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Adopted: 10 December 2025

DOI: 10.2903/j.efsa.2026.9843

efsa JOURNAL

SCIENTIFIC OPINION

Assessment of genetically modified soybean MON 94313 (application GMFF-2022-6595)

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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

Genetically modified soybean MON 94313 was developed to confer tolerance to dicamba, glufosinate, 2,4-D and mesotrione-based herbicides. These properties were achieved by introducing the *dmo, pat, ft_t.1 and tdo* expression cassettes. The molecular characterisation data and bioinformatics analyses do not identify issues requiring food/feed safety assessment. None of the identified differences in the agronomic/phenotypic and compositional characteristics tested between soybean MON 94313 and its conventional counterpart need further assessment, except for methionine and Gly m Bd 28K, which underwent additional evaluation and were found to not raise any safety or nutritional concerns. The GMO Panel does not identify safety concerns regarding the toxicity and allergenicity of the DMO, PAT, FT_T.1 and TDO proteins as expressed in soybean MON 94313 and finds no evidence that the genetic modification would change the overall safety of soybean MON 94313. In the context of this application, the consumption of food and feed from soybean MON 94313 does not represent a nutritional concern in humans and animals, and no post-market monitoring of food/feed is considered necessary. In the case of release of processed soybean MON 94313 material, or accidental spillage of viable GM soybean seeds into the environment, this would not raise environmental safety concerns. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of soybean MON 94313. The GMO Panel concludes that soybean MON 94313 is as safe as its conventional counterpart and the tested non-GM soybean varieties with respect to potential effects on human and animal health and the environment.

KEYWORDS

DMO, FT_T.1, genetic engineering, GM, MON 94313, PAT, soybean (*Glycine max*), TDO and import and processing

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SUMMARY

Following the submission of application GMFF-2022-6595 under Regulation (EC) No 1829/2003 from Bayer CropScience LP (referred to hereafter as 'the applicant'), the Panel on Genetically Modified Organisms of the European Food Safety Authority (referred to hereafter as 'GMO Panel') was asked to deliver a Scientific Opinion on the safety of genetically modified (GM) herbicide-tolerant soybean (*Glycine max* L.) MON 94313 according to Regulation (EU) No 503/2013. The scope of application GMFF-2022-6595 is for import, processing and food and feed uses within the European Union (EU) of MON 94313 and does not include cultivation in the EU.

In this scientific opinion, the GMO Panel reports on the outcome of its risk assessment of soybean MON 94313 according to the scope of the application GMFF-2022-6595. The GMO Panel conducted the assessment of soybean MON 94313 in line with the principles described in Regulation (EU) No 503/2013 and its applicable guidelines for the risk assessment of GM plants. The molecular characterisation data establish that soybean MON 94313 contains a single insert consisting of one copy of the *dmo*, *pat*, *ft_t.1* and *tdo* expression cassettes. The quality of the sequencing methodology and data sets was assessed by the EFSA GMO Panel and complies with the requirements listed in the EFSA Technical Note. Bioinformatics analyses of the sequences encoding the newly expressed proteins (NEPs), the sequences corresponding to open reading frames (ORFs) within the insert or spanning the junctions between the insert and genomic DNA as well as the flanking regions do not raise safety concerns. The stability of the inserted DNA and of the introduced traits is confirmed over several generations. The methodology used to quantify the levels of the DMO, PAT, FT_T.1 and TDO proteins is considered adequate. The protein characterisation data comparing the biochemical, structural and functional properties of plant and *Escherichia coli*-produced DMO, PAT, FT_T.1 and TDO proteins indicate that these proteins are equivalent, and the *E. coli*-produced proteins can be used in the safety studies.

Considering the selection of test materials, the field trial sites and associated management practices, as well as the agronomic/phenotypic characterisation as indicator of the overall field trial quality, the GMO Panel concludes that the field trials are appropriate to support the comparative analysis. None of the identified differences in the agronomic/phenotypic and compositional characteristics tested between soybean MON 94313 and its conventional counterpart need further assessment, except for methionine and Gly m Bd 28K, which underwent additional evaluation and were found to not raise any safety or nutritional concerns. The GMO Panel does not identify safety concerns regarding the toxicity and allergenicity of the DMO, PAT, FT_T.1 and TDO proteins as expressed in soybean MON 94313 and finds no evidence that the genetic modification would change the overall safety of soybean MON 94313. In the context of this application, the consumption of food and feed from soybean MON 94313 does not represent a nutritional concern in humans and animals. The GMO Panel concludes that soybean MON 94313 is as safe as the conventional counterpart and non-GM soybean reference varieties tested, and no post-market monitoring of food/feed is considered necessary.

Considering the introduced traits, the outcome of the agronomic and phenotypic analysis and the routes and levels of exposure, soybean MON 94313 would not raise safety concerns in the case of release of processed soybean MON 94313 or accidental spillage of viable GM soybean seeds into the environment. The post-market environmental monitoring (PMEM) plan and reporting intervals are in line with the intended uses of MON 94313.

Based on the relevant publications identified through the literature searches, the GMO Panel does not identify any safety issue pertaining to the intended uses of MON 94313.

The GMO Panel concludes that soybean MON 94313 is as safe as its conventional counterpart and the tested non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment.

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1 | INTRODUCTION

The scope of the application GMFF-2022-6595 is for food and feed uses, import and processing of soybean MON 94313 and does not include cultivation in the European Union (EU). Soybean MON 94313 was developed to confer tolerance to dicamba, glufosinate, 2,4-D and mesotrione-based herbicides.

1.1 | Background

On 16 September 2022, the European Food Safety Authority (EFSA) received from the Competent Authority of The Netherlands application GMFF-2022-6595 for authorisation of soybean MON 94313 (Unique Identifier MON-94313-8), submitted by Bayer CropScience LP (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003.[1] Following receipt of application EFSA-Q-2022-00575, EFSA informed EU Member States and the European Commission and made the application available to them. Simultaneously, EFSA published a summary of the application.[2]

EFSA checked the application for compliance with the relevant requirements of Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013,[3] with the EFSA guidance documents, and when needed, asked the applicant to supplement the initial application. On 1 December 2022, EFSA declared the application valid.

From validity date, EFSA and the Panel on Genetically Modified Organisms of the European Food Safety Authority (referred to hereafter as 'GMO Panel') endeavoured to respect a time limit of 6 months to issue a scientific opinion on application EFSA-Q-2022-00575. Such time limit was extended whenever EFSA and/or 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 EU Member States and European Commission (for further details, see the section 'Documentation', below). In accordance with Regulation (EC) No 1829/2003, EFSA consulted the nominated risk assessment bodies of EU Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC.[4] The EU Member States had 3 months to make their opinion known on application EFSA-Q-2022-00575 as of the 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 MON 94313 in the context of its scope as defined in application EFSA-Q-2022-00575.

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. In addition to the present scientific opinion, EFSA was also asked to report on the particulars listed under Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003, but not to give an opinion on them because they pertain to risk management.[5]

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a confidential and a non-confidential version of a dossier following the 'EFSA guidelines for the submission of an application to comply with the specific provisions of Regulation (EU) No 503/2013', [3]. and of the 'Administrative Guidance for the preparation of applications' (EFSA, 2021a, 2021b).

In accordance with Art. 38 of Regulation (EC) No 178/2002[6] 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.[7]

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,[8] EFSA carried out a public consultation on the

[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/study-inventory/EFSA-Q-2022-00575.

[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]Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 12.3.2001, p. 1–38.

[5]These particulars are available online at: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00330.

[6]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, p. 1–48.

[7]https://open.efsa.europa.eu/questions/EFSA-Q-2022-00330.

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

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non-confidential version of the application from 20 September to 11 October 2023 for which no comments were received.

The GMO Panel based its scientific assessment of soybean MON 94313 on the valid dossier GMFF-2022-6595, additional information provided by the applicant during the risk assessment, scientific comments submitted by EU Member States and relevant scientific publications.

2.2 | Methodologies

The GMO Panel conducted its assessment in line with the principles described in Regulation (EU) No 503/2013, the applicable guidelines (i.e. EFSA GMO Panel, 2010a, 2011a, 2011b, 2015; EFSA Scientific Committee, 2011) and explanatory notes and statements (i.e. EFSA, 2010, 2014, 2017, 2018, 2019a, 2019b; EFSA GMO Panel, 2010b, 2018, 2021a) for the risk assessment of GM plants.

For this application, in the context of the contracts OC/EFSA/GMO/2018/04, OC/EFSA/MESE/2022/03-01-SC17, OC/EFSA/GMO/2020/01, OC/EFSA/GMO/2021/06, EOI/EFSA/SCIENCE/2020/01 – CT 02 GMO and EOI/EFSA/2022/01 – CT NIF 2023 02, the contractors performed preparatory work for the evaluation of the applicant's literature search, the completeness and quality of DNA sequencing information, the bioinformatics analyses on soybean MON 94313 and methods applied for the statistical analysis of the 90-day and 28-day toxicity studies.

3 | ASSESSMENT[9]

3.1 | Introduction

Soybean MON 94313 expresses genes encoding a dicamba mono-oxygenase (DMO) protein, the phosphinothricin acetyltransferase (PAT) protein, a 2,4-D dioxygenase protein (FT_T.1) and the triketone dioxygenase (TDO) protein to confer tolerance to dicamba, glufosinate, 2,4-D and mesotrione-based herbicides, respectively.

3.2 | Systematic literature review

The GMO Panel assessed the applicant's literature searches on MON 94313, which include a scoping review, according to the guidelines given in EFSA (2010, 2019b).

A systematic review as referred to in Regulation (EU) No 503/2013 has not been provided in support to the risk assessment of application GMFF-2022-6595. Based on the outcome of the scoping review, the GMO Panel agrees that there is limited value of undertaking a systematic review for soybean MON 94313 at present.

The GMO Panel considered the overall quality of the performed literature searches acceptable. The literature searches identified three non-peer-reviewed relevant publications on soybean MON 94313 from the websites of key organisations. The relevant publications are listed in Appendix A.

None of the relevant records/publications identified through the literature searches reported information pointing to safety issues associated with soybean MON 94313 relevant to the scope of this application.

3.3 | Molecular characterisation[10]

3.3.1 | Transformation process and vector constructs

Soybean MON 94313 was developed by *Agrobacterium tumefaciens* (also known as *Rhizobium radiobacter*)-mediated transformation. Meristem explants of soybean variety A3555 were co-cultured with a disarmed *A. tumefaciens* strain AB30 containing the vector PV-GMHT529103. The plasmid PV-GMHT529103 used for the transformation contains two separate T-DNAs, each with a right and left border: T-DNA I with the *dmo*, *pat*, *ft_t.1* and *tdo* expression cassettes, and T-DNA II with the *aadA* and the *splA* expression cassettes. Although both T-DNAs were initially inserted during transformation, they were not genetically linked, and T-DNA II was segregated away; therefore, only T-DNA I is present in the soybean MON 94313 genome.

T-DNA I carries four expression cassettes containing the following genetic elements:

– The *dmo* expression cassette, consisting of the promoter, leader sequence and intron of the polyubiquitin gene *UBQ3* from *Arabidopsis thaliana*; the chloroplast targeting sequence of the *APG6* gene from *Arabidopsis thaliana*; the plant

[9] https://open.efsa.europa.eu/dossier/GMFF-2022-5890.

[10] Additional information: 16/2/2023, 22/6/2023, 03/8/2023, 21/9/2023, 29/1/2024, 21/2/2024 and 19/7/2024.

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codon-optimised coding sequence (CDS) of the dicamba mono-oxygenase (*dmo*) protein from *Stenotrophomonas maltophilia*; the 3′ UTR sequence of the aluminium-induced *SALI3-2* gene from *Medicago truncatula*.
- The *pat* expression cassette, consisting of the synthetic GSP579 promoter, based on multiple promoter and 5′ UTR sequences from *Arabidopsis thaliana* (To et al., 2021); the synthetic GSI102 intron, based on multiple intron sequences from *Arabidopsis thaliana* (To et al., 2021); the plant codon-optimised CDS of the phosphinothricin N–acetyltransferase (PAT) protein of *Streptomyces viridochromogenes*; the 3′ UTR of a putative Hsp20 gene from *Medicago truncatula*.
- The *ft_t.1* expression cassette, consisting of promoter, 5′ UTR and intron of the polyubiquitin gene *UBQ10* from *Arabidopsis thaliana*; the plant codon optimised CDS of a modified version of the R-2,4 dichlorophenoxypropionate dioxygenase (*RdpA*) gene of *Sphingobium herbicidovorans* that encodes an aryloxyphenoxypropionate (FOP) and 2,4-D dioxygenase protein (FT_T.1); the guf-Mt2 3′ UTR of a gene of unknown function from *Medicago truncatula*.
- The *tdo* expression cassette, consisting of the synthetic GSP576 promoter, based on multiple promoter and 5′ UTR sequences from *Arabidopsis thaliana* (To et al., 2021) and the GSI17 intron, based on multiple intron sequences from *Arabidopsis thaliana* (To et al., 2021); the codon-optimised CDS of the *triketone dioxygenase* (TDO) gene from *Oryza sativa*; the GST7 3′ UTR, based on multiple 3′ UTR sequences from *Zea mays* (To et al., 2021).

T-DNA II carries two expression cassettes containing the following genetic elements:

- The *splA* expression cassette, consisting of promoter, 5′ UTR and enhancer sequences of an unknown seed protein gene (*Usp*) from *Vicia faba*, the CDS of the *splA* gene from *Agrobacterium tumefaciens* encoding the sucrose phosphorylase protein, and the 3′ UTR of the nopaline synthase (*nos*) gene from *Agrobacterium tumefaciens*.
- The *aadA* expression cassette, consisting of the enhancer of the 35S promoter of figwort mosaic virus (FMV), the promoter, 5′ UTR and intron sequences of the *EF–1α* gene from *Arabidopsis thaliana*, the chloroplast targeting sequence of the *SHKG* gene from *Arabidopsis thaliana*, the CDS of the *aadA* gene from *E. coli* and the 3′ UTR of the *E9* gene from *Pisum sativum*.

The vector backbone contains elements necessary for the maintenance and selection of the plasmid in bacteria.

T-DNA II was used for selecting the transformed plants and, after self-pollination of R0 plants, only those in which T-DNA II was segregated away were selected in the R1 generation.

3.3.2 | Transgene constructs in the GM plant

Molecular characterisation of soybean MON 94313 was performed by next-generation sequencing (NGS) and junction sequence analysis (JSA) to determine insert copy number and confirm the absence of plasmid backbone and T-DNA II sequences and NGS on PCR-amplified fragments to determine size and organisation of the inserted sequences.

The EFSA GMO Panel assessed the data and found it compliant with the requirements listed in EFSA GMO Panel (2018), both in terms of the approach, the coverage and sensitivity.

NGS/JSA of the whole genome indicated that soybean MON 94313 contains a single insert, consisting of a single copy of the T-DNA I in the same configuration as in the PV-GMHT529103 transformation vector. NGS/JSA also indicated the absence of vector backbone and T-DNA II sequences in the soybean genome.

The nucleotide sequence of the entire insert of soybean MON 94313 together with 1000 bp of the 5′ and 1000 bp of the 3′ flanking regions was determined. The insert of 10196 bp is identical to the T-DNA I of PV-GMHT529103, except for the deletion of 215 bp of the right border region and 210 bp of the left border region.

A comparison with the pre-insertion locus indicated that 40 bp was deleted from the soybean genomic DNA. The possible interruption of known endogenous soybean genes by the insertion in soybean MON 94313 was evaluated by bioinformatics analyses of the pre-insertion locus and of the genomic sequences flanking the insert. The results of these analyses did not indicate the interruption of any known endogenous gene in soybean MON 94313.

The results of segregation (see Section 3.3.5) and bioinformatics analyses are compatible with a single insertion in the nuclear genome.

Bioinformatics analyses of the amino acid sequence of the newly expressed DMO, PAT, FT_T.1 and TDO proteins revealed no significant similarities to toxins and allergens. In addition, bioinformatics analyses of the newly created open reading frames (ORFs) within the insert and spanning the junctions between the insert and genomic DNA also did not indicate significant similarities to toxins or allergens.

To assess the possibility for horizontal gene transfer (HGT) by homologous recombination (HR), the applicant performed a sequence identity analysis of the inserted DNA in soybean MON 94313, which consists of four expression cassettes containing plant-derived regulatory sequences and plant codon optimised CDSs, with microbial DNA. The likelihood and potential consequences of plant-to-bacteria transfer are described in Section 3.6.1.2.1.

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3.3.3 | Protein characterisation and equivalence

Soybean MON 94313 expresses four new proteins: DMO, PAT, FT_T.1 and TDO. Given the technical restraints in producing large enough quantities from plants, these proteins were recombinantly produced in *Escherichia coli*. A set of biochemical methods was employed to demonstrate the equivalence between the soybean and *E. coli*-derived DMO, PAT, FT_T.1 and TDO. Purified proteins from these two sources were characterised and compared in terms of their biochemical, structural and functional properties.

DMO protein characterisation and equivalence

Sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) and western blot (WB) analysis showed that both plant and *E. coli*-produced DMO proteins had the expected molecular weight of ~35 kDa and were comparably immunoreactive to DMO protein-specific antibodies. Glycosylation detection analysis demonstrated that none of the DMO proteins were glycosylated. Amino acid sequence analysis of the plant-derived and the previously analysed *E. coli*-produced DMO protein by mass spectrometry (MS) methods showed that both proteins matched the deduced sequence as defined by the *dmo* gene that is identical to that assessed in the previously assessed event MON 87429 (EFSA GMO Panel, 2022). Functional equivalence was demonstrated by an in vitro assay which showed that plant and *E. coli*-derived DMO proteins had comparable enzymatic activity.

PAT protein characterisation and equivalence

SDS-PAGE and WB analysis showed that both plant and *E. coli*-produced PAT proteins had the expected molecular weight of ~22 kDa and were comparably immunoreactive to PAT protein-specific antibodies. Glycosylation detection analysis demonstrated that none of the PAT proteins were glycosylated. Amino acid sequence analysis of the plant-derived and the previously analysed *E. coli*-produced PAT protein by MS methods showed that both proteins matched the deduced sequence as defined by the *pat* gene that is identical to that assessed in previously assessed events such as maize 1507 and maize MON 87429 (EFSA, 2005; EFSA GMO Panel, 2022). In addition, the MS data showed that the N-terminal methionine of the plant-produced PAT protein was truncated. Such modifications are common in eukaryotic proteins (e.g. Polevoda & Sherman, 2000). Functional equivalence was demonstrated by an in vitro assay which showed that plant and *E. coli*-derived PAT proteins had comparable enzymatic activity.

