the validity date, EFSA and its scientific Panel on Genetically Modified Organisms (hereafter referred to as 'the GMO Panel') endeavoured to respect a time limit of six months to issue a scientific opinion on application EFSA-GMO-RX-020. Such time limit was extended whenever EFSA and/or its GMO Panel requested supplementary information to the applicant. According to Regulation (EC) No 1829/2003, any supplementary information provided by the applicant during the risk assessment was made available to the MS and EC (for further details, see the section 'Documentation', below).

In accordance with Regulation (EC) No 1829/2003, EFSA consulted the nominated risk assessment bodies of the MS, including national Competent Authorities within the meaning of Directive 2001/18/EC[7]. The MS had three months to make their opinion known on application EFSA-GMO-RX-020 as of date of validity.

1.2. Terms of Reference as provided by the requestor

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA and its GMO Panel were requested to carry out a scientific risk assessment of soybean A5547-127 for the renewal of authorisation for placing on the market of products containing, consisting of, or produced from GM soybean A5547-127 in the context of its scope as defined in application EFSA-GMO-RX-020.

According to Regulation (EC) No 1829/2003, this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation including the opinions of the nominated risk assessment bodies of the MS.[8]

In addition to the present scientific opinion on soybean A5547-127, EFSA and its GMO Panel were also asked to report on the particulars listed under Articles 6(5) and 18(5) of

[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.
[2] Available online: https://open.efsa.europa.eu/questions/EFSA-Q-2021-00003.
[3] Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. OJ L157, 8.6.2013, p. 1–48.
[4] 2012/81/EU: Commission Implementing Decision of 10 February 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A5547-127 (ACS-GMØØ6-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 40/10, 14.2.2012.
[5] Commission Implementing Decision (EU) 2019/1195 of 10 July 2019 amending Decisions 2008/730/EC, 2008/837/EC, 2009/184/EC, 2011/354/EU, Implementing Decisions 2012/81/EU, 2013/327/EU, (EU) 2015/690, (EU) 2015/697, (EU) 2015/699, (EU) 2016/1215, (EU) 2017/1208 and (EU) 2017/2451 as regards the authorisation holder and the representative for the placing on the market of genetically modified soybean, cotton, oilseed rape and maize. Official Journal of the European Union L 187/43, 12.7.2019.
[6] Dossier: Soybean A5547-127 – Annex I.
[7] 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.
[8] Opinions of the nominated risk assessment bodies of EU Member States can be found at https://open.efsa.europa.eu/questions/EFSA-Q-2021-00003.

Regulation (EC) No 1829/2003. The relevant information is made available in Open EFSA,[2] including the information required under Annex II to the Cartagena Protocol, a labelling proposal, a post-market environmental monitoring (PMEM) plan as provided by the applicant; the method(s), validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it and the appropriate reference materials.

2. Data and methodologies

2.1. Data

The data for application EFSA-GMO-RX-020 submitted according to EFSA requirements (EFSA GMO Panel, 2015; EFSA, 2019a) and provided by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

In the frame of the contracts OC/EFSA/GMO/2020/01 and OC/EFSA/GMO/2018/04, contractors performed preparatory work and delivered reports on the methods applied by the applicant in performing sequencing and literature search, respectively.

2.1.1. Post-market monitoring reports[9]

Based on the outcome of the initial food and feed risk assessment, a case-specific post-market monitoring plan for monitoring of GM food and feed was not required by the authorisation decision. The implementation of a PMEM plan, consisting of a general surveillance plan to check for any adverse effects on the environment arising from soybean A5547-127, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of soybean A5547-127 (EFSA GMO Panel, 2011), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided 10 annual PMEM reports covering a reporting period from February 2012 till June 2021. The annual PMEM reports submitted by the applicant included (1) commodity crop (GM and non-GM) imports into the EU by country of origin and destination; (2) the description of a centralised system established by EuropaBio[10] for the collection of information recorded by various operators (federations involved in soybean import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of soybean A5547-127; (3) the reports of the surveillance activities conducted by such operators; and (4) the review of relevant scientific peer-reviewed studies retrieved from literature searches.

2.1.2. Systematic search and evaluation of literature[11]

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed a systematic literature search covering the period from October 2011 till June 2020 in accordance with the recommendations on literature search outlined in EFSA (2010, 2019b). The literature review was updated covering the period until January 2022.

