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Assessment of genetically modified soybean 40-3-2 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-023)

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Abstract

Following the submission of application EFSA-GMO-RX-023 under Regulation (EC) No 1829/2003 from Bayer Agriculture BV on behalf of Bayer CropScience LP, 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 40-3-2, 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. Under the assumption that the DNA sequence of the event in soybean 40-3-2 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-023 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean 40-3-2.

Keywords: soybean, 40-3-2, renewal, Articles 11 and 23, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

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Summary

Following the submission of application EFSA-GMO-RX-023 under Regulation (EC) No 1829/2003 from Bayer Agriculture BV on behalf of Bayer CropScience LP, 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 40-3-2. The scope of the renewal application EFSA-GMO-RX-023 is for the renewal of the placing on the market of products containing, consisting of, or produced from soybean 40-3-2, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-023, 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-023 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 bioinformatic 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.

Under the assumption that the DNA sequence of the event in soybean 40-3-2 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-023 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean 40-3-2 (EFSA GMO Panel, 2010).

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1. Introduction

1.1. Background

On 08 February 2021, the European Food Safety Authority (EFSA) received from the European Commission (EC) application EFSA-GMO-RX-023 for the renewal of the authorisation of soybean 40-3-2 (Unique Identifier MON-Ø4Ø32-6), submitted by Bayer Agriculture BV on behalf of Bayer CropScience LP (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003[1].

Following receipt of application EFSA-GMO-RX-023, 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 17 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-RX-40-3-2 and the publication of the EFSA scientific opinion (EFSA GMO Panel, 2010), the placing on the market of soybean 40-3-2 for products containing, consisting of, or produced from this GM soybean, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2012/82/EU[4] and Commission Implementing Decision (EU) 2019/1579 amending Decisions 2008/933/EC, 2009/813/EC, 2009/814/EC and 2010/429/EU and Implementing Decisions 2012/82/EU, 2012/83/EU, 2012/347/EU, 2013/649/EU, (EU) 2015/683, (EU) 2015/684, (EU) 2015/685, (EU) 2015/686, (EU) 2015/687, (EU) 2015/688, (EU) 2015/689, (EU) 2015/693, (EU) 2015/695, (EU) 2015/696, (EU) 2015/700, (EU) 2015/701, (EU) 2015/2279, (EU) 2015/2281, (EU) 2016/1216, (EU) 2016/1217, (EU) 2017/1207, (EU) 2018/1111, (EU) 2018/2045 and (EU) 2018/2046 as regards the representative of the authorisation holder for placing on the market certain genetically modified food and feed in the Union.[5] A copy of the original authorisation 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-023. This 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-023 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 40-3-2 for the renewal of authorization

[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, pp. 1–23.
[2] Available online: https://open.efsa.europa.eu/questions/EFSA-Q-2021-00077
[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, pp. 1–48.
[4] Commission Implementing Decision 2012/82/EU of 10 February 2012 authorising the continued marketing of products containing, consisting of, or produced from genetically modified soybean 40-3-20 (MON-Ø4Ø32-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 40/14, 14.2.2012.
[5] Commission Implementing Decision (EU) 2019/1579 of 18 September 2019 amending Decisions 2008/933/EC, 2009/813/EC, 2009/814/EC and 2010/429/EU and Implementing Decisions 2012/82/EU, 2012/83/EU, 2012/347/EU, 2013/649/EU, (EU) 2015/683, (EU) 2015/684, (EU) 2015/685, (EU) 2015/686, (EU) 2015/687, (EU) 2015/688, (EU) 2015/689, (EU) 2015/693, (EU) 2015/695, (EU) 2015/696, (EU) 2015/700, (EU) 2015/701, (EU) 2015/2279, (EU) 2015/2281, (EU) 2016/1216, (EU) 2016/1217, (EU) 2017/1207, (EU) 2018/1111, (EU) 2018/2045 and (EU) 2018/2046 as regards the representative of the authorisation holder for placing on the market certain genetically modified food and feed in the Union. Official Journal of the European Union L 244/8, 24.9.2019.
[6] Dossier: Soybean 40-3-2 – 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, pp. 1–38.

for placing on the market of products containing, consisting of, or produced from GM soybean 40-3-2 in the context of its scope as defined in application EFSA-GMO-RX-023.

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 40-3-2, EFSA and its GMO Panel were also asked to report on the particulars listed under Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003. The relevant information is made available in the Open EFSA portal,[9] 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-023 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/2021/06 and OC/EFSA/GMO/2018/04, contractors performed preparatory work and delivered reports on the methods applied by the applicant in performing updated bioinformatic analyses and literature search, respectively.

2.1.1. Post-market monitoring reports[10]

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 PMEM plan, consisting of a general surveillance plan to check for any adverse effects on the environment arising from soybean 40-3-2, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of soybean 40-3-2 (EFSA GMO Panel, 2010), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided 10 annual PMEM reports covering a reporting period from October 2012 to June 2021. The annual PMEM plans 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 managed by EuropaBio[11] for the collection of information recorded by various operators (federations involved in soybean grains import, storage and processing) on any observed adverse effect(s) on human health and the environment arising from handling of soybean possibly containing soybean 40-3-2; (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[12]

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed systematic literature searches covering the period from January 2010 until April 2022, in accordance with the recommendations on literature search outlined in EFSA (2010, 2019b).