FT_T.1 protein characterisation and equivalence

SDS-PAGE and WB analysis showed that both plant and *E. coli*-produced FT_T.1 proteins had the expected molecular weight of ~34 kDa and were comparably immunoreactive to FT_T.1 protein-specific antibodies. Glycosylation detection analysis demonstrated that none of the FT_T.1 proteins were glycosylated. Amino acid sequence analysis of the plant-derived and the previously analysed *E. coli*-produced FT_T.1 protein by MS methods showed that both proteins matched the deduced sequence as defined by the *ft_t.1* gene. Functional equivalence was demonstrated by an in vitro assay which showed that plant and *E. coli*-derived FT_T.1 proteins had comparable enzymatic activity.

TDO protein characterisation and equivalence

SDS-PAGE and WB analysis showed that both plant and *E. coli*-produced TDO proteins had the expected molecular weight of ~37 kDa and were comparably immunoreactive to TDO protein-specific antibodies. Glycosylation detection analysis demonstrated that none of the TDO proteins were glycosylated. Amino acid sequence analysis of the plant-derived and the previously analysed *E. coli*-produced TDO protein by MS methods showed that both proteins matched the deduced sequence as defined by the *tdo* gene. In addition, the MS data showed that the N-terminal methionine of the plant- and microbe-produced TDO protein was truncated. Such modifications are common in eukaryotic proteins (e.g. Polevoda & Sherman, 2000). Functional equivalence was demonstrated by an in vitro assay which showed that plant and *E. coli*-derived TDO proteins had comparable enzymatic activity.

The protein characterisation data comparing the biochemical, structural and functional properties of plant and *E. coli*-produced DMO, PAT, FT_T.1, and TDO proteins indicate that these proteins are equivalent, and the *E. coli*-derived proteins can be used in the safety studies.

3.3.4 | Information on the expression of the insert

Protein levels of DMO, PAT and FT_T.1 were analysed by Luminex multiplexed antibody-linked bead-based assays and those of TDO were analysed by enzyme-linked immunosorbent assay (ELISA) on material harvested in a field trial across five locations in the USA during the 2020 growing season. Samples analysed included flower (BBCH 61–71), forage (BBCH 77), grain (BBCH 99), leaf (BBCH 14–15, BBCH 17–69, BBCH 61–71, BBCH 77) and root (BBCH 77) from plants treated and not treated with dicamba, glufosinate, 2,4-D and mesotrione herbicides. The mean values and standard errors of protein

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expression levels in flowers ($n = 20$), forage ($n = 20$) and grains ($n = 20$) of the DMO, PAT, FT_T.1 and TDO proteins used to estimate human and animal dietary exposure (see Section 3.5.4) are reported in Table 1.

TABLE 1 Mean values ($n = 20$) and standard deviation of NEP levels in grains [μg/g dry weight (dw) and μg/g fresh weight (fw)] and forage and flowers (μg/g dw) from MON 94313.

	Dicamba, glufosinate, 2,4-D and mesotrione herbicide treatment			
	Not treated		Treated	
Tissue	μg/g dry weight (dw)	μg/g fresh weight (fw)	μg/g dry weight (dw)	μg/g fresh weight (fw)
Grain (BBCH 99)				
DMO	38[a] ± 1.3[b] (27–47)[c]	35 ± 1.2 (25–43)	40 ± 1.2 (32–49)	37 ± 1.1 (29–45)
FT_T.1	5.7 ± 0.14 (4.2–7.0)	5.3 ± 0.13 (3.9–6.5)	6.1 ± 0.16 (4.7–7.2)	5.7 ± 0.15 (4.4–6.6)
PAT	3.5 ± 0.082 (2.5–4.2)	3.2 ± 0.076 (2.3–3.9)	3.8 ± 0.14 (2.6–4.6)	3.5 ± 0.13 (2.4–4.3)
TDO	4.8 ± 0.36 (2.2–7.8)	4.4 ± 0.34 (2.1–7.2)	5.0 ± 0.36 (2.8–8.1)	4.6 ± 0.33 (2.6–7.5)
Forage (BBCH 77)				
DMO	130 ± 4.5 (100–170)		150 ± 7.4 (100–230)	
FT_T.1	10 ± 0.28 (7.9–13)		11 ± 0.48 (7.5–15)	
PAT	11 ± 0.70 (5.3–19)		12 ± 0.74 (6.7–18)	
TDO	11 ± 0.60 (4.3–14)		12 ± 0.58 (8.8–17)	
Flower (BBCH 61–71)				
DMO	26 ± 1.8 (12–45)		25 ± 1.2 (16–39)	
FT_T.1	19 ± 0.88 (12–26)		18 ± 0.74 (13–25)	
PAT	17 ± 0.66 (10–21)		17 ± 0.49 (11–21)	
TDO	12 ± 0.96 (5.7–20)		13 ± 0.92 (2.3–20)	

[a]Mean value.
[b]Standard error.
[c]Range.

3.3.5 | Inheritance and stability of inserted DNA

Genetic stability of soybean MON 94313 insert was assessed using NGS to sequence the insert and the flanking regions from five generations (R3, R4, R5, R6, R7), while segregation analysis was performed by PCR-based analysis from three consecutive generations (F2, F3, F4). The results indicate that all the plants tested retained a single copy of the insert and flanking regions, which were stably inherited.

The results support the presence of a single insertion, segregating in a Mendelian fashion.

3.3.6 | Conclusion on molecular characterisation

The molecular characterisation data establish that soybean MON 94313 contains a single insert consisting of one copy of the *dmo*, *pat*, *ft_t.1* and *tdo* expression cassettes. Bioinformatics analyses of the sequences encoding the newly expressed proteins, the sequences corresponding to ORFs within the insert or spanning the junctions between the insert and genomic DNA, as well as the flanking regions, do not raise any safety concerns. The stability of the inserted DNA was confirmed over several generations. The methodology used to quantify the levels of the DMO, PAT, FT_T.1 and TDO proteins is considered adequate. The protein characterisation data comparing the biochemical, structural and functional properties of plant and *E. coli*-derived DMO, PAT, FT_T.1 and TDO proteins indicate that the *E. coli*-derived proteins are equivalent to the corresponding plant-derived ones and that the *E. coli*-derived proteins can be used in the safety studies.

3.4 | Comparative analysis[11]

3.4.1 | Overview of studies conducted for the comparative analysis

Application EFSA-Q-2022-00575 presents data on agronomic and phenotypic characteristics as well as on forage and seed composition of soybean MON 94313 (Table 2).

[11]Additional information: 16/2/2023.

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TABLE 2 Overview of the comparative analysis studies to characterise the soybean MON 94313 provided in application EFSA-Q-2022-00575.

Study focus	Study details	Comparator	Non-GM reference varieties
Agronomic, phenotypic and compositional analysis	Field study, USA, 2020, eight sites[a]	A3555	15[b]

Abbreviation: GM, genetically modified.

[a]The field trial sites were located in Story and Jefferson, Iowa; Warren, Illinois; Clinton, Indiana; Butler, Missouri; York, Nebraska; Miami, Ohio; and Walworth, Wisconsin.

[b]Non-GM soybean with their corresponding maturity group indicated in brackets were Asgrow A3253 (3.2); Asgrow A3956 (3.9); Channel 3241C (3.2); Channel 3341C (3.3); DairyLand DSR3200 (3.2); LG Seeds C3400 (3.4); LG Seeds C3848 (3.8); Pioneer P35A41 (3.5); Pioneer P38A10 (3.8); Stewart 3326C (3.3); Stewart 3916C (3.9); Stine 33I03 (3.3); Stine 36H02 (3.9); Stine 3920-2 (3.6); Stone 3915C (3.9).

3.4.2 | Experimental field trial design and statistical analysis

At each field trial site, the following materials were grown in a randomised complete block design with four replicates: soybean MON 94313 not exposed to the intended herbicides, soybean MON 94313 exposed to the intended herbicides, the comparator A3555 and four non-GM reference varieties.

The agronomic, phenotypic and compositional data were analysed as specified by EFSA GMO Panel (2010b, 2011a). This includes, for each of the two treatments of MON 94313, the application of a difference test (between the GM soybean and the comparator) and an equivalence test (between the GM soybean and the set of non-GM commercial reference varieties). The results of the equivalence test are categorised into four possible outcomes (I-IV, ranging from equivalence to non-equivalence).[12]

3.4.3 | Suitability of selected test materials

3.4.3.1 | *Selection of the test materials*

Soybean MON 94313 was obtained using the non-GM soybean variety A3555 as recipient line, which was also used as the non-GM comparator in the field trials. The EFSA GMO Panel considers the selected variety (A3555) to be the conventional counterpart for the comparative analysis.

The GM soybean MON 94313 and its conventional counterpart belong to maturity group 3.5 that is appropriate for a wide range of growing environments across North America.

Commercial non-GM reference varieties with maturity groups ranging from 3.2 to 3.9 were included in the field trials (see Table 2). Based on the provided information on the maturity group, the GMO Panel considers the selected non-GM reference varieties appropriate for the comparative assessment.

3.4.3.2 | *Seed production and quality*

Seeds of soybean MON 94313 and the conventional counterpart used in the 2020 field trials (see Table 2) were produced, harvested and stored under similar conditions before being sown in the field trials. The seed lots were verified for their purity via event-specific quantitative PCR analysis. The seeds were tested for their germination capacity under warm and cold temperature conditions.[13] Germination capacity of soybean MON 94313 was compared with its conventional counterpart and of four reference soybean varieties.[14] Differences were observed that indicate a lower germination capacity of the conventional counterpart relative to soybean MON 94313.[15] The germination capacity of soybean MON 94313 was within the range of the non-GM reference varieties. The GMO Panel considers that the starting seed used as test material in the agronomic, phenotypic and compositional studies was acceptable.

3.4.3.3 | *Conclusion on suitability*

The GMO Panel concludes that the soybean MON 94313, the conventional counterpart and the non-GM soybean reference varieties were properly selected and are therefore acceptable for the comparative analysis.

[12]In detail, the four outcomes are category I (indicating full equivalence to the non-GM reference varieties); category II (equivalence is more likely than non-equivalence); category III (non-equivalence is more likely than equivalence); and category IV (indicating non-equivalence).

[13]Warm temperature condition corresponds approximately to 25° for 8 days and cold to 10°C for 7 days followed by 7 days at 25°C.

[14]These were Stewart 3326C; DairyLand DSR3200; Asgrow A3253 and Stewart 3916C.

[15]GM soybean MON 94313 showed a mean germination of 100% and 99.3% while the non-GM comparator showed a mean of 97.5% and 96.3% under warm and cold temperature conditions, respectively.

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3.4.4 | Representativeness of the receiving environments

3.4.4.1 | *Selection of field trial sites*

The selected field trials sites were located in commercial soybean growing regions of the United States. The soil and climatic characteristics of the selected fields[16] correspond to optimal, near optimal and sub-optimal conditions for soybean cultivation (Sys et al., 1993). The GMO Panel considers that the selected sites reflect commercial soybean-growing regions in which the test materials are likely to be grown.

3.4.4.2 | *Meteorological conditions*

Maximum and minimum mean temperatures and sums of precipitation were provided for each site on a weekly basis. No exceptional weather conditions were reported at any of the selected sites; therefore, the GMO Panel considers that the meteorological data set falls within the historical range of climatic conditions normally occurring at these sites.

3.4.4.3 | *Management practices*

The field trials included plots containing soybean MON 94313, plots with the conventional counterpart and plots with non-GM soybean reference varieties, managed according to local agricultural practices. In addition, the field trials included plots containing soybean MON 94313 managed following the same agricultural practices and exposed to the dicamba, glufosinate, 2,4-D and mesotrione-based herbicides. Glufosinate-ammonium and mesotrione-containing herbicides were applied as a single application at the BBCH 12–13 growth stage,[17] while 2,4-D- and dicamba-containing herbicides were applied as a single application at the BBCH 15–17.

The justification provided by the applicant in support of the application of herbicides was not sufficiently detailed. However, based on the indication of the manufacturers, the GMO Panel considers that the rate and amount of the intended herbicides were adequate. The GMO Panel considers that the management practices, including sowing, harvesting and application of plant protection products, were appropriate for the selected receiving environments.

3.4.4.4 | *Conclusion on representativeness*

The GMO Panel concludes that the geographical locations, soil and climatic characteristics, meteorological conditions and management practices of the field trial sites are typical for receiving environments where the tested materials could be grown.

3.4.5 | Agronomic and phenotypic analysis

Ten agronomic and phenotypic endpoints[18] plus information on abiotic stressors, disease incidence and arthropod damage were collected from the field trial sites (see Table 2).

The statistical analysis (Section 3.4.2) was applied to all the endpoints, with the following results:

- For soybean MON 94313 (not treated with the intended herbicides), the test of difference identified statistically significant differences with the comparator for days to flowering and seed weight. All these endpoints fell under equivalence category I or II.
- For soybean MON 94313 (treated with the intended herbicides), the test of difference identified statistically significant differences with the comparator for days to maturity, plant height and seed weight. All these endpoints fell under equivalence category I.

3.4.6 | Compositional analysis

Soybean MON 94313 seeds and forage harvested from eight sites (Table 2) were analysed for 76 constituents (seven in forage and 69 in seeds), including those recommended by OECD (OECD, 2012). The statistical analysis was not applied to nine seed constituents because their concentration in more than half of the samples was below the limit of quantification.[19]

[16]Soil types of the field trials were silt loam, silty clay loam, clay loam, loam and sandy loam; soil organic matter ranged from 0.7% to 2.7%; pH ranged from 5.7 to 7.0; average temperatures and sum of precipitations during the usual soybean growing season ranged, respectively, from 14.9°C to 20.2°C and from 256 to 808 mm.

[17]BBCH scale describes phenological stages (Meier, 2001).

[18]Early stand count, days to flowering, days to maturity, plant height, lodging, fruit count, final stand count, moisture, yield and seed weight.

[19]Caprylic acid (C8:0), capric acid (C10:0), lauric acid (C12:0), myristoleic acid (C14:1), pentadecanoic acid (C15:0), pentadecenoic acid (C15:1), γ-linolenic acid (C18:3), eicosatrienoic acid (C20:3), arachidonic acid (C20:4).

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The statistical analysis was applied to a total of 67 constituents (60 in seeds[20] and seven in forage[21]); a summary of the outcome of the test of difference and the test of equivalence is presented in Table 3:

- For soybean MON 94313 not treated with the intended herbicides, statistically significant differences with the conventional counterpart were found for 31 endpoints (one in forage and 30 in seeds). All these endpoints for which significant differences were found between soybean MON 94313 and the conventional counterpart fell under equivalence category I or II. The equivalence test could not be done for methionine and Gly m Bd 28K because of the lack of variation among the non-GM reference varieties.
- For soybean MON 94313 treated with the intended herbicides, statistically significant differences with the conventional counterpart were found for 19 endpoints (one in forage and 18 in seeds). All these endpoints for which significant differences were found between soybean MON 94313 and the conventional counterpart fell under equivalence category I or II.

TABLE 3 Outcome of the comparative compositional analysis in seeds and forage for MON 94313. The table shows the number of endpoints in each category.

		Test of difference[a]			
		Not-treated[c]		Treated[c]	
		Not different	Significantly different	Not different	Significantly different
Test of equivalence[b]	Category I/II	36	29[d]	46	19[d]
	Category III/IV	–	–	–	–
	Not categorised	–	2[e]	2[f]	–
	Total endpoints	67		67	

[a]Comparison between soybean MON 94313 and its conventional counterpart.

[b]Four different outcomes: category I (indicating full equivalence to the non-GM reference varieties); category II (equivalence is more likely than non-equivalence); category III (non-equivalence is more likely than equivalence); and category IV (indicating non-equivalence). Not categorised means that the test of equivalence was not applied because of the lack of variation among the non-GM reference varieties.

[c]Treated/not treated with the intended herbicides.

[d]Endpoints with significant differences between soybean MON 94313 and its conventional counterpart falling in equivalence category I–II. For forage, treated only: ash; not treated only: total fat. For seeds, treated only: protein, total fat, gly m 7; not treated only: phosphorus, alanine, cystine, serine, tryptophan, heptadecanoic acid (C17:0), heptadecenoic acid (C17:1), linoleic acid (C18:2), arachidic acid (C20:0), genistein, gly m 4, phytic acid, raffinose; both treated and not treated: carbohydrates, moisture, aspartic acid, glutamic acid, isoleucine, leucine, lysine, proline, valine, palmitic acid (C16:0), oleic acid (C18:1), linolenic acid (C18:3), α-tocopherol, daidzein, glycitein.

[e]Endpoints not categorised for equivalence and with significant differences between the soybean MON 94313 and its conventional counterpart: methionine and Gly m Bd 28K (seeds, not treated).

[f]Endpoints not categorised for equivalence and without significant differences between soybean MON 94313 and its conventional counterpart: methionine and Gly m Bd 28K (seeds, treated).

The GMO Panel assessed all significant differences between soybean MON 94313 and its conventional counterpart, taking into account potential impact on plant metabolism and the natural variability observed for the set of non-GM reference varieties. Quantitative results for the endpoints showing significant differences between soybean MON 94313 and its conventional counterpart, where the equivalence test was not applied because of the lack of variation among the non-GM reference varieties, are given in Table 4.

TABLE 4 Quantitative results (estimated means and equivalence limits) for compositional endpoints in seeds and forage that are further assessed based on the results of the statistical analysis.

		Soybean MON 94313[a]			Non-GM reference varieties	
	Endpoint	Not treated	Treated	Conventional counterpart	Mean	Equivalence limits
Seeds	Methionine (% dw)	0.62*	0.64	0.65	0.62	–
	Gly m Bd 28k (% dw)	0.83*	0.79	0.77	0.77	–

Abbreviations: dw, dry weight; Treated, treated with the intended herbicides; not treated: treated only with conventional herbicides (see Section 3.4.4.3).

[a]For the MON 94313, significantly different values are marked with an asterisk.

[20]Seed constituents included proximates and fibre content (ash, carbohydrates, moisture, protein, total fat, acid detergent fibre (ADF) and neutral detergent fibre (NDF)), minerals (calcium and phosphorus), amino acids (alanine, arginine, aspartic acid, cystine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine and valine), fatty acids (myristic acid (C14:0), palmitic acid (C16:0), palmitoleic acid (C16:1), heptadecanoic acid (C17:0), heptadecenoic acid (C17:1), stearic acid (C18:0), oleic acid (C18:1), linoleic acid (C18:2), linolenic acid (C18:3), arachidic acid (C20:0), eicosenoic acid (C20:1), eicosadienoic acid (C20:2) and behenic acid (22:0)), vitamins (α-tocopherol, and phylloquinone), isoflavones (daidzein, genistein and glycitein), endogenous allergens (gly m 1, gly m 3, gly m 4, gly m 5 (β-conglycinin), gly m 6 (glycinin), gly m 7, gly m 8, gly m Bd 28k, gly m Bd 30k, Kunitz trypsin inhibitor), other compounds (phytic acid, raffinose, soybean lectin, stachyose, trypsin inhibitor).

