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Assessment of genetically modified soybean A2704-12 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-009)

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Abstract

Following the submission of application EFSA-GMO-RX-009 under Regulation (EC) No 1829/2003 from Bayer CropScience N.V., the Panel on Genetically Modified Organisms of the European Food Safety Authority 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 A2704-12, for food and feed uses, import and processing, 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. In addition, the applicant provided sequence data on the soybean A2704-12 event using material from a commercial variety currently on the market and intended to be marketed in the coming years. 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-009 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean A2704-12.

Keywords: Soybean, A2704-12, renewal, Articles 11 and 23, Regulation (EC) No 1829/2003

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Summary

Following the submission of application EFSA-GMO-RX-009 under Regulation (EC) No 1829/2003 from Bayer CropScience N.V., 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 A2704-12. The scope of renewal application EFSA-GMO-RX-009 is for placing on the market of products containing, consisting of, or produced from soybean A2704-12, excluding cultivation within the European Union.

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-009, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. The data received in the context of the renewal application EFSA-GMO-RX-009 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, updated bioinformatics analyses, and additional studies performed by or on behalf of the applicant. In addition, the applicant provided sequence data on the soybean A2704-12 event using material from a commercial variety currently on the market and intended to be marketed in the coming years. 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-009 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean A2704-12 (EFSA, 2007).

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1. Introduction

1.1. Background

On 3 November 2017, the European Food Safety Authority (EFSA) received from the European Commission (DG SANTE) application EFSA-GMO-RX-009 by Bayer CropScience N.V. for the renewal of authorisation of genetically modified (GM) soybean A2704-12 (Unique Identifier ACS-GMØØ5–3) for the placing on the market of products containing, consisting of, or produced from this GM soybean for import and processing submitted within the framework of Regulation (EC) No 1829/2003[1]. Before sending the application to EFSA, the European Commission confirmed whether the data submitted in the context of this renewal application were in line with the legal requirements laid down in Articles 11 and 23 of Regulation (EC) No 1829/2003.

After receiving application EFSA-GMO-RX-009, and in accordance with Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed Member States and made the summary of the application available to the public on the EFSA website.[2]

On 9 March 2018, EFSA declared the application valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003. EFSA made the valid application available to Member States and the European Commission, and consulted nominated risk assessment bodies of Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC following the requirements of Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, to request their scientific opinion. Member States had three months after the opening of the Member State commenting period (until 9 June 2018) to make their opinion known.

Following the submission of application EFSA-GMO-NL-2005-18 and the publication of the EFSA scientific opinion (EFSA, 2007), the placing on the market of soybean A2704-12 for products containing, consisting of, or produced from this GM soybean, excluding cultivation in the European Union, was authorised by Commission Decision 2008/837/EC[3]. A copy of this authorisation was provided by the applicant.[4]

EFSA requested additional information on 26 March 2018 and 8 May 2018. The applicant submitted their replies on 27 April 2018 and 19 June 2018, respectively.

In giving its scientific opinion to the European Commission, the Member States and the applicant, and in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, EFSA has endeavoured to respect a time limit of six months from the acknowledgement of the valid application. As additional information was requested by the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel), the time limit of 6 months was extended accordingly, in line with Articles 6(1), 6(2), 18(1), and 18(2) of Regulation (EC) No 1829/2003.

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 and thus will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5).

1.2. Terms of Reference as provided by the requestor

The GMO Panel was requested to carry out a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the placing on the market of products containing, consisting of, or produced from GM soybean A2704-12, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003.

Where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food and feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas should be indicated in accordance with Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

[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: http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2017-00721
[3] COMMISSION DECISION of 8 September 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 247/50, 16.9.2008.
[4] Dossier: Soybean A2704-12 renewal – Annex 1.

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 and feed and/or food and feed produced from it), which are matters related to risk management.

2. Data and methodologies

2.1. Data

The data for application EFSA-GMO-RX-009 provided by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

The applicant submitted sequence data on soybean A2704-12 single event[5] derived from material of an early generation (T4) of soybean A2704-12 (fourth generation after the original transformant) and from material of a commercially available soybean A2704-12 variety currently on the market and indicated that these sequences are identical.