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. Altogether 899 publications were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined *a priori* by the applicant, two publications were identified as relevant for food and feed safety assessment or molecular characterisation. The relevant publications are listed in Appendix A.

2.1.3. Updated bioinformatic data[12]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic data set for soybean A5547-127 event including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed protein and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer (EFSA, 2017), and a safety assessment of the newly expressed

[9] Dossier: Soybean A5547-127 – Annex II, additional information: 15/3/2022.
[10] The responsibilities of EuropaBio in coordinating activities of technology providers on the post-market environmental monitoring of GM crops was taken over by CropLife Europe as of 1st January 2021.
[11] Dossier: Soybean A5547-127 – Annex III; additional information: 5/11/2021, 30/11/2021, 15/3/2022.
[12] Dossier: Soybean A5547-127 – Annex III; additional information: 23/8/2021. Spontaneous information: 13/4/2022.

protein PAT regarding its capacity to trigger coeliac disease (EFSA GMO Panel, 2017a). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

2.1.4. Additional documents or studies provided by the applicant[13]

In line with the renewal guidance requirements (EFSA GMO Panel, 2015; EFSA, 2019a), the applicant provided an overview on the worldwide approvals of soybean A5547-127 and searched for any available full reports of studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU (Appendix B).

The relevance of the listed studies for molecular characterisation, human and animal safety and the environment was assessed by the applicant.

2.1.5. Overall assessment as provided by the applicant[14]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of soybean A5547-127 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA GMO Panel, 2011).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation[15]

The applicant indicated in the dossier that the environmental post-market monitoring plan is appropriate and does not need any changes.

2.2. Methodologies

The GMO Panel assessed the application for renewal of the authorisation of soybean A5547-127 for food and feed uses in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003. The GMO Panel took into account the requirements described in its guideline for the risk assessment of renewal applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015). The comments raised by the nominated risk assessment bodies of EU Member States were taken into consideration during the scientific risk assessment.

3. Assessment

3.1. Evaluation of the post-market monitoring reports

During the general surveillance activities covering the authorisation period of soybean A5547-127, no adverse effects were reported by the applicant.

3.2. Evaluation of the systematic search and evaluation of literature

The GMO Panel assessed the applicant's literature searches on soybean A5547-127 and the newly expressed protein PAT. The overall quality of the performed literature searches is acceptable.

The GMO Panel acknowledges that no publications raising a safety concern for human and animal health and the environment which would change the original risk assessment conclusions on soybean A5547-127 (EFSA GMO Panel, 2011) have been identified by the applicant.

3.3. Evaluation of the updated bioinformatic data

The results of the updated bioinformatic analyses to assess the interruption of soybean endogenous genes confirm previous results indicating that no endogenous genes have been interrupted by event A5547-127 (EFSA GMO Panel, 2011, 2017b, 2019).

Analyses of the amino acid sequence of the newly expressed PAT protein reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. The updated bioinformatic analyses of the newly created ORFs within the insert do not indicate sequence similarities to toxins or allergens in soybean A5547-127. In addition, the updated bioinformatic analysis of the newly created ORFs spanning the junctions with genomic DNA confirms previous results which did not indicate

[13] Dossier: Soybean A5547-127 – Annex III; additional information: 5/11/2021, 15/3/2022.
[14] Dossier: Soybean A5547-127 – Annex III.
[15] Dossier: Soybean A5547-127 – Part III – Summary.

sequence similarities to toxins or allergens in soybean A5547-127 (EFSA GMO Panel, 2011, 2017b, 2019).

The updated bioinformatic analyses for event A5547-127 revealed a DNA sequence that could provide sufficient length and identity which could facilitate horizontal gene transfer (HGT) by double homologous recombination. The analyses confirm the assessment provided in the context of previous Scientific Opinions (EFSA GMO Panel, 2011, 2017b, 2019). Given the results of this analysis, the GMO Panel concludes that the unlikely, but theoretically possible, HGT of recombinant genes from event A5547-127 to bacteria does not raise any environmental safety concern.

3.4. Evaluation of the additional documents or studies provided by the applicant

The GMO Panel evaluated the full study reports of the additional studies provided, including a new sequencing study (Appendix B). The sequencing data are compliant with the requirements laid down in the EFSA Technical Note on the quality of DNA sequencing for the molecular characterisation of genetically modified plants (EFSA GMO Panel, 2018).[16] The study confirms that the sequence of the event in recent plant material (year of collection 2020) is identical to the sequence of the event in the originally assessed application (EFSA GMO Panel, 2011).

