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SCIENTIFIC OPINION

Assessment of genetically modified soybean MON 87769 for renewal authorisation under Regulation (EC) No 1829/2003 (dossier GMFF-2023-21253)

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

Following the submission of dossier GMFF-2023-21253 under Regulation (EC) No 1829/2003 from 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 stearidonic acid producing genetically modified soybean MON 87769, 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, post-market monitoring reports, an evaluation of the literature retrieved by a scoping review, a search for 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. Under the assumption that the DNA sequence of the event in soybean MON 87769 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2023-21253 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 87769.

KEYWORDS

Articles 11 and 23, MON 87769, Regulation (EC) No 1829/2003, renewal, soybean

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SUMMARY

Following the submission of dossier GMFF-2023-21253 under Regulation (EC) No 1829/2003 from 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 stearidonic acid producing genetically modified soybean MON 87769. The scope of the renewal dossier GMFF-2023-21253 is for the renewal of the placing on the market of soybean MON 87769 for food and feed uses, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account dossier GMFF-2023-21253, 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 dossier GMFF-2023-21253 contained: post-market environmental monitoring reports, post-market monitoring reports, an evaluation of the literature retrieved by a scoping review, a search for 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.

Under the assumption that the DNA sequence of the event in soybean MON 87769 considered for renewal is identical to the sequences of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2023-21253 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 87769 (EFSA GMO Panel, 2014).

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1 | INTRODUCTION

1.1 | Background

On 11 March 2024, the European Food Safety Authority (EFSA) received from the European Commission (EC) dossier GMFF-2023-21253 for the renewal of the authorisation of soybean MON 87769 (Unique Identifier MON-87769-7), submitted by Bayer CropScience LP (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003.[1]

Following receipt of dossier GMFF-2023-21253, EFSA informed the Member States (MS) and made the summary of the application available to the public on the Open EFSA portal.[2]

EFSA checked the dossier 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 25 July 2024 EFSA declared the application valid and made the valid application available to the MS and the European Commission (EC).

Following the submission of application EFSA-GMO-UK-2009-76 and the publication of the EFSA scientific opinion (EFSA GMO Panel, 2014), the placing on the market of soybean MON 87769 for (a) foods and food ingredients containing, consisting of, or produced from this GM soybean, (b) feed containing, consisting of, or produced from this GM soybean, and (c) products containing this GM soybean or consisting of it for any other use than (a) and (b), excluding cultivation in the EU, was authorised by Commission Implementing Decision (EU) 2015/686.[4] A copy of these authorisations were provided by the applicant.[5]

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 6 months to issue a scientific opinion on dossier GMFF-2023-21253. 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 5).

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.[6] The MS had 3 months to make their opinion known on dossier GMFF-2023-21253 as of date of validity.

1.2 | Terms of Reference as provided by the requestor

EFSA and its GMO Panel were requested to carry out a scientific risk assessment of soybean MON 87769 for the renewal of authorisation, according to Articles 11 and 23 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 including the opinions of the nominated risk assessment bodies of the MS.[7]

In addition to the present scientific opinion on soybean MON 87769, 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 OpenEFSA portal,[8] 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 applicant has submitted a confidential and a non-confidential version of the dossier GMFF-2023-21253 following the EFSA requirements as detailed in EFSA GMO Panel (2015a) and EFSA (2021).

[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-2024-00152.
[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 (EU) 2015/686 of 24 April 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87769 (MON-87769-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council*. Amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019 and by Commission Implementing Decision (EU) 2021/184 of 12 February 2021.
[5]Dossier number: GMFF-2023-21253. Technical dossier – Information to support the risk assessment – The authorization for the placing of the GM food and/or feed onto the market in EU.
[6]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.
[7]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.
[8]https://open.efsa.europa.eu/questions/EFSA-Q-2024-00152.