[21]Forage constituents included moisture, protein, total fat, ash, carbohydrates, acid detergent fibre (ADF) and neutral detergent fibre (NDF).

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3.4.7 | Conclusion on comparative analysis

Considering the selection of test materials, the field trial sites and the associated management practices, as well as the agronomic–phenotypic characterisation as an indicator of the overall field trial quality, the GMO Panel concludes that the field trials are appropriate to support the comparative analysis.

Considering the natural variability observed for the set of non-GM reference varieties, the GMO Panel concludes that:

- None of the differences identified in agronomic and phenotypic characteristics tested between soybean MON 94313 and the conventional counterpart need further assessment regarding their potential environmental impact.
- None of the differences identified in forage and seed composition between the soybean MON 94313 and the conventional counterpart need further assessment regarding food and feed safety except for methionine and Gly m Bd 28K, which are further assessed in Sections 3.5.5 and 3.5.3.2, respectively.

3.5 | Food/feed safety assessment[22]

3.5.1 | Overview of overarching information for food/feed assessment

3.5.1.1 | *Compositional analysis*

The compositional analysis of soybean MON 94313 and the conventional counterpart provided by the applicant and assessed by the GMO Panel is described in Section 3.4.6.

3.5.1.2 | *Newly expressed proteins*

Four proteins, DMO, PAT, FT_T.1 and TDO, are newly expressed in soybean MON 94313.

The FT_T.1 and TDO proteins as expressed in soybean MON 94313 have not been previously assessed by the GMO Panel.

The PAT and DMO proteins in soybean MON 94313 are identical to those previously assessed by the GMO Panel, which found no safety concerns for humans and animals (i.e. farmed and companion animals) (EFSA GMO Panel, 2017a, 2017b, 2022). Therefore, the PAT and DMO proteins will not be further considered in Section 3.5.1.2.2.

3.5.1.2.1 | *Molecular characterisation*

The protein characterisation of the DMO, PAT, FT_T.1 and TDO proteins provided by the applicant and assessed by the GMO Panel is described in Section 3.3.3. Furthermore, the equivalence between the soybean MON 94313 and the *E. coli*-derived proteins used in safety studies was demonstrated.

3.5.1.2.2 | *History of safe use for consumption as food/feed of NEPs*

a. Information on the source organism

The FT_T.1 protein is encoded by the *ft_t.1* gene, a modified version of the *RdpA* gene, which encodes R-2,4-dichlorophenoxypropionate dioxygenase. This gene is derived from *S. herbicidovorans*, a Gram-negative soil bacterium not associated with human disease (Zipper et al., 1996; Takeuchi et al., 2001; Muller et al., 2006). This information on the source organism has been previously assessed in maize MON 87429 by the GMO Panel (EFSA GMO Panel, 2022).

The native TDO protein, also known as HIS1 (HPPD inhibitor sensitive 1), is encoded by an optimised version of the *tdo* gene from *Oryza sativa*, a crop plant with a long history of consumption in food and feed (Fukagawa & Ziska, 2019; Zhang, 2022). TDO protein expression is tissue-specific, with the highest levels observed in leaf blades and sheaths with little to no expression detected in roots (Brabham et al., 2022; Maeda et al., 2019). It is noted that rice leaves are not commonly used to produce food for human consumption. Occasionally, rice leaves may be used as animal feed for ruminants, in particular in tropical regions where the availability of feed is affected by a long dry season. This use is often in the form of rice straw, a by-product of rice grain production that includes both leaves and stems. Rice straw is not commonly used as a primary feed source due to its high levels of lignification and silicification, slow ruminal degradation of carbohydrates, low nitrogen content and unbalanced mineral composition (Idan et al., 2023; Sarnklong et al., 2010). Furthermore, the applicant provided additional information,[23] consisting of western blot and MS-based protein identification analyses performed on grains of three commercially available japonica rice varieties (two Koshihikari rice, and one Calrose Brown rice) and one indica variety (Jasmine rice). These analyses confirmed the presence of the TDO protein in the rice grain of these japonica varieties but not in the indica variety. The GMO Panel considers that this information offers additional contextual

[22]Dossier Part II – Section 1.4, 1.5, 1.6, 2, 3, 4, 7, and additional information: 16/2/2023, 15/3/2023, 22/6/2023, 18/10/2023, 29/1/2024, 21/2/2024, 20/8/2024, 09/12/2024, 28/2/2025, 26/3/2025, 16/4/2025, 13/8/2025, 23/9/2025, 21/10/2025. Spontaneous information: 16/4/2025, 16/11/2025.
[23]Spontaneous information: 16/11/2025 (REG-2025-0254).

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familiarity with the source. However, because of the absence of quantitative data, it does not demonstrate a history of safe use for consumption of the TDO protein.

b. Information on structure, function and mode of action of NEPs

The FT_T.1 protein is a Fe (II)/α-ketoglutarate-dependent dioxygenase, characterised by a β-helix fold and three metal-binding residues. These enzymes require iron as a metallo-cofactor and alpha-ketoglutarate as a co-substrate to degrade specific compounds. In the case of FT_T.1, these compounds include synthetic auxin and aryloxyphenoxypropionate herbicides (Chekan et al., 2019; Larue et al., 2019; Muller et al., 2006; Schleinitz et al., 2004). This information has been previously assessed by the GMO Panel (EFSA GMO Panel, 2022).

The TDO protein is a Fe (II)/α-ketoglutarate-dependent dioxygenase characterised by seven β strands that form a β-jellyroll or double-stranded β-helix topology (Duff et al., 2024). Its active site is similar to other oxygenases, with three key metal-binding residues, two histidine residues and one aspartic acid or glutamic acid residue, coordinating an iron atom essential for the enzyme's catalytic function (Duff et al., 2024; Hausinger, 2004). The enzyme utilises iron and α-ketoglutarate as cofactors in the degradation of β-triketone herbicides, including mesotrione (Dai et al., 2022). These α-ketoglutarate-dependent dioxygenases have been identified in a wide variety of organisms, including bacteria, fungi, plants and vertebrates, which have been extensively consumed by both humans and animals with no reported adverse effects (Hausinger, 2004; Kundu, 2012). However, as stated by the applicant, the specific function of the TDO protein in rice remains unknown (Maeda et al., 2019), and no consumption data for the native protein in rice grain are available.

c. Information on identity/homology of NEPs to wild-type proteins and/or other proteins in conventional food and feed sources

The FT_T.1 protein expressed in soybean MON 94313 is highly similar to the FT_T protein expressed in maize MON 87429 (EFSA GMO Panel, 2022), differing in three amino acids across the full-length sequence. Both proteins are modified versions of the wild-type RdpA protein.

The TDO protein expressed in soybean MON 94313 is identical to the HIS1 protein expressed in *Oryza sativa*, except for the N-terminal truncation of M at position 1 (See Section 3.3.3).

d. Overall conclusion of the history of safe use

The GMO Panel considers that the depth of information provided was insufficient to duly document the history of safe use for FT_T.1 and TDO consumption.

3.5.1.2.3 | *Substrate specificity*

The applicant provided a substrate specificity study for TDO. In this study, different plant endogenous metabolites were selected from the NAPRALERT database by the applicant (Bisson et al., 2016). These metabolites, alongside HPPD-inhibitor positive controls, were screened *in silico*, resulting in a selection of potential substrates based on their combined 2D and 3D structural characteristics using mesotrione as a reference molecule. These compounds were subsequently tested in vitro. The results showed that TDO had no significant activity with putative plant substrates and was specifically active against the β-triketone class of HPPD-inhibiting herbicide compounds (e.g. mesotrione, tembotrione and sulcotrione).

The applicant provided a substrate specificity study for FT_T.1 following a methodology similar to that of TDO above. However, for the *in silico* analysis, 2,4-D was used as the reference molecule and 11 synthetic herbicide compounds (FOPs and synthetic auxin herbicides) that were known substrates for FT_T enzymes and were used as positive controls. These synthetic herbicide compounds were also included in the in vitro screening, which showed FT_T.1 to be highly specific to the herbicidal substrates.

The substrate specificity of the DMO protein has been previously assessed by the GMO Panel indicating that this enzyme has a high specificity for dicamba (EFSA GMO Panel, 2013). This assessment considered a number of naturally occurring benzoic, phenolic and phenylpropanoic acids, which showed structural similarities with dicamba. Furthermore, the DMO proteins expressed in soybean MON 94313 and in soybean MON 87708 only differ on the amino acid positions 2 and 112, which are sterically distant from the catalytic site and consequently do not have an impact on the interaction with the substrate (D'Ordine et al., 2009; Dumitru et al., 2009). Therefore, the conclusions by the GMO Panel regarding studies on substrate specificity previously performed in the frame of soybean MON 87708 also apply to soybean MON 94313.

The PAT protein has been assessed by the GMO Panel in the past (EFSA GMO Panel, 2017a, 2021, 2024). PAT enzyme activity is limited to the acetylation of the glufosinate-ammonium substrate (Hérouet et al., 2005). The GMO Panel is not aware of additional information that would change its previous assessments.

3.5.1.2.4 | *Stability of NEPs*

Protein stability is one of several relevant parameters to consider in the weight-of-evidence approach in the protein safety assessment (EFSA GMO Panel, 2010c, 2011a, 2017b, 2021). The term protein stability encompasses several properties such

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as thermal stability, pH-dependent stability, proteolytic stability and physical stability (e.g. tendency to aggregate), among others (Li et al., 2019). It has been shown that a prominent trait attributed to food allergens and protein safety is protein stability (Breiteneder & Mills, 2005; Costa et al., 2021; Foo & Müller, 2021; Helm, 2001).

a. Effect of temperature and pH on NEPs

The effects of temperature and pH on PAT protein as expressed in soybean MON 94313 were previously evaluated by the GMO Panel (EFSA GMO Panel, 2017a, 2017c).

The applicant also provided additional experimental studies on the effects of temperature on the DMO, FT_T.1 and TDO proteins as expressed in soybean MON 94313, using a microbial recombinant system (Section 3.3.3). Independent samples of DMO, TDO and FT_T.1 proteins were incubated for 15 or 30 min at 25°C, 37°C, 55°C, 75°C and 95°C followed by SDS-PAGE or by a bioassay measuring their functional activity. The studies showed that the functional activity of both DMO and TDO proteins was strongly diminished at temperatures of 55°C and above when incubated for 15 and 30 min. In the case of the FT_T.1 protein, its functional activity was strongly diminished when incubated for 30 min at 55°C and when incubated for 15 and 30 min at 75°C and above.

In relation to the effect of pH on the DMO, FT_T.1 and TDO proteins, the molecular mass and immunoreactivity of the proteins were unchanged at pH 1.2 and 7.5.

b. In vitro protein degradation by proteolytic enzymes

In vitro protein degradation studies on PAT protein as expressed in soybean MON 94313 were previously evaluated by the GMO Panel (EFSA GMO Panel, 2017a).

Furthermore, the applicant provided independent studies on in vitro protein degradation (i.e. resistance to pepsin in solutions at pH ~ 1.2) of the DMO, FT_T.1 and TDO proteins, as expressed in soybean MON 94313, produced in a microbial recombinant system (Section 3.3.3). The integrity of the test DMO, FT_T.1 and TDO proteins in samples incubated at various time points was analysed by SDS-PAGE followed by protein staining or by western blotting.

Independent samples of the DMO and TDO proteins were degraded by pepsin in less than 0.5 min of incubation. In these two studies, a peptide fragment of ~3.5 kDa was visible after 5 min of incubation but it disappeared at the 10 min time point. The applicant stated that sequential (pepsin followed by pancreatin) degradation assays were not performed because no DMO and TDO protein fragments were present after 10 min digestion of pepsin. Furthermore, the applicant provided an analysis of the resistance to degradation by pancreatin in solutions at pH ~ 7.5. The DMO and TDO proteins were degraded after 5 min of incubation when analysed by western blotting.

In the case of the FT_T.1 protein, it was degraded by pepsin in less than 0.5 min of incubation. Two transient fragments of ~3.5 and 6 kDa were observed by SDS-PAGE analysis up to the 20 min time point of the pepsin digestion. Furthermore, the applicant provided an analysis of the resistance to degradation by pancreatin in solutions at pH ~ 7.5. The FT_T.1 protein was degraded after 5 min of incubation when analysed by western blotting. Lastly, the applicant also provided a study in which the FT_T.1 protein was subjected to a sequential digestion, pepsin (for 2 min) followed by pancreatin (for 2 h). The transient peptide fragments seen in the pepsin analysis were degraded at 5 min of exposure to pancreatin when analysed by SDS-PAGE. The sequential addition of digestive enzymes (i.e. gastric digestion conditions followed by an intestinal in vitro digestion) has been proposed as part of several alternative protocols of the classical pepsin resistance test to more closely simulate the physiological conditions of gastrointestinal digestion (EFSA GMO Panel, 2021). This is in line with Codex Alimentarius which indicates that alternative in vitro digestion protocols may be used where adequate justification is provided (Codex Alimentarius, 2009).

3.5.1.2.5 | *Synergistic and antagonistic interactions among NEPs*

The potential for a functional interaction among the four proteins has been assessed regarding human and animal health. Based on current scientific knowledge on the biological function of the four proteins (Table 5), no synergistic or antagonistic interactions between these four proteins which could raise safety concerns for food and feed from soybean MON 94313 are expected.

TABLE 5 Intended effects and modes of action of NEPs in soybean MON 94313.

Protein	Intended effect and mode of action in GM plant
DMO	The DMO protein confers tolerance to dicamba-containing herbicides acting by catalysing the demethylation of dicamba into the non-herbicidal compound 3,6-dichlorosalicylic acid and formaldehyde (Herman et al., 2005).
PAT	The PAT protein confers tolerance to glufosinate-based herbicides acting by acetylating L-phosphinothricin, the active isomer of the glufosinate herbicide.
FT_T.1	The FT_T.1 protein confers tolerance to 2,4-D herbicides. It is an alpha-ketoglutarate-dependent non-haem iron dioxygenase. The common reaction mechanism involves the formation of an iron oxygen intermediate that targets specific substrates, leading, in the case of FT_T.1 protein, to the degradation of synthetic auxin herbicides.
TDO	The TDO protein confers tolerance to mesotrione, a β-triketone herbicide. It is an alpha-ketoglutarate-dependent non-haem iron dioxygenase.

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3.5.1.3 | *Effect of processing*

Soybean MON 94313 will undergo existing production processes used for conventional soybean. Based on the outcome of the comparative assessment, processing of the GM soybean into food and feed products is not expected to result in products being different from those of conventional non-GM soybean varieties currently in the EU market.[24]

3.5.2 | Toxicology assessment

The strategies to assess the toxicological impact of any changes on the whole genetically modified food and feed resulting from the genetic modification focus on the assessment of (i) NEPs; (ii) new constituents other than NEPs; (iii) altered levels of food and feed constituents; and (iv) the whole genetically modified food and feed.

3.5.2.1 | *Assessment of NEPs*

Four proteins (DMO, PAT, FT_T.1 and TDO) are newly expressed in soybean MON 94313.

3.5.2.1.1 | *NEP previously assessed*

The PAT and DMO proteins were previously assessed by the GMO Panel in the context of other applications and no safety concerns for humans and animals (i.e. farmed and companion animals) were identified (EFSA GMO Panel, 2017a, 2017b, 2022). These proteins have been extensively characterised and identified to match the expected deduced amino acid sequences (Section 3.3). Updated bioinformatics analyses revealed no similarities of the PAT and DMO proteins with known toxins. The GMO Panel is not aware of any new information that would change the previous conclusion on the safety of the PAT and DMO proteins.

3.5.2.1.2 | *NEP not previously assessed*

A weight-of-evidence approach was followed by the GMO Panel to assess the toxicological profile of the newly expressed FT_T.1 and TDO proteins. The GMO Panel considered all the information relevant for their hazard assessment, including molecular characterisation, substrate specificity, history of safe use for consumption as food and feed of NEPs, stability of NEPs and synergistic or antagonistic interactions (Section 3.5.1.2). Furthermore, updated bioinformatics analyses for similarity to toxins and in vivo toxicity studies are described below.

Bioinformatics analyses

Updated bioinformatics analyses of the amino acid sequences of FT_T.1 and TDO proteins revealed no relevant similarities to known toxins (Section 3.3.2).

In vivo toxicity studies

For the assessment of the FT_T.1 and TDO proteins, the applicant provided 28-day and acute toxicity studies with each protein. The outcomes of the in vivo toxicity studies with the FT_T.1 and TDO proteins are described below.

Acute toxicity studies

An acute toxicity study in CD-1 mice, administered *E. coli*-produced FT_T.1 protein by gavage at the dose of 2000 mg/kg (body weight (bw)), showed no adverse effects.

An acute toxicity study in CD-1 mice, administered *E. coli*-produced TDO protein by gavage at the dose of 2000 mg/kg (bw), showed no adverse effects.

28-day repeated dose toxicity study with FT_T.1 protein

The 28-day repeated dose toxicity study in mice with the FT_T.1 protein was conducted in accordance with OECD TG 407 (2008) and the principles of good laboratory practice.

Crl:CD-1 mice (20/sex per group), 8- to 9-week-old at the start of dosing were allocated to five groups. Groups were administered by oral gavage: the test substance (FT_T.1 protein) at targeted nominal doses of 1000, 100 or 10 mg/kg bw per day (high, medium and low FT_T.1 protein groups); 1000 mg/kg bw per day of bovine serum albumin (BSA control group); and the vehicle (vehicle control group).

[24]On-going assessment of novel food applications (https://food.ec.europa.eu/food-safety/novel-food/authorisations/summary-applications-and-notifications_en).

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Mice were randomised to treatment groups (males and females separately) using a stratified randomisation block designed to achieve similar group mean body weights (± 20% of the mean for each sex). Animals were individually housed.

The test substance used in this study was produced by a recombinant system and reported as 100% pure. The amino acid sequence analysis by mass fingerprint analysis of the *E. coli* -produced FT_T.1 used in this 28-day toxicity study matched the deduced sequence as defined by the *ft_t.1* gene. This protein had the expected molecular weight and immunoreactivity to FT_T.1-specific antibodies, was not glycosylated and showed functional activity.

The first 10 animals per group were subject to in-life procedures and observations and to terminal procedures in accordance with OECD TG 407 (2008), except coagulation analysis; the remaining 10 animals per group were used to evaluate coagulation parameters, body weight, food consumption and clinical observation parameters only.

Deviations from the protocol reported in the study were considered minor and with no impact on the results of the study.

An appropriate range of statistical tests was performed on the results of the study. A detailed description of the methodology and statistically significant findings identified in mice is reported in Appendix B.1.