Overall, the new additional documents or studies provided by the applicant do not raise any concern for human and animal health and the environment, which would change the original risk assessment conclusions on soybean A5547-127.

3.5. Evaluation of the overall assessment as provided by the applicant

The GMO Panel evaluated the overall assessment provided by the applicant and confirms that there is no evidence in renewal application EFSA-GMO-RX-020 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on soybean A5547-127.

3.6. Evaluation of the monitoring plan and proposal for improving the conditions of the original authorisation

The PMEM plan covers general surveillance of imported GM plant material, including soybean A5547-127. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in soybean grains import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. The GMO Panel is of the opinion that the scope of the plan provided by the applicant is consistent with the scope of application EFSA-GMO-RX-020, but reminds that monitoring is related to risk management, and thus, the final adoption and implementation of the PMEM plan falls outside the mandate of EFSA.

4. Conclusions

The GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-020 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean A5547-127 (EFSA GMO Panel, 2011).

5. Documentation as provided to EFSA

1) Letter from the European Commission to EFSA received on 4 January 2021 for the continued marketing of genetically modified soybean A5547-127 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by BASF Agricultural Solutions Seed US LLC (EFSA-GMO-RX-020).
2) Application EFSA-GMO-RX-020 validated by EFSA, 7 May 2021.
3) Request for supplementary information to the applicant, 2 July 2021.
4) Receipt of supplementary information from the applicant, 23 August 2021.
5) Request for supplementary information to the applicant, 20 September 2021.
6) Receipt of supplementary information from the applicant, 5 November 2021.
7) Request for supplementary information to the applicant, 16 November 2021.

[16] Additional information: 23/8/2021, 5/11/2021, 15/3/2022.

8) Receipt of supplementary information from the applicant, 30 November 2021.
9) Request for supplementary information to the applicant, 14 December 2021.
10) Receipt of supplementary information from the applicant, 15 March 2022.
11) Receipt of spontaneous information from the applicant, 13 April 2022.

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EFSA (European Food Safety Authority), Gennaro A, Gomes A, Herman L, Nogué F, Papadopoulou N and Tebbe C, 2017. Technical report on the explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms. EFSA supporting publication 2017;EN-1273, 11 pp. https://doi.org/10.2903/sp.efsa.2017.EN-1273

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Abbreviations

EC	European Commission
EU	European Union
GM	genetically modified
GMO	genetically modified organism
GMO Panel	EFSA Panel on Genetically Modified Organisms
HGT	horizontal gene transfer

ORFs	open reading frames
PMEM	post-market environmental monitoring
PAT	phosphinothricin acetyltransferase

Appendix A – List of relevant publications identified by the applicant through systematic literature searches (October 2011 to January 2022)

References
EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2011. Scientific Opinion on application (EFSA-GMO-NL-2008-52) for the placing on the market of herbicide tolerant genetically modified soybean A5547-127 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. The EFSA Journal (2011); 9(5): 2147, 1–28. https://doi.org/10.2903/j.efsa.2011.2147
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Appendix B – List of additional studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU with regard to the evaluation of the safety of the food and feed for humans, animal or the environment from soybean A5547-127

Study identification	Title
M-293249-03-1	Nutritional impact assessment report on glufosinate ammonium tolerant soybean transformation event A5547-127
M-360323-02-1	Nutritional impact assessment report on glufosinate ammonium tolerant soybean transformation event A5547-127
M-441962-01-1	Detailed insert characterization of Glycine max transformation event A5547-127 by Southern blot analysis
M-444581-01-1	A5547-127 soybean: 2-dimensional gel electrophoresis analysis of soybean endogenous food allergens
M-479996-02-1	Dietary exposure assessment of Chinese consumers to glufosinate ammonium tolerant soybean A5547-127
M-563074-02-1	A5547-127 soybean - Dietary exposure assessment of Mexican consumers to glufosinate ammonium tolerant soybean A5547-127 and the PAT/pat protein
M-603162-01-1	A5547-127 soybean - Inheritance of the insert over generations
NG-25148	Sequencing of the A5547-127 soybean transgenic locus in a commercial variety (2020)