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In accordance with Art. 38 of the Regulation (EC) No 178/2002[9] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, the non-confidential version of the dossier has been published on OpenEFSA. According to Art. 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[10] EFSA carried out a public consultation on the non-confidential version of the dossier from 17 March to 7 April 2025 for which no comments were received.

The GMO Panel based its scientific assessment of soybean MON 87769 on the valid dossier GMFF-2023-21253, additional information provided by the applicant during the risk assessment, relevant scientific comments submitted by EU MS and peer-reviewed scientific publications.

In the frame of the contracts OC/EFSA/MESE/2022/03-01-SC17 and OC/EFSA/GMO/2021/06, the contractor performed preparatory work and delivered reports on the methods applied by the applicant in performing literature search and updated bioinformatic analyses, respectively.

2.1.1 | Post-market- monitoring and post-market environmental monitoring reports[11]

Post-market monitoring

Soybean MON 87769 expressed a Δ6 desaturase protein and a Δ15 desaturase protein both involved in the desaturation of endogenous fatty acids into stearidonic acid (SDA).

During the pre-market risk assessment of soybean MON 87769, the compositional analysis in seeds showed an alteration of the fatty acid profile as compared to its conventional counterpart; this alteration was characterised by the appearance of four new fatty acids (SDA, γ-linolenic acid and two trans-fatty acids) and a reduction in linoleic acid (LA) (EFSA GMO Panel, 2014).

The nutritional assessment in humans was focused on SDA as the most significant modification in MON 87769 soybean oil, and on the consequences of the reduction in the level of the essential fatty acid linoleic acid. At the time of the pre-market risk assessment, dietary intake estimations were considered to assess the nutritional relevance of the changes, using a replacement scenario assuming the consumption of different foods containing MON 87769 soybean oil. Based on these assumptions, the GMO Panel concluded that the consumption of soybean MON 87769 does not represent a nutritional concern in humans (EFSA GMO Panel, 2014).

Notwithstanding the safety of soybean MON 87769, the GMO Panel recommended that the applicant should provide a proposal for a post-market monitoring (PMM) plan with the aim to confirm the expected consumption and the application of conditions of use in accordance with Regulation (EC) No 1829/2003.

As specified in the market authorisation (Commission Implementing Decision (EU) 2015/686 of 24 April 2015; Art. 5 and Annex (g)), the authorisation holder should collect import data into Europe of soybean MON 87769 oil and MON 87769 soybeans for oil extraction for the placing on the market as or in products for food. Following the identification of imports, available information on consumption should be collected (i.e. quantities of vegetable oil consumption by Member State, including shifts in quantities between the different types of oils consumed; data on the different categories of food and feed uses of MON 87769 oil). Based on this information, the pre-market nutritional assessment might need revision, accordingly.

The applicant provided annual PMM reports for soybean MON 87769 oil and soybean for oil extraction for the placing on the market as or in products for food only for the period 2015–2023 in line with EFSA GMO Panel Opinion (2014) and Commission Implementing Decision (EU) 2015/686. The outcome of the PMM reports is presented in Section 3.1.

Post-market environmental monitoring

Based on the outcome of the initial food and feed risk assessment, a post-market environmental monitoring plan for monitoring of GM food and feed was 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 MON 87769, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of soybean MON 87769 (EFSA GMO Panel, 2014), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided 10 annual PMEM reports covering a reporting period from April 2015 to June 2024. 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 established by EuropaBio[12] for the collection of informa-

[9]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, pp. 1–48.

[10]Decision available at: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf.

[11]Dossier number: GMFF-2023-21253. Technical dossier – Information to support the risk assessment – Post-market monitoring and post-market environmental monitoring reports; additional information: 04/12/2025.

[12]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 1st January 2021.

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tion 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 possibly containing soybean MON 87769; (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[13]

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed scoping reviews covering the period from January 2014 to February 2025, in accordance with the recommendations on literature search outlined in (EFSA, 2010, 2019).