There were no FT_T.1-related incidents of mortality or clinical signs. No FT_T.1-related adverse findings were identified in any of the investigated parameters. No FT_T.1-related clinical observations or ophthalmology findings were detected.

A small number of statistically significant findings were noted, but these were not considered adverse effects of treatment for one or more of the following reasons:

- were within the normal variation[25] for the parameter in mice of this age;
- were of small magnitude;
- were identified at only a small number of time intervals with no impact on the overall value;
- exhibited no consistent pattern with related parameters or endpoints;
- exhibited no consistency with increasing dose levels.

At necropsy, no gross pathology findings related to the administration of the test item were observed. The microscopic examinations of a wide range of organs and tissues did not identify relevant differences in the incidence or severity of the histopathological findings related to the administration of the test item compared to the controls.

The GMO Panel concludes that no adverse effects were observed in this 28-day mice toxicity study on the microbially produced FT_T.1 protein, at doses up to 1000 mg/kg bw per day.

Overall conclusions of the toxicological assessment of FT_T.1 protein

Based on the above information, the GMO panel concludes that the presence of FT_T.1 protein in GM crops does not represent a toxicological concern from the consumption of food or feed.

28-day repeated dose toxicity studies with TDO protein

Two 28-day toxicity studies in CD-1 mice with TDO protein were made available by the applicant.

In an initial study, TDO was administered by gavage at 10, 100 or 1000 mg/kg bw per day. Lesions in the upper respiratory tract were present at the mid- and top doses. The applicant concluded that the observed effects were due to the gavage administration rather than to any intrinsic hazard of TDO and submitted a second 28-day study with TDO in the diet at nominal doses of 10, 100 or 1000 mg/kg bw per day. No adverse effects were reported in the dietary study.

The applicant also submitted published papers, studies on the physicochemical properties and structural stability of TDO and other comparator proteins and considerations of the relevance of the exposure routes used in the in vivo studies to support the case that the effects seen in the gavage study were unlikely to be relevant to human and animal exposures to TDO in food or feed. Considering the above-mentioned findings, the GMO panel used a weight-of-evidence (WoE) approach to assess if there were any toxicological concerns presented by TDO protein present in soybean MON94313. Details of the studies and WoE conclusions are presented below.

Detailed assessment of the 28-day studies on TDO protein

28-day (gavage) repeated dose toxicity study with TDO protein

The 28-day gavage toxicity study in mice with the TDO protein was conducted in accordance with OECD TG 407 (2008) and to the principles of good laboratory practice.

Groups of Crl:CD-1 mice (20/sex per group), 8- to 9-week-old at the start of dosing were allocated to five groups. Groups were administered by oral gavage: the test substance (TDO protein) at targeted nominal doses of 1000, 100 or 10 mg/kg bw per day (high, medium and low TDO protein groups); 1000 mg/kg bw per day of bovine serum albumin (BSA control group); and the vehicle.

[25]Although animals used in a toxicology study are of the same strain, from the same supplier and are closely matched for age and body weight at the start of the study, they exhibit a degree of variability in the parameters investigated during the study. This variability is evident even within control groups. To help reach a conclusion on whether a statistically significant finding in a test group is 'adverse' account is taken of whether the result in the test group is outside the normal range for untreated animals of the same strain and age. To do this, a number of sources of information are considered, including the standardised effect size, the standard deviations and range of values within test and control groups in the study and, if applicable, data from other studies performed in the same test facility within a small timeframe and under almost identical conditions (Historic Control Data).

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Mice were randomised to treatment groups (males and females separately) using a stratified randomisation block designed to achieve similar group mean body weights (± 20% of the mean for each sex). The GMO Panel noted that animals were singly housed.

The test substance used in this study was produced by a recombinant system and contained about 100% TDO protein. The amino acid sequence analysis of the E. coli-produced TDO used in this 28-day toxicity study was performed by MS and matched the deduced sequence defined by the *tdo* gene. This protein had the expected molecular weight and immunoreactivity to TDO-specific antibodies, was not glycosylated and showed functional activity.

The first 10 animals per group were subject to in-life procedures and observations and terminal procedures in accordance with OECD TG 407 (2008), except coagulation analysis; the remaining 10 animals per group were used to evaluate coagulation parameters, body weight, food consumption and clinical observation parameters only.

Deviations to the protocol reported in the study were considered minor deviations with no impact on the study results.

An appropriate range of statistical tests was performed on the results of the study and a detailed description of the methodology and of statistically significant findings identified in mice is reported in Appendix B.2.

A total of four deaths were recorded: two high-dose males (days 8 and 15) and two high-dose females (days 18 and 26). A series of lesions of the lungs and upper respiratory tract were reported in high-dose and mid-dose animals, which increased in severity/incidence with increasing dose. No histopathological findings were recorded at the low-dose level.

Following EFSA's requests, the applicant provided additional information[26] to support the hypothesis that the adverse effects observed in this 28-day gavage mouse toxicity study were due to gastric reflux associated with the specific characteristics of the TDO formulation used in the gavage administration and were unlikely to be relevant to exposures of TDO in food or feed. The information showed that, when tested alongside a panel of comparator proteins (DMO, FT_T.1, Cry1B.2 and BSA) in low pH buffers, the TDO protein exhibited distinct characteristics:

- Precipitation behaviour: Among the proteins tested, TDO was the only protein that precipitated at mid/high concentrations within physiologically relevant murine gastric pH conditions (approximately pH 2.5–3.0). All other comparator proteins did not precipitate across the tested pH range (pH 2.5–4.0), except for one protein comparator that precipitated only under the most extreme pH (2.5) and only at the highest concentration;
- Buffering capacity: The applicant's characterisation indicates that TDO formulations exhibit greater buffering capacity than those of the other comparator proteins and shift the pH of the buffering solution towards the protein's isoelectric region, promoting concentration-dependent protein aggregation and persistence of TDO precipitates.
- Structural stability/biophysical profile: Structural analyses showed that TDO has a higher proportion of solvent-exposed flexible loop regions and lower thermal stability (lower melting point) compared with the proteins in the panel. These features are consistent with a greater propensity of TDO to undergo pH-dependent conformational change and aggregation.

Collectively, these observations and available scientific literature[27] provide a plausible explanation by which mid/high-concentration gavage formulations of TDO could rapidly form persistent aggregates under acidic conditions. These aggregates could delay gastric emptying and thereby promote gastro-oesophageal reflux and secondary aspiration of the gastric content, which would be consistent with the observed respiratory tract lesions. Moreover, the lack of systemic findings at equivalent doses in the dietary study supports the interpretation that the gavage effects represent a local, route-specific event rather than a systemic toxic property of TDO. The mechanistic and physicochemical evidence indicates that these effects arise only under gavage-specific conditions (i.e. delivery of a high-concentration bolus of purified protein in a simple buffer and in the absence of a food matrix) that do not reflect typical human or animal dietary exposure. The GMO panel concludes that the gavage study is not relevant for the safety assessment of soybean MON 94313.

28-day (dietary) repeated dose toxicity study with TDO protein

The 28-day repeated dose toxicity feeding study in mice with the TDO protein was conducted in accordance with OECD TG 407 (2008) and to the principles of good laboratory practice (GLP).

Groups of Crl:CD1(ICR) mice (20/sex per group), approximately 8 weeks old at the start of dosing, were allocated to five groups. Groups were administered diets containing respectively: the test substance (TDO protein) at targeted nominal doses of 1000, 100 or 10 mg/kg bw per day (high, medium and low TDO protein groups); 1000 mg/kg bw per day of bovine serum albumin (BSA control group) or a basal diet (control group).

Mice were randomised to treatment groups (males and females separately) using a stratified randomisation block designed to achieve similar group mean body weights (± 20% of the mean for each sex). The GMO Panel noted that animals were singly housed.

The test substance used in this study was produced by a recombinant system and reported as 100% pure. The amino acid sequence analysis of the *E. coli*-produced TDO used in this 28-day toxicity study was determined by MS and matched the deduced sequence as defined by the *tdo* gene. This protein had the expected molecular weight and immunoreactivity to TDO-specific antibodies, was not glycosylated and showed functional activity.

[26]Additional information: 29/1/2024, 5/6/2024, 26/3/2025, 16/4/2025, 13/8/2025, 23/9/2025, 21/10/2025; spontaneous information: 16/11/2025.

[27]Additional information: 29/1/2024, 13/8/2025 (Damsch et al., 2011).

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In-life procedures and observations and terminal procedures were conducted in accordance with OECD TG 407 (2008), except for satellite animals that were not subjected to some in-life procedures (ophthalmology, functional observational battery, motor activity), clinical chemistry and pathology investigations.

Deviations to the protocol reported in the study were considered minor deviations with no impact on the study results.

Based on the results of concentration analysis by ELISA, the applicant confirmed the expected dietary concentrations (6.638, 0.664 and 0.066 g/kg diet in males and 5, 0.5 and 0.05 g/kg diet in females). The results of the test diet analysis indicated that the diet preparations were homogeneous and exhibited acceptable stability. Achieved mean intakes at the low concentration were 11.6 and 10.1 mg/kg bw per day in males and females, respectively; at the mid concentration were 111.9 and 106.4 mg/kg bw per day in males and females, respectively; and at the high concentration were 1074.0 and 1094.8 mg/kg bw per day in males and females, respectively. Activity of TDO protein in the diet was not investigated, but presence and homogeneity were confirmed using ELISA. Following a request from EFSA, the applicant clarified that the diet was prepared using standard procedures with no additional heating or processing that would be anticipated to compromise the activity/structure of the TDO protein. This was considered acceptable by the GMO Panel.

An appropriate range of statistical tests was performed on the results of the study and a detailed description of the methodology and of statistically significant findings identified in mice is reported in Appendix B.3.

There were no test diet-related incidents of mortality or clinical signs. No test diet-related adverse findings were identified in any of the investigated parameters (including the lung and upper respiratory tract). A small number of statistically significant findings were noted, but these were not considered adverse effects of treatment for one or more of the following reasons:

- were within the normal variation[27] for the parameter in mice of this age;
- were of small magnitude;
- were identified at only a small number of time intervals with no impact on the overall value;
- exhibited no consistent pattern with related parameters or endpoints.
- exhibited no consistency with increasing dose levels.

No gross pathology findings related to the administration of the test diet were observed at necropsy, and the microscopic examinations of a wide range of organs and tissues did not identify relevant differences in the incidence or severity of the histopathology findings related to the administration of the test diet compared to the control groups.

The GMO Panel concludes that no adverse effects were observed in mice in this dietary 28-day toxicity study on *E. coli*-produced TDO protein, at nominal dietary exposures up to 1000 mg/kg bw per day.

Overall conclusions of the toxicological assessment of TDO protein

A weight of evidence assessment was conducted by the GMO Panel to collectively evaluate the relevant information. This included:

- *in silico* data on homology with known toxins (Section 3.3.2);
- enzymatic activity data, including substrate specificity studies showing TDO's activity is restricted to β-triketone herbicides (Section 3.5.1.2.3);
- *in vitro* data on digestion of TDO protein (Section 3.5.1.2.4);
- data on the precipitation, structure and stability of TDO compared to BSA and other comparator proteins tested;
- the outcome of the 28-day dietary study which showed no adverse effects;
- consideration of the relevance of the exposure routes used in the studies to likely exposures in animals and humans.

On the basis of the integrated weight of evidence, the GMO panel concludes that the presence of TDO protein in GM crops is unlikely to represent a toxicological concern from the consumption of food or feed.

3.5.2.2 | *Assessment of new constituents other than NEPs*

Based on the outcome of the studies considered in the comparative analysis and molecular characterisation, no new constituents other than NEPs have been identified in seeds and forage from soybean MON 94313. Therefore, no further food/feed safety assessment of components other than NEPs is required.

3.5.2.3 | *Assessment of altered levels of food and feed constituents*

Based on the outcome of the studies considered in the comparative analysis and molecular characterisation, no altered levels of food and feed constituents have been identified in seeds and forage from soybean MON 94313, except for methionine and Gly m Bd 28K (Section 3.4.6). These changes are considered not to represent a toxicological concern, considering the biological role of the affected constituent and the magnitude of the changes. Therefore, no further toxicological assessment is needed. Further information on the relevance of these findings is provided in Sections 3.5.5.1 and 3.5.5.2, with additional details on Gly m Bd 28K available in Section 3.5.3.2.

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3.5.2.4 | *Testing of the whole genetically modified food and feed*

Based on the outcome of the molecular characterisation, comparative analysis and toxicological assessment, no indications of findings relevant to food and feed safety have been identified for soybean MON 94313 related to the stability and expression of the insert, and to modifications of toxicological concern in the composition of soybean MON 94313 (Sections 3.3, 3.4 and 3.5). Therefore, animal studies with food/feed derived from soybean MON 94313 are not considered necessary by the GMO Panel (EFSA GMO Panel, 2011a). In accordance with Regulation (EU) No 503/2013, the applicant provided a 90-day feeding study in rats fed with diets containing grains derived from soybean MON 94313.

In this study, pair-housed Crl:CD (SD) rats (16 per sex per group; 2 rats per cage) were allocated to three groups using a randomised complete block design with eight replications per sex.

Groups were fed diets containing soybean MON 94313 meal at 30% and 15% of inclusion level (the latter supplemented with 15% of the non-GM comparator soybean) and the non-GM comparator (inclusion level 30%).

The study was adapted from OECD test guideline 408 (OECD, 2018), aligned with EFSA Scientific Committee guidance (EFSA Scientific Committee, 2011) and complied with the principles of good laboratory practice (GLP) with some minor deviations described in the study report, not impacting the study results and interpretation.

The stability of the test and control materials was not analytically verified; however, it was confirmed that the diet was used in accordance with product expiration declared by the diet manufacturer. The GMO Panel considered this acceptable evidence that the constituents of the diets would be stable for the duration of the treatment. Furthermore, diet preparation procedures and regular evaluations of the mixing methods guaranteed the homogeneity and the proper concentration of the test or control substances in them.

Event-specific PCR analysis confirmed the presence of the event MON 94313 in GM grains and diets and excluded the presence of the event in the related controls.

Both the GM meals and diets were analysed for nutrients, antinutrients and potential contaminants. Balanced diets were formulated based on the specifications for PMI Certified Rodent LabDiet® #5002.

Feed and water were provided ad libitum. In-life procedures and observations and terminal procedures were conducted in accordance to OECD TG 408 (2018).

An appropriate range of statistical tests was performed on the results of the study. Detailed description of the methodology and of statistically significant findings identified in rats given diets containing meal derived from soybean MON 94313 is reported in Appendix B.4.

There were no test diet-related incidents of mortality or clinical signs. No test diet-related adverse findings were identified in any of the investigated parameters. A small number of statistically significant findings were noted, but these were not considered adverse effects of treatment for one or more of the following reasons:

- were within the normal variation[27] for the parameter in rats of this age;
- were of small magnitude;
- were identified at only a small number of time intervals with no impact on the overall value;
- exhibited no consistent pattern with related parameters or endpoints;
- exhibited no consistency with increasing incorporation levels.

No gross pathology findings related to the administration of the test diet were observed at necropsy, and the microscopic examinations of a wide range of organs and tissues did not identify relevant differences in the incidence or severity of the histopathological findings related to the administration of the test diet compared to the control group.

The GMO Panel concludes that this study is in line with the requirements of Regulation (EU) No 503/2013 and that no treatment-related adverse effects were observed in rats after feeding diets containing soybean MON 94313 meal at 15% or 30% for 90 days.

3.5.3 | Allergenicity

The strategies to assess the potential risk of allergenicity focus: (i) on the source of the recombinant proteins; (ii) on the potential of NEPs to induce sensitisation or to elicit allergic reactions in already sensitised persons; and (iii) on whether the transformation may have altered the allergenic properties of the modified plant. Furthermore, the assessment also takes into account potential adjuvant properties of NEPs, which is defined as the ability to enhance an allergic reaction.

3.5.3.1 | *Assessment of allergenicity of NEPs*

A weight-of-evidence approach was followed, taking into account all of the information obtained on NEPs, as no single piece of information or experimental method yielded sufficient evidence to predict allergenicity (Codex Alimentarius, 2009; EFSA GMO Panel, 2011a, 2017b; Regulation (EU) No 503/2013).

The *dmo, pat, ft_t.1* and *TDO* genes originate from *S. maltophilia*, *S. viridochromogenes, S. herbicidovorans* and *O. sativa*, respectively, none of which are considered common allergenic sources. The safety of the PAT and DMO proteins has been previously assessed by the GMO Panel and no safety concerns were identified (EFSA GMO Panel, 2017a, 2017c, 2022).

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Updated bioinformatics analyses of the amino acid sequences of the DMO, PAT, FT_T.1 and TDO proteins, using the criterion of more than 35% identity in a sliding window of 80 amino acids, revealed no relevant similarities to known allergens.

The studies on protein stability of the DMO, PAT, FT_T.1 and TDO proteins have been described in Section 3.5.1.2. In addition, the GMO Panel did not find an indication that the newly expressed DMO, PAT, FT_T.1 and TDO proteins at the levels expressed in soybean MON 94313 might be adjuvants.

Furthermore, the applicant provided information on the safety of the DMO, PAT, FT_T.1 and TDO proteins regarding their potential hazard to cause a coeliac disease response.[28] For such assessment, the applicant followed the principles described in the EFSA GMO Panel guidance document (EFSA GMO Panel, 2017b). The assessment of the DMO, FT_T.1 and TDO proteins identified no perfect or relevant partial matches with known coeliac disease peptide sequences. The assessment of the PAT protein revealed partial matches containing the Q/E-X1-P-X2 motif and required further investigations. These partial matches have been previously assessed by the EFSA GMO Panel (EFSA GMO Panel, 2024). Briefly, based on additional considerations on the position and nature of amino acids flanking the motif (EFSA GMO Panel, 2017b), the relevant peptides containing the motif do not raise concern as they fail to mimic gluten sequences. Therefore, no indications of safety concerns were identified by the GMO Panel.

In the context of this application, the GMO Panel considers that there are no indications that the newly expressed DMO, PAT, FT_T.1 and/or TDO proteins in MON 94313 may be allergenic.

3.5.3.2 | *Assessment of allergenicity of the whole GM plant*

Soybean is considered a common allergenic food (OECD, 2012). Therefore, any potential change in the endogenous allergenicity of the GM plant should be assessed (Regulation (EU) No 503/2013). For such assessment, the applicant included in the comparative analysis specific allergens relevant for soybean (Section 3.4.6) quantified using liquid chromatography with tandem MS, which has been previously considered acceptable (EFSA GMO Panel, 2010c, 2017b; Fernandez et al., 2013; Selb et al., 2017). These allergens were selected based on the list of potential soybean allergens described in the pertinent OECD document (OECD, 2012), and a scientific rationale supporting their selection was provided by the applicant and considered acceptable by the GMO Panel.

