

Aan de staatssecretaris van Openbaar Vervoer en Milieu
Ministerie van Infrastructuur en Waterstaat
De heer A.A. Aartsen
Postbus 20901
2500 EX Den Haag

DATUM 16 februari 2026
KENMERK CGM/260216-01
ONDERWERP Advies Import en verwerking van gg-soja MON 94313 x MON 89788

Geachte heer Aartsen,

Naar aanleiding van een adviesvraag over de milieurisico's van import en verwerking van gg-soja MON 94313 x MON 89788 (GMFF-2023-17394), ontwikkeld door Bayer CropScience LP, deelt de COGEM u het volgende mee. Op verzoek van het Food-Feed loket voor ggo-markttoelatingen is het advies in het Engels geschreven.

Samenvatting:

- De COGEM is gevraagd te adviseren over de mogelijke milieurisico's van import en verwerking van de genetisch gemodificeerde (gg-)soja MON 94313 x MON 89788;
- MON 94313 x MON 89788 is verkregen door conventionele kruising tussen de gg-soja ouderlijnen MON 94313 en MON 89788;
- In deze kruisingslijn worden genen tot expressie gebracht die zorgen voor tolerantie tegen verschillende herbiciden;
- De COGEM heeft eerder positief geadviseerd over import en verwerking van beide ouderlijnen;
- Er zijn geen verwilderde soja-populaties in Nederland en er zijn geen wilde verwanten aanwezig;
- De moleculaire informatie voldoet aan de eisen van de COGEM en er is geen reden om aan te nemen dat de ingebrachte genen kunnen leiden tot verwildering;
- Gezien het bovenstaande is de COGEM van oordeel dat de milieurisico's van de import en verwerking van gg-soja MON 94313 x MON 89788 verwaarloosbaar klein zijn.



De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,

Prof. dr. ing. Sybe Schaap
Voorzitter COGEM

c.c.

- Drs. Y. de Keulenaar, Hoofd Bureau ggo
- Ministerie van IenW, Directie Omgevingsveiligheid en milieurisico's, DG Milieu en Internationaal
- Ing. M.A.C. Möllers, Food-Feed loket

Advice Import & processing of GM soybean MON 94313 × MON 89788

COGEM advice CGM/260216-01

COGEM has been requested to evaluate the environmental risks associated with the authorisation for import, processing and food and feed use of genetically modified (GM) soybean MON 94313 × MON 89788 (GMFF-2023-17394), as submitted by Bayer Agriculture BV on behalf of Bayer CropScience LP.

GM soybean MON 94313 × MON 89788 was produced by crossing the parental soybean lines MON 94313, and MON 89788 using traditional breeding methods. Both parental lines were generated by *Agrobacterium tumefaciens* mediated transformation. MON 94313 expresses the *dmo*, *pat*, *ft_t.1* and *tdo* genes conferring tolerance to several herbicides. MON 89788 expresses the *cp4 epsps* gene, which confers tolerance to herbicides containing the active ingredient glyphosate. For an overview and description of the introduced genes and traits in GM soybean MON 94313 × MON 89788, see Table 1.

Table 1. Description of the introduced genes and traits.

Introduced genes	Encoded proteins	Regulatory elements	Traits
<i>dmo</i> (MON 94313)	Dicamba mono-oxygenase (DMO), codon optimised coding sequence originally derived from <i>Stenotrophomonas maltophilia</i> . ^{1,2}	Promoter, leader and intron of the polyubiquitin gene <i>ubq3</i> from <i>Arabidopsis thaliana</i> . Chloroplast targeting sequence of the APG6 gene from <i>A. thaliana</i> . 3'UTR sequence of the <i>Saliz-2</i> gene from <i>Medicago truncatula</i> .	Tolerance to dicamba-containing herbicides.
<i>pat</i> (MON 94313)	Phosphinothricin N-acetyltransferase (PAT), codon optimised coding sequence originally derived from <i>Streptomyces viridochromogenes</i> . ³	Synthetic promoter and 5'UTR based on multiple promoter and 5'UTR sequences from <i>A. thaliana</i> . Synthetic intron based on multiple intron sequences from <i>A. thaliana</i> . 3'UTR sequence of a putative <i>Hsp20</i> gene from <i>M. truncatula</i>	Tolerance to glufosinate-ammonium-containing herbicides.
<i>ft_t.1</i> (MON 94313)	FOPs and 2,4-D dioxygenase (FT_T.1), a modified version of the R-2,4 dichlorophenoxypropionate dioxygenase (<i>rdpA</i>) gene of <i>Sphingobium herbicidovorans</i> . ⁴⁻⁵	Promoter, leader and intron of the polyubiquitin gene <i>ubq10</i> from <i>A. thaliana</i> . 3' UTR sequence from an expressed gene of unknown function from <i>M. truncatula</i> .	Tolerance to members of the synthetic auxin herbicide family, such as 2,4-D. (In maize FT_T.1 also confers tolerance to aryloxyphenoxypropionate (FOP) containing herbicides, but soybean is tolerant to FOP by nature.)
<i>tdo</i> (MON 94313)	Triketone dioxygenase (TDO), codon optimised coding sequence originally derived from <i>Oryza sativa</i> . ⁶	Synthetic promoter and 5'UTR based on multiple promoter and 5'UTR sequences from <i>A. thaliana</i> . Synthetic intron based on multiple intron sequences from <i>A. thaliana</i> . Synthetic 3'UTR based on multiple 3'UTR sequences from <i>Zea mays</i> .	Tolerance to β -triketone herbicides, such as mesotrione.