The applicant clarified that the soybean A2704-12 commercial variety has been available on the market since 2016 and is intended to be marketed in the coming years. The applicant also clarified that the A2704-12 event sequence reported in this renewal application is the sequence submitted in the original application EFSA-GMO-NL-2005-18 (EFSA, 2007), corrected for eight nucleotides, two of which affect newly created open reading frames (ORFs) within the insert and spanning the junction sites (EFSA, 2018).

2.1.1. Post-market monitoring reports[6]

Based on the outcome of the initial food and feed risk assessment, a post-market monitoring plan for monitoring of GM food and feed was not required by the authorisation decision. The implementation of a post-market environmental monitoring (PMEM) plan, consisting of a general surveillance plan to check for any adverse effects on the environment arising from soybean A2704-12, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of soybean A2704-12 (EFSA, 2007), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided eight annual PMEM reports covering a reporting period from September 2008 to June 2016. The annual PMEM plans submitted by the applicant included (1) the description of a centralised system established by EuropaBio for the collection of information recorded by various operators (federations involved in soybean seeds import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of soybean possibly containing soybean A2704012; (2) the reports of the surveillance activities conducted by such operators; and (3) the review of relevant scientific peer-reviewed studies retrieved from literature searches.

2.1.2. Systematic search and evaluation of literature[7]

In addition to the eight separate literature searches provided as part of the annual PMEM reports, the applicant performed a systematic literature search for soybean A2704012 and the newly expressed phosphinothricin *N*-acetyltransferase (PAT) protein covering the period from 1 September 2007 till 10 January 2018, in accordance with the recommendations on literature searching outlined in EFSA (2010, 2017a).

Searches against electronic bibliographic databases and internet searches to specialist databases were performed to identify relevant publications. Altogether, 564 publications were retrieved. After applying the eligibility/inclusion criteria defined *a priori* by the applicant, six publications were identified as relevant for food and feed safety assessment, molecular characterisation and environmental safety assessment. The list of relevant publications is provided in Appendix A.

[5] Dossier: Soybean A2704-12 renewal – Section 3.
[6] Dossier: Soybean A2704-12 renewal – Section 2.
[7] Dossier Soybean A2704-12 renewal – Section 3a; additional information: 27/4/2018.

2.1.3. Updated bioinformatic data[8]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for the soybean A2704-12 event (using the corrected sequence) 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 ORFs within the insert and spanning the junction sites, and an analysis of possible horizontal gene transfer (EFSA, 2017b). The outcome of the updated bioinformatic analyses is presented in Section 3.3. On 8 May 2018, EFSA requested supplementary information on the partial deletion of the endogenous gene previously reported in the frame of the original application EFSA-GMO-NL-2005-18. On 19 June 2018, the applicant provided the supplementary information which included information on the function of the interrupted endogenous gene and a risk assessment of its interruption with respect to the agronomic–phenotypic characteristics and composition of soybean A2704-12.

2.1.4. Additional documents or studies provided by the applicant[9]

The applicant provided an overview on the worldwide approvals of soybean A2704-12 and a list containing the summaries of all 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.

On 26 March 2018, the GMO Panel requested the applicant to provide the full study reports of five of these studies considered potentially relevant for safety assessment. The applicant submitted the requested information on 27 April 2018.

2.1.5. Overall assessment as provided by the applicant[10]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of soybean A2704-12 for food and feed use and processing in the EU does not change the outcome of the original risk assessment (EFSA, 2007).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation[11]

The applicant indicated in the dossier that the environmental 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 A2704-12 for food and feed uses, import and processing 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 Member States are addressed in Annex G of EFSA's overall opinion[12] and 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 A2704-12, no adverse effects were reported by the applicant.

[8] Dossier: Soybean A2704-12 renewal – Section 3b; additional information: 19/6/2018.
[9] Dossier: Soybean A2704-12 renewal – Section 3c; additional information: 27/4/2018.
[10] Dossier: Soybean A2704-12 renewal – Section 4.
[11] Dossier: Soybean A2704-12 renewal – Section 5.
[12] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00992

3.2. Evaluation of the systematic search and evaluation of literature

The GMO Panel assessed the applicant's literature searches on soybean A2704-12. Although the overall quality of the performed literature searches is acceptable, the GMO Panel considers that future searches could be improved. The GMO Panel therefore recommends the applicant for future searches to:

- ensure that enough search term variation is used (covering possible synonyms, related terms, acronyms, spelling variants, old and new terminology, brand and generic names, lay and scientific terminology, common typos, translation issues);
- include trait terms;
- include controlled vocabulary (subject indexing) in the searches when available (in addition to/combination with text words);
- use wider proximity operators (5W).