It is noted that the level of Gly m Bd 28K in soybean MON 94313 (untreated) showed to be statistically different as compared to the conventional counterpart (see Section 3.4.6). No equivalence limits were available for this endpoint. Despite the relative increase in Gly m Bd 28K identified in the GM when compared to non-GM,[29] no concerns were identified by the GMO Panel because: (i) no other changes were identified for any of the other nine allergens analysed; (ii) this endpoint showed no consistent differences in the treated material; (iii) the magnitude of the change accounted for ~5%; (iv) the upper limit of Gly m Bd 28K value in non-GM reference varieties was higher than that in the GM variety; (v) the low quantitative relevance of the Gly m Bd 28K in the overall allergen repertoire (~0.1%); and (vi) available information in the literature showing multi-year natural variation from non-GM varieties (Hill et al., 2017). Therefore, no changes in the levels of endogenous allergens raising concern were identified by the GMO Panel.

In the context of this application, the GMO Panel considers that there is no evidence that the genetic modification might substantially change the overall allergenicity of soybean MON 94313 when compared with that of the conventional counterpart and the non-GM reference varieties tested.

3.5.4 | Dietary exposure assessment to new constituents

In line with Regulation (EU) No 503/2013, the applicant provided dietary exposure estimates to DMO, PAT, FT_T.1 and TDO proteins newly expressed in soybean MON 94313. Dietary exposure was estimated based on protein expression levels reported in this application for soybean MON 94313 treated with the intended herbicides (dicamba, glufosinate, 2,4-D and mesotrione), the currently available consumption data and feed practices, the foods and feeds currently available on the market and the described processing conditions.

For the purpose of estimating dietary exposure, the levels of the newly expressed proteins in soybean MON 94313 seeds, forage and flowers[30] were derived from material harvested in a field trial across five locations in the United States during the 2020 growing season (Table 1, Section 3.3.4).

3.5.4.1 | *Human dietary exposure*

Chronic and acute estimations of dietary exposure to DMO, PAT, FT_T.1 and TDO proteins newly expressed in soybean MON 94313 were provided. The applicant followed the methodology described in the EFSA Statement 'Human dietary exposure assessment to newly expressed protein in GM foods' to anticipate human dietary exposure making use of summary statistics of consumption (EFSA, 2019a).

[28]Technical dossier Section 1.5, additional information 30/6/2022.

[29]Technical dossier, Study ID: REG-2021-0122.

[30]Flowers (growth stage BBCH 61–71) were used as surrogates of pollen for the analysis of the newly expressed proteins in soybean MON 94313.

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Human dietary exposure was estimated across European countries on different population groups: young population (infants, toddlers, 'other children'), adolescents, adult population (adults, elderly and very elderly) and special populations (pregnant and lactating women). Since no specific consumption data were available on commodities containing, consisting of or obtained from soybean MON 94313 seeds, a conservative scenario with 100% replacement of conventional soybean by the GM soybean was considered. Consumption figures for all relevant commodities (e.g. soya bread, textured soy protein, soya drink, tofu, etc.) were retrieved from the EFSA Comprehensive European Food Consumption Database.[31]

Mean protein expression values on a fresh weight basis are considered as the most adequate to estimate human dietary exposure (both acute and chronic) when working with raw primary commodities that are commonly consumed as processed blended commodities (EFSA, 2019a). Different recipes and factors were considered to estimate the amount of soybean seeds in the consumed commodities before assigning newly expressed protein levels to the relevant commodities.[32] No losses in the newly expressed proteins during processing were considered.

The highest anticipated acute dietary exposure (highly exposed population) was in the age class 'Infants' with estimates up to 510 μg/kg bw per day for DMO, 78.5 μg/kg bw per day for FT_T.1, 63.4 μg/kg bw per day for TDO and 48.2 μg/kg bw per day for PAT. The main contributor to the exposure in the dietary survey with the highest estimates would be 'Follow-on formula, soya-based, powder'. In the dietary exposure scenario anticipating acute consumption of soybean-derived protein supplements, the highest estimates would range between 60.6 μg/kg bw per day for PAT and 641 μg/kg bw per day for DMO proteins (in the adult population).

The highest anticipated chronic dietary exposure (highly exposed population) was in the age class 'Infants' with estimates up to 171 μg/kg bw per day for DMO, 26.4 μg/kg bw per day for FT_T.1, 21.3 μg/kg bw per day for TDO and 16.2 μg/kg bw per day for PAT. The main contributor to the exposure in the dietary survey with the highest estimates would be 'Follow-on formula, soya-based, powder'. In the dietary exposure scenario anticipating chronic consumption of soybean-derived protein supplements, the highest estimates would range between 39.4 μg/kg bw per day for PAT and 416 μg/kg bw per day for DMO proteins (in the adult population).

The GMO Panel considers pollen supplements as a possible contributor to the dietary exposure to DMO, PAT, FT_T.1 and TDO, under the assumption that these supplements might be made of pollen from soybean MON 94313. Due to the technical challenges related to the collection of pollen from soybean flowers (e.g. closed flowers, low amounts produced), the applicant analysed the presence of the newly expressed proteins in flowers as pollen surrogates (see Table 1). Following EFSA's request, detailed information was provided on how the flowers were collected and the parts included (sepals, petals, pistils and stamens).[33] The GMO Panel acknowledges the substantial uncertainty using flowers as surrogates of pollen adds to the expression levels and, therefore, to the dietary exposure assessment. However, in the absence of identified hazards posed by the newly expressed proteins, these expression levels are accepted as surrogates.

Consumption data on pollen supplements are available for few consumers across seven different European countries.[31] The low number of consumers available adds uncertainty to the exposure estimations which should be interpreted with care and only allows the estimation of dietary exposure for average consumers. The highest mean acute dietary exposure would be between 9.1 μg/kg bw per day for TDO and 17.4 μg/kg bw per day for DMO proteins in the elderly population. Similarly, the highest mean chronic dietary exposure in consumers of pollen supplements would be between 6.0 μg/kg bw per day for TDO and 11.6 μg/kg bw per day for DMO proteins, also in the elderly population.

3.5.4.2 | *Animal dietary exposure*

Anticipated dietary exposure to DMO, PAT, FT_T.1 and TDO proteins in soybean MON 94313 was estimated across different animal species, as described below, assuming the consumption of soybean products commonly entering the feed supply chain (i.e. soybean meal and forage). A conservative scenario with 100% replacement of conventional soybean products by the soybean MON 94313 products was considered.

Mean levels (dry weights) of NEPs in grains and forage from soybean MON 94313 treated with the intended herbicide used for animal dietary exposure are listed in Table 1 in Section 3.3.4.

Mean levels (dry weight) of the NEPs in soybean meal were calculated to be 1.28-fold higher than in soybean grains, based on adjusting factors that take into account the protein content in these feed materials relative to soybean seed (OECD 2012) and assuming that no protein is lost during their processing.

The applicant estimated dietary exposure to DMO, PAT, FT_T.1 and TDO proteins via the consumption of soybean meal in broiler, finishing pig and lactating dairy cow, based on default values for animal body weight, daily feed intake and inclusion rates (percentage) of soybean feedstuffs in diets/rations, as provided for the EU by OECD, 2009. Estimated dietary exposure in the concerned animals is reported in Appendix C.

To further integrate the assessment, the GMO Panel estimated the animal dietary exposure to DMO, PAT, FT_T.1 and TDO proteins via the consumption of forage in dairy cows and laying hens. Consumption of soybean forage is based on estimates for animal body weight and daily feed intake, and inclusion rates of soybean forage in animal diets (EFSA GMO Panel, 2023). Estimated dietary exposures based on the consumption of soybean forage are reported in Appendix C.

[31] https://www.efsa.europa.eu/en/applications/gmo/tools. From version updated in March 2022.

[32] Example: 100 grams of tofu contains approximately 26 g of soybean seeds. This results in ~0.9 μg of PAT per gram of tofu as compared to the 3.5 μg/g reported as DMO mean concentration in the treated soybean seeds (see Table 1).

[33] Additional information 03/8/2023.

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3.5.5 | Nutritional assessment of endogenous constituents

The intended traits of soybean MON 94313 are to confer tolerance to dicamba, glufosinate, 2,4-D and mesotrione herbicides, with no intention to alter nutritional parameters. However, levels of methionine and Gly m Bd 28K in seeds were significantly different from its non-GM comparator (see Section 3.4.6). The assessment of Gly m Bd 28K is described in Section 3.5.3. The nutritional assessment of methionine considered its biological relevance, the role of soybean as a contributor to its total intake and the magnitude and direction of the observed changes.

3.5.5.1 | *Human nutrition*

Although methionine is an indispensable amino acid (EFSA NDA Panel, 2012), the relatively small decrease (~5%) in not treated soybean MON 94313 as compared to its conventional counterpart does not raise any nutritional concern, also considering the presence of this amino acid in all dietary proteins.

3.5.5.2 | *Animal nutrition*

Methionine is an essential amino acid in all animal species (EFSA FEEDAP Panel 2012). The relatively small decrease (~5%) in not treated soybean MON 94313 as compared to its conventional counterpart does not raise any nutritional concern, also considering the presence of this amino acid in all dietary proteins. Furthermore, amino acids are usually balanced and supplemented in complete diets.

3.5.6 | Post-market monitoring of GM food/feed

Soybean MON 94313, as described in this application, does not raise any nutritional concern and is as safe as its conventional counterpart and the non-GM reference varieties tested. The GMO Panel concludes that, based on the information considered in its safety assessment, a post-market monitoring plan for food and feed is not necessary.

3.5.7 | Conclusions on the food/feed safety assessment

The proteins DMO, PAT, FT_T.1 and TDO newly expressed in soybean MON 94313 do not raise safety concerns for human and animal health. No interactions between NEPs relevant for food and feed safety were identified. The GMO Panel does not identify indications of safety concerns regarding allergenicity or adjuvanticity related to the presence of NEPs in soybean MON 94313. The GMO Panel finds no evidence that the genetic modification impacts the overall safety of soybean MON 94313 food and feed. Based on the outcome of the comparative assessment and the nutritional assessment, the GMO Panel concludes that the consumption of soybean MON 94313 does not represent any nutritional concern, in the context of the scope of this application. The GMO Panel concludes that soybean MON 94313, as described in this application, is as safe as the conventional counterpart and the non-GM reference varieties tested, and no post-market monitoring of food/feed is considered necessary.

3.6 | Environmental risk assessment and monitoring plan

3.6.1 | Environmental risk assessment[34]

Considering the scope of this application, which excludes cultivation, the environmental risk assessment (ERA) mainly takes into account: (1) the exposure of microorganisms to recombinant DNA in the gastrointestinal tract of animals fed with GM material and of microorganisms present in environments exposed to manure and faeces of these animals; and (2) the deliberate or accidental release of GM material into the environment, including spillage of viable soybean MON 94313 seeds during transportation and/or processing (EFSA GMO Panel, 2010a).

3.6.1.1 | *Persistence and invasiveness of the GM plant*

Cultivated soybean (*Glycine max* (L.) Merr.) is a species in the subgenus *Soja* of the genus *Glycine*. The species originated from eastern Asia and is a highly domesticated crop, generally unable to survive in the environment without proper management (Lu, 2005).

Occasional feral GM soybean plants may occur outside cultivation areas, but survival is limited mainly by a combination of low competitiveness, absence of a dormancy phase and susceptibility to plant pathogens (OECD, 2000). Additionally,

[34]Additional information: 16/2/2023.

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soybean is a sub-tropical species susceptible to cold climatic conditions (Bramlage et al., 1978; Staniak et al., 2020; Szczerba et al., 2021; Tyagi & Tripathi, 1983), although cold tolerance varies across maturity groups and among cultivars (Alsajri et al., 2019; Wang et al., 2023). Soybean can grow as volunteers, and the presence of volunteers of *G. max* was occasionally reported in some areas of Italy where soybean is intensively cultivated (Celesti-Grapow et al., 2010). However, as for the same reasons mentioned above, soybean seeds and seedlings usually do not survive during cold winters (Matsushita et al., 2020; Owen, 2005), and any soybean volunteers can be effectively controlled by mechanical methods or appropriate chemical control (Bond & Walker, 2009; Jhala et al., 2013; Soltani et al., 2019). Owing to this, soybean plants are often not considered problematic volunteers in temperate climates (Jhala et al., 2021). Thus, the establishment and survival of feral and volunteer soybean in the EU are currently limited and transient.

It is unlikely that the intended trait of soybean MON 94313 will provide a selective advantage to soybean plants, except when they are exposed to dicamba, glufosinate, 2,4-D and mesotrione-based herbicides. However, if this were to occur, this fitness advantage will not allow the GM plant to overcome other biological and abiotic factors (described above) limiting the plant's persistence and invasiveness. Therefore, the presence of the intended trait will not affect the persistence and invasiveness of the GM plant.

The GMO Panel concludes that it is very unlikely that soybean MON 94313 will differ from conventional soybean hybrid varieties in their ability to survive until subsequent seasons or to establish occasional feral plants under European environmental conditions in case of accidental release into the environment of viable soybean MON 94313 seeds.

3.6.1.2 | *Potential for gene transfer*

A prerequisite for any gene transfer is the availability of pathways for the transfer of genetic material, either through horizontal gene transfer (HGT) of DNA or through vertical gene flow via cross-pollination from feral plants originating from spilled grains.

3.6.1.2.1 | *Plant-to-microorganism gene transfer*

Genomic DNA can be a component of food and feed products derived from soybean. It is well documented that such DNA becomes substantially degraded during processing and digestion in the human or animal gastrointestinal tract. However, bacteria in the digestive tract of humans and animals, and in other environments, may be exposed to fragments of DNA, including the recombinant fraction of such DNA.

Current scientific knowledge of recombination processes in bacteria suggests that horizontal transfer of non-mobile, chromosome-located DNA fragments between unrelated organisms (such as from plants to bacteria) is not likely to occur at detectable frequencies under natural conditions (for further details, see EFSA, 2009).

Homologous recombination is known to facilitate horizontal transfer of non-mobile, chromosomal DNA fragments to bacterial genomes. This requires the presence of at least two stretches of DNA sequences that are similar in the recombining DNA molecules. In the case of sequence identity with the transgene itself, recombination would result in gene replacement. In the case of identity with two or more regions flanking recombinant DNA, recombination could result in the insertion of additional DNA sequences in bacteria and thus confer the potential for new properties.

In addition to homology-based recombination processes, at a lower transformation rate, the non-homologous end joining and microhomology-mediated end joining are theoretically possible (EFSA, 2009; Hülter & Wackernagel, 2008). Independently of the transfer mechanism, the GMO Panel did not identify a selective advantage that a theoretical HGT would provide to bacterial recipients in the environment.

The bioinformatics analyses for event MON 94313 revealed that there are no elements providing sufficient similarity to known bacterial DNA which would facilitate homologous recombination including the sequences of bacterial origin encoding for DMO, PAT and FT_T.1 that were modified (see Section 3.3.1).

In summary, there is no indication for an increased likelihood of horizontal transfer of DNA from soybean MON 94313 to bacteria. Given the nature of the recombinant DNA, the GMO Panel identified no safety concern linked to an unlikely but theoretically possible HGT.

3.6.1.2.2 | *Plant-to-plant gene transfer*

The potential for occasional feral soybean MON 94313 plants originating from seed import spills to transfer recombinant DNA to sexually compatible plants and the environmental consequences of this transfer were considered.

For plant-to-plant gene transfer to occur, imported GM soybean seeds need to germinate and develop into plants in areas containing sympatric wild relatives and/or cultivated soybean with synchronous flowering and environmental conditions favouring cross-pollination. It must be noted that most soybean MON 94313 seeds are processed in the countries of production or in ports of importation.

Vertical gene transfer from soybean (*G. max*) is limited to the species of the subgenus *Soja* to which *G. max* belongs to, as well as the wild relatives *G. soja* and *G. gracilis* (Zhang et al., 2023). Although wild relatives exist elsewhere, no wild relatives of the subgenus *Soja* have been reported in Europe so far (Dorokhov et al., 2004; Lu, 2005). Therefore, vertical gene transfer from GM soybean is restricted to cultivated soybean (*G. max*).

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Soybean is an annual, almost completely self-pollinating crop with a percentage of cross-pollination usually below 1% (Abud et al., 2007; Lu, 2005; OECD, 2000; Ray et al., 2003; Yoshimura et al., 2006), although natural cross-pollination rates can fluctuate significantly among different soybean varieties under particular environmental conditions, such as favourable climate for pollination and an abundance of pollinators (Ahrent & Caviness, 1994; Caviness, 1966; Gumisiriza & Rubaihayo, 1978; Kikuchi et al., 1993; Lu, 2005; Ray et al., 2003).

The potential of spilled soybean seeds to establish, grow and produce pollen is extremely low and transient (see Section 3.6.1.1). Therefore, the likelihood/frequency of cross-pollination between occasional feral GM soybean plants resulting from seed spillage and weedy or cultivated soybean plants is also extremely low. Even if cross-pollination would occur, the GMO Panel is of the opinion that the likelihood of environmental effects as a consequence of the spread of genes from occasional feral GM soybean plants in Europe will not differ from that of conventional soybean varieties for the reasons given in Section 3.6.1.1, even if exposed to the intended herbicides.

In conclusion, the GMO Panel considers that the likelihood of environmental effects as a consequence of the spread of genes from soybean MON 94313 in Europe will not differ from that of conventional soybean varieties.

3.6.1.3 | *Interactions of the GM plant with target organisms*

Taking the scope of application GMFF-2022-6595 (no cultivation) and the absence of target organisms into account, potential interactions of occasional feral soybean MON 94313 plants arising from seed import spills with target organisms are not considered a relevant issue.

3.6.1.4 | *Interactions of the GM plant with non-target organisms*

The environmental risk assessment considers potential effects of the GM plant on populations of non-target organisms, defined as all those species directly or indirectly exposed to the GM plant and which are not targets of the newly expressed metabolite(s) it expresses. The GMO Panel evaluated the potential hazards of the NEPs and considered that the environmental exposure of non-target organisms to spilled GM soybean material or occasional feral GM soybean plants arising from spilled soybean MON 94313 grains will be limited. Additionally, ingested proteins are typically degraded before entering the environment through manure and faeces of animals fed with GM soybean (Harmon & Swanson, 2020; Miner-Williams et al., 2014; Mok & Urschel, 2020; Santos-Hernández et al., 2018; van Bruchem et al., 1985), and the data provided for the assessment of protein stability (see Section 3.5.1.2.4) support that also the NEPs will be degraded. As compared to non-GM soybean, the GMO Panel considers that potential interactions of soybean MON 94313 with non-target organisms do not raise any environmental safety concern.