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. After applying the eligibility/inclusion criteria defined a priori by the applicant, four publications were identified as relevant for food and feed safety assessment. The relevant publications are listed in Appendix A.

2.1.3 | Updated bioinformatic[14]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatics dataset for soybean MON 87769 including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed proteins 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 proteins PjΔ6D and NcΔ15D regarding their capacity to trigger celiac disease symptoms (EFSA GMO Panel, 2017). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

2.1.4 | Additional documents or studies performed by or on behalf of the applicant[15]

In line with the renewal guidance requirements (EFSA, 2021; EFSA GMO Panel, 2015a), the applicant provided an overview on the worldwide approvals of soybean MON 87769 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.

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[16]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of soybean MON 87769 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA GMO Panel, 2014).

2.1.6 | Monitoring plan and proposal for improving the conditions of the original authorisation[17]

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 MON 87769 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

[13]Dossier number: GMFF-2023-21253. Technical dossier – Information to support the risk assessment – New information-Systematic search and evaluation of the literature; additional information: 26/8/2025.

[14]Dossier number: GMFF-2023-21253. Technical dossier – Information to support the risk assessment – New information- Updated bioinformatics; additional information: 20/1/2025, 26/8/2025.

[15]Dossier number: GMFF-2023-21253. Technical dossier – Information to support the risk assessment – New information-Additional documents or studies performed by or on behalf of the applicant; additional information: 26/8/2025; 02/12/2025.

[16]Dossier number: GMFF-2023-21253. Technical dossier – Information to support the risk assessment – New information- Overall assessment.

[17]Dossier number: GMFF-2023-21253. Technical dossier – Information to support the risk assessment – Post-market environmental monitoring plan.

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(EC) No 1829/2003 (EFSA GMO Panel, 2015a). The opinions 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 and post-market environmental monitoring reports

Post-market monitoring

As authorisation holder, the applicant collaborated with third parties, such as farmers, crushers and exporters to collect information on the quantities of MON 87769 soybean oil and MON 87769 soybean for oil extraction imported in the EU for the placing on the market as or in products for food. On the basis of this information, the applicant confirmed that no MON 87769 soybean oil or MON 87769 soybean for crushing into oil was exported to the EU for the placing on the market as or in products for food. Therefore, the GMO Panel considers that there is no need to update the pre-market nutritional assessment.

Post-market environmental monitoring

The GMO Panel assessed the nine PMEM reports submitted by the applicant. During the general surveillance activities covering the authorisation period of soybean MON 87769, no adverse effects were reported by the applicant. This was confirmed by the evaluation of the results of the annual literature searches and the annual communications by the operators collating reports of adverse effects from their member organisations and companies. No safety concerns were identified by the GMO Panel.

3.2 | Evaluation of the systematic search and evaluation of literature

The GMO Panel assessed the applicant's literature searches on soybean MON 87769 and the newly expressed proteins PjΔ6D and NcΔ15D. The overall quality of the performed literature searches is acceptable.

The GMO Panel reviewed the publications identified as relevant by the applicant. No new information raising safety concerns for human and animal health and the environment which would change the original risk assessment conclusions on soybean MON 87769 was identified (EFSA GMO Panel, 2014).

3.3 | Evaluation of the updated bioinformatic analyses

Updated bioinformatics analyses to assess the potential interruption of soybean endogenous genes confirm previous results indicating that no known endogenous genes were interrupted (EFSA GMO Panel, 2014, 2015b).

The updated analysis of the amino acid sequence of the newly expressed proteins PjΔ6D and NcΔ15D reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. Moreover, the updated bioinformatics analyses of the newly created ORFs within the insert and spanning the junctions between the insert and genomic DNA confirm previous results which did not indicate sequence similarities to toxins or allergens (EFSA GMO Panel, 2014, 2015b).