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 A2704-12 (EFSA, 2007) have been identified by the applicant.

3.3. Evaluation of the updated bioinformatic data

The results of the updated bioinformatic analyses of soybean A2704-12 using the corrected event sequence (EFSA, 2018) confirm the previous conclusions on the partial deletion of an endogenous gene. Based on the information from updated databases submitted in the frame of this renewal application, this gene is identified as *SEOe*, a member of the sieve element occlusion (SEO) multigene family encoding for *Glycine max* SEO proteins. The *SEOe* gene is one of four genes in subgroup 5 of the SEO gene family, thereby indicating that functional redundancy for this gene in the soybean genome is likely. In addition, the original agronomic, phenotypic and compositional analyses of soybean A2704-12 (including endpoints that may be relevant to the reported biological role of SEO proteins in photoassimilate translocation via the phloem network such as plant height, yield and fiber content) did not indicate relevant differences as compared to the non-GM comparator.

Analyses of the amino acid sequence of the newly expressed PAT protein reveal no significant similarities to toxins or allergens. In addition, bioinformatic analyses of the newly created ORFs (using the corrected event sequence) within the insert or spanning the junctions with genomic DNA reveal no significant similarities to toxins and allergens.

Updated bioinformatic analyses of the recombinant DNA present in soybean A2704-12 reveal sufficient sequence identity at both ends of the inserted cassette by the disrupted *bla* gene. This could facilitate double homologous recombination with *bla* genes as they can occur in environmental bacteria. The recombination event, however, would result in the disruption of such genes in the recipients. In addition, the insertion of a *pat* gene codon-optimised for plants regulated by a plant virus promoter would probably lack PAT activity in potential recipient bacteria. Therefore, bacteria in which the described double homologous recombination would occur would lose their antibiotic resistance and acquire a plant codon-optimised *pat* gene for which a selective advantage, compared to natural variants of *pat* genes as they occur in environmental bacteria, cannot be expected. The results of updated bioinformatic analyses confirm the previous conclusions that the unlikely, but theoretically possible, horizontal transfer of recombinant genes from soybean A2704-12 to bacteria does not raise any environmental safety concern (EFSA, 2007).

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

The GMO Panel evaluated the summary and/or full study reports of the additional studies provided and (Appendix B). This new information does not raise any concern for human and animal health and the environment, which would change the original risk assessment conclusions on soybean A2704-12.

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-009 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on soybean A2704-12.

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 A2704-12. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in soybean seeds 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 soybean A2704-12, 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

Based on the data provided, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-009 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean A2704–12 (EFSA, 2007).

Documentation provided to EFSA

1) Letter from the European Commission to EFSA received on 3 November 2017 for the continued marketing of genetically modified soybean A2704-12 in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Bayer CropScience N.V. (EFSA-GMO-RX-009).
2) Acknowledgement letter, dated 7 November 2017, from EFSA to the European Commission.
3) Letter from EFSA to applicant dated 15 December 2017 requesting additional information under completeness check.
4) Letter from applicant to EFSA received on 16 February 2018 providing additional information under completeness check.
5) Letter from EFSA to applicant dated 9 March 2018 delivering the 'Statement of Validity' for application EFSA-GMO-RX-009.
6) Letter from EFSA to applicant dated 26 March 2018 requesting additional information and stopping the clock.
7) Letter from applicant to EFSA received on 27 April 2018 providing additional information.
8) Letter from EFSA to applicant dated 30 April 2018 re-starting the clock from 27 April 2018.
9) Letter from EFSA to applicant dated 8 May 2018 requesting additional information and stopping the clock.
10) Letter from applicant to EFSA received on 19 June 2018 providing additional information.
11) Letter from EFSA to applicant dated 19 June 2018 re-starting the clock from 19 June 2018.