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. Altogether 917 publications were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, 98 peer-reviewed and non-peer reviewed publications were identified as relevant for food and feed safety assessment or molecular characterisation. The relevant publications are listed in Appendix A.

[8] Opinions of the nominated risk assessment bodies of EU Member States can be found at the Open EFSA Portal https://open.efsa.europa.eu/questions, querying the assigned Question Number.
[9] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00077
[10] Dossier: Soybean 40-3-2 – Annex II; additional information: 18/3/2022.
[11] The responsibilities of EuropaBio in coordinating activities of technology providers on the post-market environmental monitoring of GM crops were taken over by CropLife Europe as of 1 January 2021.
[12] Dossier: Soybean 40-3-2 – Annex III; additional information: 18/3/2022, 15/7/2022.

2.1.3. Updated bioinformatic data[13]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for soybean 40-3-2 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, 2017a), and a safety assessment of the newly expressed protein CP4 EPSPS regarding its capacity to trigger celiac disease (EFSA GMO Panel, 2017). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

2.1.4. Additional documents or studies provided by the applicant[14]

In line with the renewal guidance requirements (EFSA GMO Panel, 2015; EFSA, 2019a), the applicant provided an overview on the worldwide approvals of soybean 40-3-2 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[15]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of soybean 40-3-2 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA GMO Panel, 2010).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation[16]

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 40-3-2 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 40-3-2, 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 40-3-2 and the newly expressed protein CP4 EPSPS. 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 40-3-2 (EFSA GMO Panel, 2010) have been identified by the applicant.

[13] Dossier: Soybean 40-3-2 – Annex III; additional information: 7/9/2021, 15/7/2022, 26/10/2022.
[14] Dossier: Soybean 40-3-2 – Annex III; additional information: 7/9/2021.
[15] Dossier: Soybean 40-3-2 – Annex III.
[16] Dossier: Soybean 40-3-2 – Part I – Request for renewal; additional information: 26/10/2022.

3.3. Evaluation of the updated bioinformatic data

The updated bioinformatic analyses to assess the interruption of soybean endogenous genes by the event 40-3-2 confirm the results previously assessed by the GMO Panel (EFSA GMO Panel, 2022).

Analyses of the amino acid sequence of the newly expressed protein CP4 EPSPS 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 40-3-2. In addition, the updated bioinformatic analysis of the newly created ORFs spanning the junctions with genomic DNA confirms previous results which did not indicate sequence similarities to toxins or allergens in soybean 40-3-2 (EFSA GMO Panel, 2010; EFSA, 2017b).

The updated bioinformatic analyses for event 40-3-2 did not reveal any DNA sequence that could provide sufficient length and identity which could facilitate horizontal gene transfer (HGT) by double homologous recombination, confirming previous conclusions (EFSA GMO Panel, 2010; EFSA, 2017b). Given the results of this analysis and that the recombinant DNA in soybean 40-3-2 does not confer selective advantages to microorganisms, the GMO Panel identified no safety concern linked to an unlikely but theoretically possible HGT.

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

The GMO Panel evaluated the reports of the additional studies provided (Appendix B). The applicant provided new information on the sequence of the event. However, the quality of the study could not be assessed since the sequencing data was not submitted. Therefore, the GMO Panel assessed this application under the assumption that the sequence of the event is identical to the sequence of the originally assessed event (EFSA GMO Panel, 2018).

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 40-3-2.

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-023 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on soybean 40-3-2.

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 40-3-2. This general surveillance is coordinated by CropLife Europe and implemented by selected operators (federations involved in soybean grains import, storage 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-023, 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

Under the assumption that the DNA sequence of the event in soybean 40-3-2 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-023 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean 40-3-2 (EFSA GMO Panel, 2010).

5. Documentation as provided to EFSA

- Letter from the European Commission to EFSA received on 8 February 2021 for the continued marketing of genetically modified soybean 40-3-2 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Bayer Agriculture BV on behalf of Bayer CropScience LP (EFSA-GMO-RX-023)

- The application was made valid on 17 May 2021
- Additional Information (Clock 1) was requested on 7 July 2021
- Additional Information (Clock 1) was received on 7 September 2021
- Additional Information (Clock 2) was requested on 21 October 2021
- Additional Information (Clock 2) was received on 18 March 2022
- Additional Information (Clock 3) was requested on 1 April 2022
- Additional Information (Clock 3) was received on 15 July 2022
- Additional Information (Clock 4) was requested on 14 September 2022
- Additional Information (Clock 4) was received on 26 October 2022

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Abbreviations

EPSPS	5-enolpyruvulshikimate-3-phosphate synthase
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

Appendix A – List of relevant publications identified by the applicant through systematic literature searches (January 2010–April 2022)

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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 40-3-2

Study identification	Title
RAR-10-346	Meta-Analysis of Grain from Commercial Roundup Ready® and Conventional Soybean Varieties Grown in the United States and Canada from 2000 to 2009
REG-10-518/ MSL0023409	Compositional Analyses of Commercial Roundup Ready® and Conventional Soybean Varieties Grown in the United States in 2010
REG-2018-0744/ MSL0030112	Sequence Analysis of the 40-3-2 Inserts in the Single Trait Product 40-3-2
SCR-2016-0535	Additional Assessment of the in vitro Digestibility of CP4 EPSPS Protein by Pepsin and Pancreatin