The applicant provided updated bioinformatic analysis to identify sequence similarity between sequences of the event MON 87769 and sequences from the updated microbial databases. The results confirmed previous conclusions (EFSA GMO Panel, 2014, 2015b). Given the results of this analysis and that the recombinant DNA in soybean MON 87769 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 performed by or on behalf of the applicant

Taking into account (i) the relevance for molecular characterisation, human and animal safety and the environment; and (ii) the scope of this renewal application, the applicant declared that there were no unpublished studies produced, controlled or sponsored by the applicant or provided to the applicant by a third party and not previously submitted to the EU since soybean MON 87769 was authorised.

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3.5 | Evaluation of the overall assessment

The GMO Panel evaluated the overall assessment provided by the applicant and confirms that there is no evidence in renewal dossier GMFF-2023-21253 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on soybean MON 87769.

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

Post-market monitoring

The GMO Panel recommends a PMM in food in accordance with Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013, and in line with the recommendations described in EFSA GMO Panel scientific Opinion (2014) and Commission Implementing Decision (EU) 2015/686. On the other hand, the GMO Panel confirms that, in line with the recommendations described in EFSA GMO Panel scientific Opinion (2014) and in accordance with Commission Implementing Decision (EU) 2015/686, a PMM in feed is not needed unless there are imports of MON 87769 soybean oil and MON 87769 soybeans for oil extraction into the EU for the placing on the market as or in products for food (Article 5 of Commission Implementing Decision (EU) 2015/686).[18]

Post-market environmental monitoring

The PMEM plan covers general surveillance of imported GM plant material, including soybean MON 87769. This general surveillance is coordinated by CropLife Europe 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 dossier GMFF-2023-21253, 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.

3.7 | Labelling

In accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003, the applicant proposed in renewal dossier GMFF-2023-21253 specific labelling for MON 87769 soybean: '*genetically modified soybean with stearidonic acid*'. The EFSA GMO Panel considered the labelling as proposed by the applicant, taking into account the altered composition and nutritional values of soybean MON 87769. In the absence of new information provided by the applicant and based on the compositional data of soybean MON 87769 seeds and the derived oil as submitted during the pre-market risk assessment (EFSA GMO Panel, 2014), the EFSA GMO Panel considers that this proposal is consistent with the compositional data of this soybean.

4 | CONCLUSIONS

Under the assumption that the DNA sequence of the event in soybean MON 87769 considered for renewal is identical to the sequences of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2023-21253 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 87769 (EFSA GMO Panel, 2014).

5 | DOCUMENTATION PROVIDED TO EFSA

- Letter from the European Commission to EFSA received on 11 March 2024 for the continued marketing of genetically modified soybean MON 87769 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Bayer CropScience LP (GMFF-2023-21253).
- The application was made valid on 25 July 2024.
- Additional Information (Clock 1) was requested on 26 November 2024.
- Additional Information (Clock 1) was received on 20 January 2025.
- Additional Information (Clock 2) was requested on 18 February 2025.
- Additional Information (Clock 2) was received on 26 August 2025.
- Additional Information (Clock 3) was requested on 01 December 2025.
- Additional Information (Clock 3) was received on 02 December 2025.

[18]The GMO Panel considered that future drivers for PMM might also be required in case of novel uses of feed products or novel feed products.

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- Additional Information (Clock 4) was requested on 04 December 2025.
- Additional Information (Clock 4) was received on 04 December 2025.

ABBREVIATIONS

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

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The Panel wishes to thank the members of its standing Working Groups on Molecular Characterisation, Food/Feed and Environmental Risk Assessment for the preparatory work on this scientific opinion.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2024-00152

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EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2014). Scientific opinion on application (EFSA-GMO-UK-2009-76) for the placing on the market of soybean MON 87769 genetically modified to contain stearidonic acid, for food and feed uses, import and processing under regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal*, *12*(5), 3644. https://doi.org/10.2903/j.efsa.2014.3644

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

List of relevant publications identified by the applicant through literature searches (January 2014 to February 2025)

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