References

EFSA (European Food Safety Authority), 2007. Opinion of the Scientific Panel on genetically modified organisms (GMO) on an application (Reference EFSA-GMO-NL-2005-18) for the placing on the market of the glufosinate-tolerant soybean A2704-12, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. EFSA Journal 2007;5(7):524, 22 pp. https://doi.org/10.2903/j.efsa.2007.524

EFSA (European Food Safety Authority), 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010;8(6):1637, 90 pp. https://doi.org/10.2903/j.efsa.2010.1637

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. EFSA Journal 2015;13(6):4129, 8 pp. https://doi.org/10.2903/j.efsa.2015.4129

EFSA (European Food Safety Authority), Devos Y, Guajardo IM, Glanville J and Waigmann E, 2017a. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market. EFSA supporting publications 2017:EN-1207, 48 pp. https://doi.org/10.2903/sp.efsa.2017.EN-1207

EFSA (European Food Safety Authority), Gennaro A, Gomes A, Herman L, Nogue F, Papadopoulou N and Tebbe C, 2017b. 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 publications 2017;14(7):EN-1273, 11 pp. https://doi.org/10.2903/sp.efsa.2017.en-1273

EFSA (European Food Safety Authority), Federici S and Paraskevopoulos K, 2018. Risk assessment of new sequencing information on genetically modified soybean A2704–12. EFSA Journal 2018;16(11):5496, 8 pp. https://doi.org/10.2903/j.efsa.2018.5496

Abbreviations

GM	genetically modified
GMO	genetically modified organisms
GMO Panel	EFSA Panel on Genetically Modified Organisms
ORFs	open reading frames
PAT	phosphinothricin *N*-acetyltransferase
PMEM	post-market environmental monitoring
SEO	sieve element occlusion

Appendix A – List of relevant publications identified by the applicant through the systematic literature search (1/9/2007–10/1/2018)

Reference
Fard NA et al., 2013. *In silico* allergenicity assessment of novel proteins derived from GMHR crops. Ortuno F and Rojas I [Eds]. Proceedings IWBBIO.
Fard NA, Minuchehr Z and Mousavi A, 2013. Allergenicity study of genetically modified herbicide resistant crops (bioinformatics assessment). Bulletin of Environment, Pharmacology and Life Sciences, 2, 24–32.
Nagy A, Pauk J, Takacs K and Gelencser E, 2008. Nutritional evaluation of the proteins of broad range herbicide resistant spring wheat (*Triticum aestivum* L.) lines. II. Resistance to digestion of marker proteins in rat model. Acta Alimentaria, 37, 159–166.
Oh J, Ko M and Lee H, 2009. Evaluation for allergenicity for genetically modified organic foods. Journal of Allergy and Clinical Immunology, 123, S244.
Schafer BW, Embrey SK and Herman RA, 2016. Rapid simulated gastric fluid digestion of in-seed/grain proteins expressed in genetically engineered crops. Regulatory Toxicology and Pharmacology, 81, 106–112.
Verma AK, Misra A, Subash S, Das M and Dwivedi PD, 2011. Computational allergenicity prediction of transgenic proteins expressed in genetically modified crops. Immunopharmacology and Immunotoxicology, 33, 410–422.

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 A2704-12

Study identification	Title
M–413199-01-1	Agronomic characteristics of glufosinate-tolerant soybean A2704-12, USA, 2006
M-534302-01-1	Structural stability analysis of early and recent generations of *Glycine max* A2704-12
M-540738-01-1	A2704-12 soybean - Inheritance of the insert over two generations
M-131221-04-1[(a)]	PAT/pat protein: Heat stability study
M-214021-03-1	PAT/pat protein: *in vitro* digestibility study in human simulated intestinal fluid
M-214025-05-1[(a)]	PAT/pat protein - *In vitro* digestibility study in human simulated gastric fluid
M-344158-01-1[(a)]	PAT protein (encoded the *pat* gene) - Acute toxicity (48 hours) to rainbow trout (*Oncorhynchus mykiss*) by intraperitoneal injection
M-395296-01-1	Measurement of PAT protein in soybean oil samples using the QualiPlate Kit for PAT from EnviroLogix
M-475440-01-1[(a)]	PAT/pat protein - Acute toxicity by oral gavage in mice
M-500889-01-1[(a)]	The effect of temperature on microbially-produced PAT/pat as assessed by ELISA

(a): Studies for which the full report was requested by the GMO Panel.