3.6.1.5 | *Interactions with biogeochemical cycles*

Biogeochemical cycles encompass the microbiologically mediated movement, transformation and storage of carbon, nitrogen and other compounds in the soil. The GMO Panel evaluated the potential hazards of the NEPs and considered that the environmental exposure to spilled GM soybean material or occasional feral GM soybean plants arising from spilled soybean MON 94313 grains will be limited, whereas exposure to manure and faeces of animals fed with soybean MON 94313 material is expected to be higher. Additionally, ingested proteins are typically degraded before entering the environment through manure and faeces of animals fed with GM soybean (Harmon & Swanson, 2020; Miner-Williams et al., 2014; Mok & Urschel, 2020; Santos-Hernández et al., 2018; van Bruchem et al., 1985), and the data provided for the assessment of protein stability (see Section 3.5.1.2.4) support that also the NEPs will be degraded. As compared to non-GM soybean, the GMO Panel considers that potential interactions of soybean MON 94313 with biogeochemical cycles do not raise any environmental safety concern.

3.6.2 | Post-market environmental monitoring

The objectives of a post-market environmental monitoring (PMEM) plan, according to Annex VII of Directive 2001/18/EC, are: (1) to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO, or its use, in the ERA is correct; and (2) to identify the occurrence of adverse effects of the GMO, or its use, on human health or the environment that were not anticipated in the ERA.

Monitoring is related to risk management, and thus, a final adoption of the PMEM plan falls outside the mandate of EFSA. However, the GMO Panel gives its opinion on the scientific rationale of the PMEM plan provided by the applicant (EFSA GMO Panel, 2011b).

As the ERA did not identify potential adverse environmental effects from soybean MON 94313, no case-specific monitoring is required.

The PMEM plan proposed by the applicant for soybean MON 94313 includes: (1) the description of a monitoring approach involving operators (federations involved in import and processing), reporting to the applicant via a centralised system, any observed adverse effect(s) of GMOs on human health and the environment; (2) a coordinating system established by CropLife Europe for the collection of information recorded by the various operators; and (3) the review of relevant

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scientific publications retrieved from literature searches (Lecoq et al., 2007; Windels et al., 2008). The applicant proposes to submit a PMEM report on an annual basis for the duration of the authorisation period.

The GMO Panel considers that the scope of the PMEM plan provided by the applicant is consistent with the intended uses of soybean MON 94313. The GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan.

3.6.2.1 | *Conclusion of the environmental risk assessment and monitoring plan*

The GMO Panel concludes that it is unlikely that soybean MON 94313 would differ from conventional crop varieties in its ability to persist under European environmental conditions. Taking into account the scope of application GMFF-2022-6595, interactions of occasional feral soybean MON 94313 plants with the biotic and abiotic environment are not considered to be relevant issues. The analysis of HGT from soybean MON 94313 to bacteria does not indicate a safety concern. Therefore, considering the introduced trait/s, the outcome of the agronomic and phenotypic analysis, and the routes and levels of exposure, the GMO Panel concludes that soybean MON 94313 would not raise safety concerns in the event of release of processed GM soybean or the accidental release of viable GM soybean seeds into the environment.

The scope of the PMEM plan provided by the applicant and the reporting intervals are in line with the intended uses of soybean MON 94313.

4 | OVERALL CONCLUSIONS

The GMO Panel was asked to carry out a scientific assessment of soybean MON 94313 for import, processing and food and feed uses in accordance with Regulation (EC) No 1829/2003. The molecular characterisation data establish that soybean MON 94313 contains a single insert consisting of one copy of the *dmo, pat, ft_t.1 and tdo* expression cassette. The quality of the sequencing methodology and data sets was assessed by the EFSA GMO Panel and is in compliance with the requirements listed in the EFSA Technical Note. Bioinformatics analyses of the sequences encoding the newly expressed proteins, the sequences corresponding to ORFs within the insert or spanning the junctions between the insert and genomic DNA, as well as the flanking regions, do not raise any safety concerns. The stability of the inserted DNA and of the introduced trait is confirmed over several generations. The methodology used to quantify the levels of the DMO, PAT, FT_T.1 and TDO proteins is considered adequate. The protein characterisation data comparing the biochemical, structural and functional properties of the MON 94313-produced DMO, PAT, FT_T.1 and TDO proteins indicate that these proteins are equivalent. Considering the selection of test materials, the field trial sites and the associated management practices, as well as the agronomic/phenotypic characterisation as an indicator of the overall field trial quality, the GMO Panel concludes that the field trials are appropriate to support the comparative analysis. None of the identified differences in the agronomic/phenotypic and compositional characteristics tested between soybean MON 94313 and its conventional counterpart needed further assessment, except for the levels of methionine and Gly m Bd 28K, which underwent additional evaluation and were found not to raise any safety or nutritional concerns. The GMO Panel does not identify safety concerns regarding the toxicity and allergenicity of the DMO, PAT, FT_T.1, TDO proteins as expressed in MON 94313, and finds no evidence that the genetic modification would change the overall allergenicity of MON 94313. In the context of this application, the consumption of food and feed from soybean MON 94313 does not represent a nutritional concern in humans and animals. The GMO Panel concludes that soybean MON 94313 is as safe as the conventional counterpart and non-GM soybean reference varieties tested, and no post-market monitoring of food/feed is considered necessary. The GMO Panel concludes that additional environmental effects as compared to conventional soybean resulting from the release of the GM soybean into the environment are unlikely. The PMEM plan and reporting intervals are in line with the intended uses of MON 94313. Based on the relevant publications identified through the literature searches, the GMO Panel does not identify any safety issues pertaining to the uses of MON 94313. The GMO Panel concludes that soybean MON 94313 is as safe as its conventional counterpart and the tested non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment.

5 | DOCUMENTATION AS PROVIDED TO EFSA

The documentation is available online at: https://open.efsa.europa.eu/questions/EFSA-Q-2022-00575.

ABBREVIATIONS

2,4-D	2,4-dichlorophenoxyacetic acid
BBCH	Biologische Bundesanstalt, Bundessortenamt and CHemical industry
bp	base pair
BSA	bovine serum albumin
bw	body weight
CDS	coding sequence
DMO	dicamba mono-oxygenase

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dw	dry weight
ELISA	Enzyme-Linked Immunosorbent Assay
ERA	environmental risk assessment
FOB	functional observational battery.
FT_T.1	Fe (II)/α-ketoglutarate-dependent dioxygenase
FMV	figwort mosaic virus
fw	fresh weight
GLP	good laboratory practice
GM	genetically modified
GMO	genetically modified organisms
GMO Panel	Panel on Genetically Modified Organisms
HGT	horizontal gene transfer
HR	homologous recombination
JSA	Junction Sequence Analysis
MS	mass spectrometry
NEP	newly expressed protein
Nos	nopaline synthase
OECD	Organisation for Economic Co-operation and Development
ORFs	open reading frames
PAT	phosphinothricin acetyltransferase
PCR	polymerase chain reaction
PMEM	post-market environmental monitoring
RdpA	2,4 dichlorophenoxypropionate dioxygenase
SDS-PAGE	sodium dodecyl sulphate polyacrylamide gel electrophoresis.
SES	standardised effect sizes
T-DNA	transfer-deoxyribonucleic acid
TDO	triketone dioxygenase
UTR	Untranslated Region
WB	Western blot
WoE	weight-of-evidence

ACKNOWLEDGEMENTS

The Panel wishes to thank the members of the Working Groups on Molecular Characterisation, Food and Feed Safety Assessment and Working Group On Comparative Analysis and Environmental Risk Assessment for the preparatory work on this scientific output and EFSA staff members Martina Bonatti, Sara Jacchia and Reinhilde Schoonjans for the support provided to this scientific output.

REQUESTOR

Competent Authority of the Netherlands

QUESTION NUMBER

EFSA-Q-2022-00575

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NOTE

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This Scientific Opinion may be subject to editing once the confidentiality decision making on the additional information received is completed.

REFERENCES

Abud, S., de Souza, P. I. M., Vianna, G. R., Leonardecz, E., Moreira, C. T., Faleiro, F. G., Júnior, J. N., Monteiro, P. M. F. O., Rech, E. L., & Aragão, F. J. L. (2007). Gene flow from transgenic to nontransgenic soybean plants in the Cerrado region of Brazil. *Genetics and Molecular Research*, *6*, 445–452.

18314732, 2026, 1, Downloaded from https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2026.9843 by European Commission, Wiley Online Library on [10/03/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Ahrent, D. K., & Caviness, C. E. (1994). Natural cross-pollination of 12 soybean cultivars in Arkansas. *Crop Science*, *34*, 376–378.
Alsajri, F. A., Singh, B., Wijewardana, C., Irby, J. T., Gao, W., & Reddy, K. R. (2019). Evaluating soybean cultivars for low- and high-temperature tolerance during the seedling growth stage. *Agronomy*, *9*, 13.
Bisson, J., McAlpine, J., Graham, J., & Pauli, G. F. (2016). *NAPRALERT, from an historical information silo to a linked resource able to address the new challenges in natural products chemistry and Pharmacognosy. Center for Natural Product Technologies* (pp. 1–2). University of Illinois at Chicago.
Bond, J. A., & Walker, T. W. (2009). Control of volunteer glyphosate-resistant soybean in rice. *Weed Technology*, *23*, 225–230.
Brabham, C., Norsworthy, J. K., Sha, X., Varanasi, V. K., & González-Torralva, F. (2022). Benzobicyclon efficacy is affected by plant growth stage, HPPD inhibitor sensitive 1 (HIS1) expression and zygosity in weedy rice (Oryza sativa). *Weed Science*, *70*, 328–334.
Bramlage, W. J., Leopold, A. C., & Parrish, D. J. (1978). Chilling stress to soybeans during imbibition. *Plant Physiology*, *61*, 525–529.
Breiteneder, H., & Mills, E. N. (2005). Molecular properties of food allergens. *Journal of Allergy and Clinical Immunology*, *115*, 14–23.
Caviness, C. E. (1966). Estimates of natural cross-pollination in Jackson soybeans in Arkansas. *Crop Science*, *6*, 211–212.
Celesti-Grapow, L., Pretto, F., Carli, E., & Blasi, C. (2010). *Flora vascolare alloctona e invasiva delle regioni d'Italia* (p. 208). Casa Editrice Università La Sapienza.
Chekan, J. R., Ongpipattanakul, C., Wright, T. R., Zhang, B., Bollinger, J. M., Rajakovich, L. J., Krebs, C., Cicchillo, R. M., & Nair, S. K. (2019). Molecular basis for enantioselective herbicide degradation imparted by aryloxyalkanoatedioxygenases in transgenic plants. *Proceedings of the National Academy of Sciences of the United States of America*, *116*, 13299–13304.
Codex Alimentarius. (2009). *Foods derived from modern biotechnology* (p. 85). Codex Alimentarius Commission, Joint FAO/ WHO Food Standards Programme. https://www.fao.org/docrep/011/a1554e/a1554e00.htm
Costa, J., Bavaro, S. L., Benede, S., Diaz-Perales, A., Bueno-Diaz, C., Gelencser, E., Klueber, J., Larre, C., Lozano-Ojalvo, D., Lupi, R., Mafra, I., Mazzucchelli, G., Molina, E., Monaci, L., Martın-Pedraza, L., Piras, C., Rodrigues, P. M., Roncada, P., Schrama, D., … Holzhauser, T. (2021). Are physicochemical properties shaping the allergenic potency of plant allergens? *Clinical Reviews in Allergy and Immunology*, *62*, 37–63. https://doi.org/10.1007/s12016-020-08810-9
Dai, S., Georgelis, N., Bedair, M., Hong, Y.-J., Qi, Q., Larue, C. T., Sitoula, B., Huang, W., Krebel, B., Shepard, M., Su, W., Kretzmer, K., Dong, J., Slewinski, T., Berger, S., Ellis, C., Jerga, A., & Varagona, M. (2022). Ectopic expression of a rice triketone dioxygenase gene confers mesotrione tolerance in soybean. *Pest Management Science*, *78*, 2816–2827. https://doi.org/10.1002/ps.6904
Damsch, S., Eichenbaum, G., Tonelli, A., Lammens, L., den Van Bulck, K., Feyen, B., Vandenberghe, J., Megens, A., Knight, E., & Kelley, M. (2011). Gavage-related reflux in rats: Identification, pathogenesis, and toxicological implications (review). *Toxicologic Pathology*, *39*(2), 348–360. https://doi.org/10.1177/0192623310388431
D'Ordine, R. L., Rydel, T. J., Storek, M. J., Sturman, E. J., Moshiri, F., Bartlett, R. K., Brown, G. R., Eilers, R. J., Dart, C., Qi, Y., Flasinski, S., & Franklin, S. J. (2009). Dicamba mono-oxygenase: Structural insights into a dynamic Rieske oxygenase that catalyzes an exocyclic monooxygenation. *Journal of Molecular Biology*, *392*, 481–497.
Dorokhov, D., Ignatov, A., Deineko, E., Serjapin, A., Ala, A., & Skryabin, K. (2004). Introgression from genetically modified plants into wild relatives. In H. C. M. den Nijs, D. Bartsch, & J. Sweet (Eds.), (pp. 151–161). CAB International.
Duff, S. M. G., Zhang, M., Zinnel, F., Rydel, T., Taylor, C. M., Chen, D., Tilton, G., Mamanella, P., Duda, D., Wang, Y., Xiang, B., Karunanandaa, B., Varagona, R., Chittoor, J., Qi, Q., Hall, E., Garvey, G., Zeng, J., Zhang, J., … Haas, J. (2024). Structural and functional characterization of triketone dioxygenase from Oryza Sativa. *Biochimica et Biophysica Acta - General Subjects*, *1868*(2), 130504. https://doi.org/10.1016/j.bbagen.2023.130504
Dumitru, R., Jiang, W. Z., Weeks, D. P., & Wilson, M. A. (2009). Crystal structure of dicamba monooxygenase: A Rieske nonheme oxygenase that catalyzes oxidative demethylation. *Journal of Molecular Biology*, *392*(2), 498–510. https://doi.org/10.1016/j.jmb.2009.07.021
EFSA (European Food Safety Authority). (2005). Opinion of the Scientific panel on genetically modified organisms on an application (reference EFSA-GMO-NL-2004-02) for the placing on the market of insect-tolerant genetically modified maize 1507, for food use, under regulation (EC) No 1829/2003 from Pioneer hi-Bred international/Mycogen seeds. *EFSA Journal*, *3*(3), 182. https://doi.org/10.2903/j.efsa.2005.182
EFSA (European Food Safety Authority). (2009). Consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ panels on the "use of antibiotic resistance genes as marker genes in genetically modified plants" and the scientific opinion of the GMO panel on "consequences of the opinion on the use of antibiotic resistance genes as marker genes in genetically modified plants on previous EFSA assessments of individual GM plants". *EFSA Journal*, *7*(6), 1108. https://doi.org/10.2903/j.efsa.2009.1108
EFSA (European Food Safety Authority). (2010). Application of systematic review methodology to food and feed safety assessments to support decision making. *EFSA Journal*, *8*(6), 1637. https://doi.org/10.2903/j.efsa.2010.1637
EFSA (European Food Safety Authority). (2014). Explanatory statement for the applicability of the Guidance of the EFSA Scientific Committee on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed for GMO risk assessment. *EFSA Journal*, *12*(10), 3871. https://doi.org/10.2903/j.efsa.2014.3871
EFSA (European Food Safety Authority), Gennaro, A., Gomes, A., Herman, L., Nogue, F., Papadopoulou, N., & 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 Publications*, *14*(7), 1273. https://doi.org/10.2903/sp.efsa.2017.en-1273
EFSA (European Food Safety Authority), Paraskevopoulos, K., Ramon, M., Dalmay, T., du Jardin, P., Casacuberta, J., Guerche, P., Jones, H., Nogué, F., Robaglia, C., & Rostoks, N. (2018). Explanatory note on the determination of newly expressed protein levels in the context of genetically modified plant applications for EU market authorisation. *EFSA Supporting Publications*, *15*(8), 1466.
EFSA (European Food Safety Authority), Gomez Ruiz, J. A., Bresson, J.-L., Frenzel, T., & Paoletti, C. (2019a). Statement on the human dietary exposure assessment to newly expressed proteins in GM foods. *EFSA Journal*, *17*(7), 5802. https://doi.org/10.2903/j.efsa.2019.5802
EFSA (European Food Safety Authority), Devos, Y., Guajardo, I. M., Alvarez, F., & Glanville, J. (2019b). 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*, EN-1614. https://doi.org/10.2903/sp.efsa.2019.en-1614
EFSA (European Food Safety Authority). (2021a). Administrative guidance for the processing of applications for regulated products (update 2021). *EFSA Supporting Publications*, *18*(3), 6471. https://doi.org/10.2903/sp.efsa.2021.EN-6471
EFSA (European Food Safety Authority). (2021b). Administrative guidance for the preparation of applications on genetically modified plants. *EFSA Supporting Publications*, *18*(3), 6473. https://doi.org/10.2903/sp.efsa.2021.EN-6473
EFSA FEEDAP Panel (Panel on Additives and Products or Substances used in Animal Feed). (2012). Scientific Opinion on DL-methionine, DL-methionine sodium salt, the hydroxy analogue of methionine and the calcium salt of methionine hydroxy analogue in all animal species; on the isopropyl ester of methionine hydroxy analogue and Dlmethionine technically pure protected with copolymer vinylpyridine/styrene in dairy cows; and on DL-methionine technically pure protected with ethylcellulose in ruminants. *EFSA Journal*, *10*(3), 2623. https://doi.org/10.2903/j.efsa.2012.2623
EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2010a). Guidance on the environmental risk assessment of genetically modified plants. *EFSA Journal*, *8*(11), 1879. https://doi.org/10.2903/j.efsa.2010.1879
EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2010b). Statistical considerations for the safety evaluation of GMOs. *EFSA Journal*, *8*(1), 1250. https://doi.org/10.2903/j.efsa.2010.1250
EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2010c). Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed. *EFSA Journal*, *8*(7), 1700. https://doi.org/10.2903/j.efsa.2010.1700

18314732, 2026, 1, Downloaded from https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2026.9843 by European Commission, Wiley Online Library on [10/03/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2011a). Scientific Opinion on guidance for risk assessment of food and feed from genetically modified plants. *EFSA Journal*, *9*(5), 2150. https://doi.org/10.2903/j.efsa.2011.2150

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2011b). Scientific Opinion on guidance on the post-market environmental monitoring (PMEM) of genetically modified plants. *EFSA Journal*, *9*(8), 2316. https://doi.org/10.2903/j.efsa.2011.2316

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2013). Scientific Opinion on application EFSA-GMO-NL-2011-93 for the placing on the market of the herbicide-tolerant genetically modified soybean MON 87708 for food and feed uses, import and processing under regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal*, *11*(10), 3355. https://doi.org/10.2903/j.efsa.2013.3355

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2015). Guidance on the agronomic and phenotypic characterisation of genetically modified plants. *EFSA Journal*, *13*(6), 4128. https://doi.org/10.2903/j.efsa.2015.4128

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli, H., Birch, A. N., Casacuberta, J., De Schrijver, A., Gralak, M. A., Jones, H., Manachini, B., Messéan, A., Nielsen, E. E., Nogué, F., Robaglia, C., Rostoks, N., Sweet, J., Tebbe, C., Visioli, F., Wal, J.-M., Poeting, A., Álvarez, F., … Ramon, M. (2017a). Scientific Opinion on an application by Monsanto (EFSA-GMO-NL-2013-114) for the placing on the market of a herbicide-tolerant genetically modified cotton MON 88701 for food and feed uses, import and processing under regulation (EC) No 1829/2003. *EFSA Journal*, *15*(3), 4746. https://doi.org/10.2903/j.efsa.2017.4746

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2017b). Guidance on allergenicity assessment of genetically modied plants. *EFSA Journal*, *15*(5), 4862. https://doi.org/10.2903/j.efsa.2017.4862

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli, H., Birch, A. N., Casacuberta, J., De Schrijver, A., Gralak, M. A., Guerche, P., Jones, H., Manachini, B., Messéan, A., Nielsen, E. E., Nogué, F., Robaglia, C., Rostoks, N., Sweet, J., Tebbe, C., Visioli, F., Wal, J. M., Gennaro, A., … Olaru, I. (2017c). Scientific Opinion on application EFSA-GMO-NL-2013-120 for authorisation of genetically modified soybean FG72 × A5547-127 for food and feed uses, import and processing submitted in accordance with regulation (EC) No 1829/2003 by Bayer CropScience LP and M.S. technologies LLC. *EFSA Journal*, *15*(4), 4744. https://doi.org/10.2903/j.efsa.2017.4744

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Casacuberta, J., Nogué, F., Naegeli, H., Birch, A. N., De Schrijver, A., Gralak, M. A., Guerche, P., Manachini, B., Messéan, A., Nielsen, E. E., Robaglia, C., Rostoks, N., Sweet, J., Tebbe, C., Visioli, F., Wal, J.-M., Moxon, S., Schneeberger, K., … Jones, H. (2018). Scientific Opinion on the technical note on the quality of DNA sequencing for the molecular characterisation of genetically modified plants. *EFSA Journal*, *16*(7), 5345. https://doi.org/10.2903/j.efsa.2018.5345

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli, H., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Mullins, E., Nogue, F., Rostoks, N., Sànchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., & Fernandez Dumont, A. (2021a). Statement on in vitro protein digestibility tests in allergenicity and protein safety assessment of genetically modified plants. *EFSA Journal*, *19*(1), 6350. https://doi.org/10.2903/j.efsa.2021.6350

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Naegeli, H., Moreno, F. J., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Ardizzone, M., De Sanctis, G., … Raffaello, T. (2021b). Scientific Opinion on the assessment of genetically modified maize NK603×T25×DAS-40278-9 and subcombinations, for food and feed uses, under regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-164). *EFSA Journal*, *19*(12), 6942. https://doi.org/10.2903/j.efsa.2021.6942

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Ardizzone, M., Camargo, A. M., … Streissl, F. (2022). Scientific Opinion on the assessment of genetically modified maize MON 87429 for food and feed uses, under regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-161). *EFSA Journal*, *20*(11), 7589. https://doi.org/10.2903/j.efsa.2022.7589

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogu, e. F., Rostoks, N., S anchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Dumont, A. F., & Ardizzone, M. (2023). Statement on animal dietary exposure in the risk assessment of feed derived from genetically modified plants. *EFSA Journal*, *21*(1), 7732. https://doi.org/10.2903/j.efsa.2023.7732

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Naegeli, H., Moreno, F. J., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Ardizzone, M., De Sanctis, G., … Xiftou, K. (2024a). Assessment of genetically modified maize DP910521 (application GMFF-2021-2473). *EFSA Journal*, *22*(8), 8887. https://doi.org/10.2903/j.efsa.2024.8887

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogue, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Ardizzone, M., Camargo, A. M., … Raffaello, T. (2024b). Assessment of genetically modified maize DP915635 for food and feed uses, under regulation(EC) No 1829/2003 (application EFSA- GMO-NL-2020-172). *EFSA Journal*, *22*(1), 8490. https://doi.org/10.2903/j.efsa.2024.8490

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies). (2012). Scientific opinion on dietary reference values for protein. *EFSA Journal*, *10*(2), 2557. https://doi.org/10.2903/j.efsa.2012.2557

EFSA Scientific Committee. (2011). EFSA guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed. *EFSA Journal*, *9*(12), 2438. https://doi.org/10.2903/j.efsa.2011.2438

Fernandez, A., Mills, E. N., Lovik, M., Spoek, A., Germini, A., Mikalsen, A., & Wal, J. M. (2013). Endogenous allergens and compositional analysis in the allergenicity assessment of genetically modified plants. *Food and Chemical Toxicology*, *62*, 1–6.

Foo, A. C. Y., & Müller, G. A. (2021). Abundance and stability as common properties of allergens. *Frontiers in Allergy*, *2*, 769728. https://doi.org/10.3389/falgy.2021.769728

Fukagawa, N. K., & Ziska, L. H. (2019). Rice: Importance for global nutrition. *Journal of Nutritional Science and Vitaminology (Tokyo)*, *65*, S2–S3. https://doi.org/10.3177/jnsv.65.S2

Gumisiriza, G., & Rubaihayo, P. R. (1978). Factors that influence outcrossing in soybean. *Zeitschrift für Acker - Und Pflanzenbau = Journal of Agronomy and Crop Science*, *147*, 129–133.

Harmon, D. L., & Swanson, K. C. (2020). Review: Nutritional regulation of intestinal starch and protein assimilation in ruminants. *Animal*, *14*, S17–S28. https://doi.org/10.1017/S1751731119003136

Hausinger, R. P. (2004). Fe(II)/α-ketoglutarate-dependent hydroxylases and related enzymes. *Critical Reviews in Biochemistry and Molecular Biology*, *39*, 21–68.

Helm, R. M. (2001). *Topic 5: Stability of known allergens (digestive and heat stability). Report of a joint FAO, WHO expert consultation on Allergenicity of food derived from biotechnology, 22–25, January 2001*. Food and Agriculture organisation of the United Nations (FAO).

Herman, P. L., Behrens, M., Chakraborty, S., Chrastil, B. M., Barycki, J., & Weeks, D. P. (2005). A three-component dicamba O-demethylase from pseudomonas maltophilia, strain DI-6: Gene isolation, characterization, and heterologous expression. *Journal of Biological Chemistry*, *280*(26), 24759–24767.

Hérouet, C., Esdaile, D. J., Mallyon, B. A., Debruyne, E., Schulz, A., Currier, T., Hendrickx, K., van der Klis, R.-J., & Rouan, D. (2005). Safety evaluation of the phosphinothricin acetyltransferase proteins encoded by the pat and bar sequences that confer tolerance to glufosinate-ammonium herbicide in transgenic plants. *Regulatory Toxicology and Pharmacology*, *41*, 134–149. https://doi.org/10.1016/j.yrtph.2004.11.002

18314732, 2026, 1, Downloaded from https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2026.9843 by European Commission, Wiley Online Library on [10/03/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Maeda, H., Murata, K., Sakuma, N., Takei, S., Yamazaki, A., Karim, M. D., Kawata, M., & Hirose, S. (2019). A rice gene that confers broad-spectrum resistance to β-triketone herbicides. *Science*, *365*, 393–396. https://doi.org/10.1126/science.aax0379

Hill, R. C., Fast, B. J., & Herman, R. A. (2017). Transgenesis affects endogenous soybean allergen levels less than traditional breeding. *Regulatory Toxicology and Pharmacology*, *89*, 70–73.

Hülter, N., & Wackernagel, W. (2008). Double illegitimate recombination events integrate DNA segments through two different mechanisms during natural transformation of Acinetobacter baylyi. *Molecular Microbiology*, *67*, 984–995.

Idan, F., Adogla-Bessa, T., Sarkwa, F. O., Frimpong, Y. O., & Antwi, C. (2023). Effects of supplementing rice straw with two fodder tree leaves and their combinations on voluntary feed intake, growth, and nitrogen utilization in sheep. *Translational Animal Science*, *7*(1), txad004. https://doi.org/10.1093/tas/txad004

Jhala, A. J., Beckie, H. J., Peters, T. J., Culpepper, A. S., & Norsworthy, J. K. (2021). Interference and management of herbicide-resistant crop volunteers. *Weed Science*, *69*, 257–273. https://doi.org/10.1017/wsc.2021.3

Jhala, A. J., Sandell, L., Kruger, G., Wilson, R., & Knezevic, Z. (2013). *Control of glyphosate-resistant volunteer soybean in corn. Crop Watch*. University of Nebraska–Lincoln.

Kikuchi, A., Murata, K., Tabuchi, K., & Sakai, S. (1993). Inheritance of seed embryo color and investigation of degree of natural cross-pollination in soybeans. *Breeding Science*, *43*(S2), 112.

Kundu, S. (2012). Distribution and prediction of catalytic domains in 2-oxoglutarate dependent dioxygenases. *Kundu BMC Research Notes*, *5*, 410.

Larue, C. T., Goley, M., Shi, L., Evdokimov, A. G., Sparks, O. C., Ellis, C., Wollacott, A. M., Rydel, T. J., Halls, C. E., Van Scoyoc, B., Fu, X., Nageotte, J. R., Adio, A. M., Zheng, M., Sturman, E. J., Garvey, G. S., & Varagona, M. J. (2019). Development of enzymes for robust aryloxyphenoxypropionate and synthetic auxin herbicide tolerance traits in maize and soybean crops. *Pest Management Science*, *75*(8), 2086–2094. https://doi.org/10.1002/ps.5393

Lecoq, E., Holt, K., Janssens, J., Legris, G., Pleysier, A., Tinland, B., & Wandelt, C. (2007). General surveillance: Roles and responsibilities the industry view. *Journal Für Verbraucherschutz Und Lebensmittelsicherheit = Journal of Consumer Protection and Food Safety*, *2*(S1), 25–28.

Li, Y., Tran, A. H., Danishefsky, S. J., & Tan, Z. (2019). Chemical biology of glycoproteins: From chemical synthesis to biological impact. *Methods in Enzymology*, *621*, 213–229.

Lu, B. R. (2005). Multidirectional gene flow among wild, weedy, and cultivated soybeans. In J. Gressel (Ed.), *Crop Ferality and volunteerism* (pp. 137–147). OECD + Taylor & Francis.

Matsushita, A., Goto, H., Takahashi, Y., Tsuda, M., & Ohsawa, R. (2020). Consideration of familiarity accumulated in the confined field trials for environmental risk assessment of genetically modified soybean (Glycine max) in Japan. *Transgenic Research*, *29*, 229–242.

Meier, U. (2001). *Growth stages of mono-and dicotyledonous plants* (2nd ed.). BBCH Monograph. Federal Biological Research Centre for Agriculture and Forestry.

Miner-Williams, W. M., Stevens, B. R., & Moughan, P. J. (2014). Are intact peptides absorbed from the healthy gut in the adult human? *Nutrition Research Reviews*, *27*(2), 308–329. https://doi.org/10.1017/S0954422414000225

Mok, C. H., & Urschel, K. L. (2020). Invited review - amino acid requirements in horses. *Asian-Australasian Journal of Animal Sciences*, *33*(5), 679–695. https://doi.org/10.5713/ajas.20.0050

Muller, T. A., Zavodszky, M. I., Feig, M., Kuhn, L. A., & Hausinger, R. P. (2006). Structural basis for the enantiospecificities ofR- and S-specific phenoxypropionate/a-ketoglutarate dioxygenases. *Protein Science*, *15*, 1356–1368.

OECD (Organisation for Economic Co-operation and Development). (2000). *Consensus document on the biology of Glycine max (l.) Merr. (soybean). ENV/JM/MONO(2000)9. Series on harmonization of regulatory oversight in biotechnology No. 15*. Organisation for Economic Co-operation and Development.

OECD (Organisation for Economic Co-operation and Development). (2008). *Test No. 407: Repeated dose 28-day Oral toxicity study in rodents, OECD guidelines for the testing of chemicals, section 4*. OECD Publishing. https://doi.org/10.1787/9789264070684-en

OECD (Organisation for Economic Co-operation and Development). (2009). *Guidance document on overview of residue chemistry studies. ENV/JM/MONO(2009)31*. Organisation for Economic Co-operation and Development.

OECD (Organisation for Economic Co-operation and Development). (2012). *Revised consensus document on compositional considerations for new varieties of soybean [Glycine max (L.) Merr.]: Key food and feed nutrients, anti-nutrients, toxicants and allergens. ENV/JM/MONO(2012)24. Series on the safety of novel foods and feeds No. 25*. Organisation for Economic Co-operation and Development.

OECD (Organisation for Economic Co-operation and Development). (2018). *Test No. 408: Repeated dose 90-day Oral toxicity study in rodents, OECD guidelines for the testing of chemicals, section 4*. OECD Publishing. https://doi.org/10.1787/9789264070707-en

Owen, M. D. K. (2005). Maize and soybeans – Controllable volunteerism without Ferality? In J. Grassel (Ed.), *Crop Ferality and volunteerism* (Vol. *448*, pp. 149–165). CRC Press.

Polevoda, B., & Sherman, F. (2000). Na-terminal acetylation of eukaryotic proteins. *Journal of Biological Chemistry*, *275*, 36479–36482.

Ray, J. D., Kilen, T. C., Abel, C. A., & Paris, R. L. (2003). Soybean natural cross-pollination rates under field conditions. *Environmental Biosafety Research*, *2*, 133–138.

Santos-Hernández, M., Miralles, B., Amigo, L., & Recio, I. (2018). Intestinal signaling of proteins and digestion-derived products relevant to satiety. *Journal of Agricultural and Food Chemistry*, *66*(39), 10123–10131. https://doi.org/10.1021/acs.jafc.8b02355

Sarnklong, C., Cone, J. W., Pellikaan, W., & Hendriks, W. H. (2010). Utilization of Rice straw and different treatments to improve its feed value for ruminants: A review. *Asian-Australasian Journal of Animal Sciences*, *23*(5), 680–692.

Schleinitz, K. M., Kleinsteuber, S., Vallaeys, T., & Babel, W. (2004). Localization and characterization of two novel genesencoding stereospecific dioxygenases catalyzing 2(2,4-dichlorophenoxy) propionate cleavage in Delftiaacidovorans MC1. *Applied Microbiology and Biotechnology*, *9*, 5357–5365.

Selb, R., Wal, J. M., Moreno, F. J., Lovik, M., Mills, C., Hoffmann-Sommergruber, K., & Fernandez, A. (2017). Assessment of endogenous allergenicity of genetically modified plants exemplified by soybean - where do we stand? *Food and Chemical Toxicology*, *101*, 139–148.

Soltani, N., Shropshure, C., & Sikkema, P. H. (2019). Control of volunteer adzuki bean and soybean in white bean with halosulfuron. *Canadian Journal of Plant Science*, *99*, 375–378.

Staniak, M., Stępień-Warda, A., Czopek, K., Kocira, A., & Baca, E. (2020). Seeds quality and quantity of soybean [Glycine max (L.) Merr.] cultivars in response to cold stress. *Agronomy*, *11*, 520.

Sys, C., Van Ranst, E., Debaveye, J., & Beernaert, F. (1993). *Land Evaluation. Part III: CROP requirements. Agricultural Publication No. 7* (p. 199). General Administration for Development Cooperation.

Szczerba, A., Płażek, A., Pastuszak, J., Kopeć, P., Hornyák, M., & Dubert, F. (2021). Effect of low temperature on germination, growth, and seed yield of four soybean (*Glycine max* L.) cultivars. *Agronomy*, *11*, 800.

Takeuchi, M., Hamana, K., & Hiraishi, A. (2001). Proposal of the genus *Sphingomonas sensu stricto* and three new genera, *Sphingobium*, *Novosphingobium* and *Sphingopyxis*, on the basis of phylogenetic and chemotaxonomic analysis. *International Journal of Systematic and Evolutionary Microbiology*, *51*, 1405–1417.

To, J. P. C., Davis, I. W., Marengo, M. S., Shariff, A., Baublite, C., Decker, K., Galvão, R. M., Gao, Z., Haragutchi, O., Jung, J. W., Li, H., O'Brien, B., Sant, A., & Elich, T. D. (2021). Expression elements derived from plant sequences provide effective gene expression regulation and new opportunities for plant biotechnology traits. *Frontiers in Plant Science*, *12*, 712179. https://doi.org/10.3389/fpls.2021.712179

Tyagi, S. K., & Tripathi, R. P. (1983). Effect of temperature on soybean germination. *Plant and Soil*, *74*(2), 273–280.

18314732, 2026, 1, Downloaded from https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2026.9843 by European Commission, Wiley Online Library on [10/03/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

van Bruchem, J., Rouwers, S. M. G., Bangma, G. A., Leffering, C. P., & van Adrichem, P. W. M. (1985). Digestion of proteins of varying degradability in sheep.1. Fermentation in and rate of passage from the reticulorumen. *Netherlands Journal of Agricultural Science*, *33*, 263–272.

Wang, X., Li, X., Zhou, Q., Song, S., & Dong, S. (2023). Comparison and evaluation of low-temperature tolerance of different soybean cultivars during the early-growth stage. *Agronomy*, *13*, 1716.

Windels, P., Alcalde, E., Lecoq, E., Legris, G., Pleysier, A., Tinland, B., & Wandelt, C. (2008). General surveillance for import and processing: The EuropaBio approach. *Journal of Consumer Protection and Food Safety*, *3*(S2), 14–16.

Yoshimura, Y., Matsuo, K., & Yasuda, K. (2006). Gene flow from GM glyphosate-tolerant to conventional soybeans under field conditions in Japan. *Environmental Biosafety Research*, *5*, 169–173.

Zhang, G. (2022). The next generation of Rice: Inter-subspecific Indica-japonica hybrid Rice. *Frontiers in Plant Science*, *13*, 857896. https://doi.org/10.3389/fpls.2022.857896

Zhang, L., Liu, L., Fang, Z., Shen, W., Dai, Y., Jia, R., Liang, J., & Liu, B. (2023). Fitness changes in wild soybean caused by gene flow from genetically modified soybean. *BMC Plant Biology*, *23*, 424.

Zipper, C., Nickel, K., Angst, W., & Kohler, H. P. E. (1996). Complete microbial degradation of both enantiomers of the chiral herbicide mecoprop [(RS)-2-(4-chloro-2-methylphenoxy) propionicacid] in an enantioselective manner by *Sphingomonas herbicidovorans* sp. nov. *Applied and Environmental Microbiology*, *62*(12), 4318–4322.

SUPPORTING INFORMATION

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

How to cite this article: EFSA GMO Panel (EFSA PANEL on Genetically Modified Organisms), Casacuberta, J., Barro, F., Braeuning, A., de Maagd, R., Epstein, M. M., Frenzel, T., Gallois, J.-L., Koning, F., Messéan, A., Moreno, F. J., Nogué, F., Savoini, G., Schulman, A. H., Tebbe, C., Veromann, E., Ardizzone, M., De Sanctis, G., Dumont, A. F., … Sánchez-Brunete, E. (2026). Assessment of genetically modified soybean MON 94313 (application GMFF-2022-6595). *EFSA Journal*, *24*(1), e9843. https://doi.org/10.2903/j.efsa.2026.9843

18314732, 2026, 1, Downloaded from https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2026.9843 by European Commission, Wiley Online Library on [10/03/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

APPENDIX A

List of relevant publications identified by the applicant through systematic literature searches (January 2012 to November 2024)

References
Canadian Food Inspection Agency (CFIA). Plants with novel traits (PNT) and novel feeds from plant sources approved in Canada.
Health Canada. Herbicide-tolerant (HT4) soybean – MON 94313. https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/herbicide-tolerant-soybean-94313.html
Food Standards Australia (FSANZ). A1276 - Food derived from herbicide-tolerant soybean line MON94313. https://www.foodstandards.gov.au/food-standards-code/applications/A1276-Food-derived-from-herbicide-tolerant-soybean-line-MON94313

18314732, 2026, 1, Downloaded from https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2026.9843 by European Commission, Wiley Online Library on [10/03/2026]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

APPENDIX B

Statistical analysis and statistically significant findings in the 28-day toxicity studies in mice and in the 90-day toxicity study in rats

B.1 | STATISTICAL ANALYSIS OF THE 28-DAY STUDY ON THE *E. COLI*-PRODUCED FT_T.1 PROTEIN IN MICE

The following endpoints were statistically analysed: body weights, body weight changes, food consumption, clinical pathology values (as applicable), absolute and relative organ weights, functional observational battery (FOB) data, locomotor activity and histopathological data. For all continuous endpoints, mean, standard deviation in terms of the standardised effect sizes (SES) of each dose group for each sex, variable and period of time interval were reported.

The main statistical analysis compared each of the three test diet groups (high, medium and low FT_T.1 protein groups) separately with the vehicle group. The analysis was performed for male and female mice separately. Continuous endpoints were analysed with a linear model (factor: diet group; for locomotor activity data: diet group, time and interaction diet group-time); for endpoints measured on a discrete scale, the comparisons were performed with Fisher's exact test as appropriate. Ranges from historical control data were provided to aid the assessment of statistically significant outcomes. Missing data were considered by the Panel and found not to have an impact on the results (Table B.1).

TABLE B.1 Statistically significant findings in the 28-day toxicity study on *E. coli*-produced FT_T.1 protein in mice.

Statistically significant parameter/endpoint	Finding (vs. control)	GMO panel interpretation
Mortality	1 male and 1 female receiving BSA. 1 low-dose female. 1 top dose male.	No consistent pattern. The top dose male had evidence of gavage error. Not an adverse effect of treatment.
Body weight/body weight gain	Increased in mid-dose males and females at some time points.	No effect at the top dose. No effect on terminal body weight. Within normal variation; very similar to BSA group. Not an adverse effect of treatment.
Food consumption	Reduced (30%[35]) in top dose females on days 21–28.	No effect on terminal body weight. Deficit vs. BSA 14%. Within normal variation. Not an adverse effect of treatment.
Lymphocyte count	Increased (30%) in mid-dose males.	No effect at top dose. No related histopathology findings. Not an adverse effect of treatment.
Mean erythrocyte volume & haemoglobin content	Reduced (4%) in top dose males.	Small magnitude. RBC count increased (2%), no change in reticulocytes. Within normal variation. Not an adverse effect of treatment.
Prothrombin time	Decreased (3%) in low dose males.	Low magnitude, no dose response. Within normal variation. Not an adverse effect of treatment.
Albumin	Reduced (5%–10%) in low- and mid-dose males	Low magnitude, no dose response. Within normal variation. Not an adverse effect of treatment.
Globulin	Increased (10%) in top dose males	Low magnitude. Within normal variation. Not an adverse effect of treatment.
A:G ratio	Decreased in mid-dose males (8%) and top dose males (15%).	Low magnitude. Within normal variation (BSA 5% lower than controls). Not an adverse effect of treatment.
Total protein	Decreased (7%) in low dose males	Low magnitude, no dose response. Within normal variation. Not an adverse effect of treatment.
Liver weight (absolute)	Increased (10%) in mid-dose males	Low magnitude, no dose response. Within normal variation. Not an adverse effect of treatment.
Brain weight (relative to body weight).	Increased (7%) in mid-dose males	Low magnitude, no dose response. Within normal variation. Not an adverse effect of treatment.
Spleen weight (absolute)	Increased (20%) in low and mid-dose males	Low magnitude, not seen at top dose. Within normal variation. Not an adverse effect of treatment.
Spleen weight (relative to body weight)	Increased in low dose (18%), mid-dose (18%) and top dose (14%) males	Low magnitude, no dose response. Within normal variation. No associated haematology or histopathology findings. Not an adverse effect of treatment.
Adrenal weight (absolute)	Increased (20%) in low dose females	Low magnitude, not seen higher doses. Within normal variation. Not an adverse effect of treatment.
Ovary / oviduct weight (absolute and relative to body weight)	Increased (20%) in low females	Low magnitude, not seen at higher doses. Within normal variation. Not an adverse effect of treatment.

(Continues)

[35]Where changes are given as percentages (e.g. reduced (30%)) this indicates the magnitude of the change relative to the control value (e.g. 30% means a value of 7 in test group animals vs. 10 in controls).

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B.2 | Statistical analysis of the 28-day (gavage) study on the *E. coli*-produced TDO protein in mice

The following endpoints were statistically analysed: body weight, body weight changes, food consumption, clinical pathology values (as applicable), absolute and relative organ weight, FOB data, locomotor activity and histopathological data. For all continuous endpoints, mean, standard deviation in terms of the SES of each dose group for each sex, variable and period or time interval were reported.

The main statistical analysis compared each of the three test diet groups (high, medium and low TDO protein groups) separately with the vehicle group. The analysis was performed for male and female mice separately. Continuous endpoints were analysed with a linear model (factor: diet group; and for locomotor activity data: diet group, time and interaction diet group-time); for endpoints measured on a discrete scale, the comparisons were performed with Fisher's exact test as appropriate. Ranges from historical control data were provided to aid the assessment of statistically significant outcomes. Missing data were considered by the Panel and found not to have an impact on the results (Table B.2).

TABLE B.2 Statistically significant findings in the 28-day (gavage) toxicity study on *E. coli*-produced TDO protein in mice.

Statistically significant parameter/endpoint	Finding (vs. control)	GMO panel interpretation
Mortality	2 males (1000 mg day 8 & 15). 2 females (1000 mg day 18 & 26) Lung lesions/nasal cavity changes reported.	There is a discussion of the effects in the study report and further experimental, mechanistic observations and scientific literature were provided by the applicant, indicating a plausible explanation by which mid/high-concentration gavage formulations of TDO could rapidly form persistent aggregates under acidic conditions. These aggregates could delay gastric emptying and thereby promote gastro-oesophageal reflux and secondary aspiration of the gastric content. Further details are given in Section 3.5.2.1.2 (see *28-day (gavage) repeated dose toxicity study with TDO protein* paragraph).
Lung and upper respiratory tract (URT) changes (inflammation; exudate; epithelial degeneration/ regeneration; hyperplasia).	Mid-dose and top dose animals of both sexes. Background incidence is typically very low or zero.	
Body weight (day 21)	Lower (6%) in top dose males	Small magnitude. Not an adverse effect of treatment.
Body weight loss (day 0–21)	Top dose males (1.9 g vs. 0.3 g in controls)	No significant effect on final body weight. Not an adverse effect of treatment.
Body weight gain (day 0–14)	Top dose females (0.09 g vs. 0.9 g in controls)	No significant effect on final body weight. Not an adverse effect of treatment.
Platelets	Increased (20%) in top dose females.	Within normal variation. No change relative to BSA. Not an adverse effect of treatment.
Albumin	Decreased (7%) in mid-dose males (main group) and top dose females (coagulation group).	Small magnitude. No change relative to BSA. Not consistent. Not an adverse effect of treatment.
Albumin:Globulin ratio	Decreased (7%) in mid-dose males (main group) and mid-dose females (coagulation group).	Small magnitude. No change relative to BSA. Not consistent and not seen at top dose. Not an adverse effect of treatment.
Liver weight (relative to body weight)	Increased (7%) in mid-dose males.	Small magnitude. No change relative to BSA. Not consistent. Not seen at top dose. No associated histopathological changes. Not an adverse effect of treatment.
Spleen weight (absolute and relative to body weight)	Increased (7%) in mid-dose males.	Small magnitude. No change relative to BSA. Not consistent, not seen at top dose. No associated histopathology or haematology findings. Not an adverse effect of treatment.

B.3 | Statistical analysis of the 28-day (dietary) toxicity study on the *E. coli*-produced TDO protein in mice

The following endpoints were statistically analysed: mortality, clinical signs, body weights, body weight gains, food consumption, neurobehavioral assessments, motor activity, ophthalmology, clinical pathology parameters (haematology, coagulation and serum chemistry), organ weights and macroscopic and microscopic examinations.

The main statistical analysis compared rats consuming the test diets at low dose – 10 mg/kg bw per day of TDO protein (Group 4 and 5, for male and female respectively), medium dose – 100 mg/kg bw per day of TDO protein (Group 6 and 7, for male and female, respectively) and high dose– 1000 mg/kg bw per day of TDO protein (Group 8 and 9, for male and female, respectively) with those consuming the vehicle diet – 0 mg/kg bw per day of TDO protein (Group 1).

Continuous data were investigated separately for each sex, variable and period or time interval, according to a linear mixed model (factor: diet) then, a pairwise comparisons, between test and vehicle groups (separately for each sex, time interval if necessary and variable), were defined within the ANOVA and tested using a Dunnett's tests (two-tailed at the significance level of 5%). For the locomotor activity data, a more complex model was set up taking into consideration the time effect and its interaction with the dose fixed effect as additional factors. Only when the interaction of the treatment per time was significant, the comparison of the treated group vs. the vehicle group was conducted within each time interval

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and tested using Dunnett's tests. Binomial category data and unordered multi-category data were analysed by Fisher's exact probabilities test.

For all continuous endpoints, mean, standard deviation in terms of the standardised effect sizes (SES) of each dose group for each sex, variable and period or time interval were reported.

Missing data were considered by the Panel and found not to have an impact on the results (Table B.3).

TABLE B.3 Statistically significant findings in the 28-day (dietary) toxicity study on *E. coli*-produced TDO protein in mice.

Statistically significant parameter/endpoint	Finding (vs. control)	GMO panel interpretation
Body weight gain (d1–8)	Increased (95%) in low-dose males.	Not seen at higher doses. No impact on terminal body weights (within 2%). Not an adverse effect of treatment (p34/70)
Body weight gain (d8–15)	Decreased (45%) in high-dose males.	No impact on terminal body weights (within 2%). Not an adverse effect of treatment (p34/70)
Food consumption (d1–8)	Decreased (15%) in top dose females.	No impact on body weights. Consistent with BSA values. Within normal variation. Not an adverse effect of treatment. (p35)
Food consumption (d8–15)	Decreased (10%) in mid-dose females.	No dose response. No impact on body weights. Consistent with BSA values. Within normal variation. Not an adverse effect of treatment. (p35)
Catalepsy duration	Increased (10%) in low-dose males.	Not seen at higher doses. Not an adverse of treatment. (p124)
Haematocrit	Increased (7%) in mid-dose females.	Not seen at the high dose. Low magnitude, within normal variation. Not an adverse effect of treatment. (p38)
Mean cell haemoglobin concentration (MCHC)	Decreased (8%) in low- and high-dose females	No dose response. Within normal variation. No change in total haemoglobin levels. Not an adverse effect of treatment. (p38/139)
Mean (red) cell volume (MCV)	Increased in all female groups (low dose, 4%; mid-dose, 10%; high dose, 6%).	No dose response. Small magnitude, within normal variation. Not an adverse effect of treatment.
Platelet count	Increased (20%) in mid-dose females.	Not seen at the high dose. Consistent with BSA group values. Not an adverse effect of treatment. (p38)
APTT	Increased (12%) in low-dose females.	Not seen at higher doses. All values within the negative control range and consistent with BSA values. Not an adverse effect of treatment. (p39)

B.4 | Statistical analysis of the 90-day toxicity study on soybean MON 94313 in rats

The following endpoints were statistically analysed: body weights, body weight changes, food consumption, clinical pathology values (as applicable), absolute and relative organ weights, functional observational battery (FOB) data, locomotor activity and histopathological data. For all continuous endpoints, mean, standard deviation in terms of the standardised effect sizes (SES) of each dose group for each sex, variable and period or time interval were reported. The main statistical analysis compared each of the two test diet groups (high and low test substance MON 94313 groups) separately with the control group. Continuous endpoints were analysed with a linear model (factor: treatment, sex and their interaction and for MA data: the time effect and its interaction with the other fixed and random effects as additional factors). Note that only when the interaction of the 'treatment per sex' was significant, the comparison of the treated (low and high dose) vs. the control group was conducted separately for the two genders. For endpoints measured on a discrete scale, the comparisons were performed with Fisher's exact test as appropriate. Ranges from historical control data were provided to aid the assessment of statistically significant differences between the test and the control diet group. Missing data were considered by the Panel and found not to have an impact on the results (Table B.4).

TABLE B.4 Statistically significant findings in the 90-day toxicity study on soybean MON 94313 in rats.

Statistically significant parameter/endpoint	Finding (vs. control)	GMO panel interpretation
Body weight/body weight gain	Increased 5%–10% in both dose groups (sexes combined)	Low magnitude. Terminal body weights within 5% of controls. Within normal variation. Not an adverse effect of treatment.
Food consumption	Increased (6%) in low dose males, weeks 6–7	Low magnitude, no dose response. Not seen consistently. Within normal variation. Not an adverse effect of treatment.
Hindlimb foot splay	Increased (17%) in low-dose groups (sexes combined)	Low magnitude, no dose response. Within normal variation. Pre-test values higher than controls. Not an adverse effect of treatment.
Eosinophil count	Increased (50%) in low-dose males.	Not seen at high dose or in females. Not an adverse effect of treatment.

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TABLE B.4 (Continued)

Statistically significant parameter/endpoint	Finding (vs. control)	GMO panel interpretation
White blood cell count	Decreased (15%) in top dose males.	Low magnitude. Within normal variation (14 test group values within control range). Not an adverse effect of treatment.
Serum ALT, AST, LDL	Decreased (15%) in both dose groups (sexes combined).	Low magnitude. Within normal variation. Decreases not adverse in isolation. No associated histopathology findings. Not an adverse effect of treatment.
Serum calcium, inorganic phosphate, creatinine, globulin and total protein	Reduced (3%, 5%, 10%, 5% and 2%, respectively) in high-dose animals (sexes combined).	Low magnitude. Within normal variation. Not an adverse effect of treatment.
Urine specific gravity	Increased (1%) in low-dose animals (sexes combined)	Low magnitude, not statistically significant at the high dose. Within normal variation. Not an adverse effect of treatment.
Urinary osmolarity, creatinine, glucose and protein.	Increased (40%–50%) in low-dose animals (sexes combined)	Not seen at the high dose. Mainly attributed to high values in three rats (1003, 1039, 1072). No other indications of kidney/urinary tract effects. Not an adverse effect of treatment.
T4	Increased (20%) in low-dose animals (sexes combined)	Low magnitude, not seen at top dose. Within normal variation. No adverse pathology findings in thyroid. Not an adverse effect of treatment.
TSH	Decreased (40%) in low-dose males	Not seen at top dose. Within normal variation, only 1 value outside control range. No adverse pathology findings in thyroid. Not an adverse effect of treatment.
Liver weight (absolute)	Increased (10%) in both dose groups (sexes combined)	Low magnitude. Within normal variation. No associated histopathology findings. Not an adverse effect of treatment
Brain weight (relative to body weight).	Decreased (3%) in top dose animals (sexes combined)	Low magnitude. Within normal variation. No associated histopathology findings. Not an adverse effect of treatment
Kidney weight (absolute)	Increased (10%) in both dose groups (sexes combined)	Low magnitude. Within normal variation. No associated histopathology findings. Not an adverse effect of treatment
Kidney weight (relative to body weight)	Increased (5%) in low-dose animals (sexes combined)	Low magnitude, not seen at top dose. Within normal variation. No associated histopathology findings. Not an adverse effect of treatment
Adrenal weight (absolute)	Increased (8%) in both dose groups (sexes combined)	Low magnitude. Within normal variation. No associated histopathology findings. Not an adverse effect of treatment
Heart weight (absolute)	Increased (8%) in top dose animals (sexes combined)	Low magnitude. Within normal variation. No associated histopathology findings. Not an adverse effect of treatment
Pituitary weight (relative to body weight)	Increased (5%) in low-dose animals (sexes combined)	Low magnitude, not seen at top dose. Within normal variation. No associated histopathology findings. Not an adverse effect of treatment.
Epididymides weight (absolute)	Increased (5%) in top dose males	Low magnitude. Within normal variation. No associated histopathology findings. Not an adverse effect of treatment
Ovary/oviduct weight (absolute)	Increased (12%) in top dose females	Low magnitude. Within normal variation. No associated histopathology findings. Not an adverse effect of treatment

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APPENDIX C

Animal dietary exposure

TABLE C.1 Dietary exposure to DMO, PAT, FT_T.1 and TDO protein (mg/kg bw per day) in livestock, based on the consumption of soybean grain and forage.

			IR (%)				
	BW (kg)	TDI feed (kg DM/animal)	Meal	DMO	PAT	FT_T.1	TDO
Lactating dairy cow	650	25	25	0.492	0.047	0.075	0.062
Finishing pigs	100	3	30	0.461	0.044	0.070	0.058
Broiler	1.7	0.12	40	1.446	0.137	0.220	0.181

TABLE C.2 Dietary exposure to DMO, PAT, FT_T.1 and TDO protein (mg/kg bw per day) in livestock, based on the consumption of forage.

			IR (%)				
	BW (kg)	TDI feed (kg DM/animal)	Forage	DMO	PAT	FT_T.1	TDO
Lactating dairy cow	650	25	20%	1.15	0.09	0.08	0.09
Laying hen	1.9	0.13	10%	1.02	0.08	0.07	0.08

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