Introduced genes	Encoded proteins	Regulatory elements	Traits
<i>cp4 epsps</i> (MON 89788)	Codon optimised variant of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme originating from <i>Agrobacterium</i> sp. strain CP49. ⁷	P-FMV/Tsf1 promoter (chimeric promoter containing enhancer sequences of the promoter of the <i>A. thaliana</i> Tsf1 gene and of the 35S promoter of Figwort mosaic virus (FMV)) and E9 3' non-translated region from the <i>rbcS2</i> gene of <i>Pisum sativum</i> .	Tolerance to glyphosate containing herbicides.

COGEM has previously advised positively on the import and processing of the parental lines MON 94313⁸ and MON 89788⁹. COGEM also recently advised positively on the import and processing of a stacked GM soybean containing both MON 94313 and MON 89788 (i.e., MON 94637 × MON 87751 × MON 87701 × MON 94313 × MON 89788)¹⁰. GM soybean line MON 89788 is authorised for placement on the market in the European Union since 2008.¹¹ MON 94313 has not yet received authorisation for placement on the EU market. A positive EFSA assessment of MON 94313 has recently been published.¹²

Soybean (*Glycine max*) is cultivated worldwide, from equatorial to temperate zones. It is a predominantly self-pollinating species. Natural outcrossing rates are generally low.^{13,14} For growth, soybean requires an optimum temperature between 25 °C and 30 °C. It is sensitive to frost and does not survive freezing conditions.^{13,14} Although the Dutch climate is not optimal for cultivation of soybean, it is cultivated in the Netherlands on a small scale (70 hectares in 2024, and approximately 110 in 2025).¹⁵ Soybean volunteers are very uncommon in the Netherlands and have never resulted in establishment of wild populations. To the best of COGEM's knowledge, there are no reports of feral soybean populations in Europe. Additionally, hybridisation with other species is not possible in Europe because there are no wild relatives of soybean.^{13,14}

The application for market authorisation of GM soybean MON 94313 × MON 89788 for import, processing and use in food and feed contains, amongst others, bioinformatic analyses, phenotypic and agronomic analysis and a post-market environmental monitoring (PMEM) plan. Bio-informatic analysis of each of the inserted elements and its 3' and 5' junctions in the genome of GM soybean MON 94313 × MON 89788 was performed to assess whether potential newly created open reading frames (ORFs) show protein sequence similarities using databases of allergens, toxins, and biologically active proteins that could be harmful to human or animal health. No indications for potential environmental risks were identified.

The applicant analysed the phenotypic and agronomic characteristics of MON 94313 × MON 89788 and found that most agronomic characteristics were equivalent in the GM crop and the non-transgenic reference varieties. One exception was 'yield' when not treated with herbicides, and 'early stand count' when treated with herbicides. For these characteristics non-equivalence to reference varieties was more likely than not. However, the observed test means for this characteristic were within the known values of soybean, and this finding has no relevance regarding the potential environmental impact of the GM crop.

There are no indications of unexpected interactions between the introduced traits from the parental lines. The introduced traits in GM soybean MON 94313 × MON 89788 will not allow the GM soybean to

survive in the Dutch environment. A post-market environmental monitoring (PMEM) plan is provided in the application.

COGEM is of the opinion that import and processing of GM soybean MON 94313 × MON 89788 poses a negligible risk to the Dutch environment. COGEM abstains from giving advice on the potential risks of incidental consumption, as a food/feed assessment is carried out by other organisations.

Referenties

1. Wang X et al. (1997). A Three-Component Enzyme System Catalyzes the O Demethylation of the Herbicide Dicamba in *Pseudomonas maltophilia* DI-6. *Appl. Environ. Microbiol.* 63: 1623-1666
2. Herman PL et al. (2005). A three component dicamba O-demethylase from *Pseudomonas maltophilia*, strain DI-6: gene isolation, characterization, and heterologous expression. *J. Biol. Chem.* 280: 24759-24767
3. Wohlleben W et al (1988). Nucleotide sequence of the phosphinothricin N-acetyltransferase gene from *Streptomyces viridochromogenes* Tü494 and its expression in *Nicotiana tabacum*. *Gene*, 70: 25-37
4. Larue CT et al. (2019). Development of enzymes for robust aryloxyphenoxypionate and synthetic auxin herbicide tolerance traits in maize and soybean crops. *Pest Manag. Sci.* 75: 2086-2094
5. Müller TA et al. (2006). Structural basis for the enantiospecificities of R- and S-specific phenoxypropionate/alpha-ketoglutarate dioxygenases. *Protein Sci.* 15: 1356-1368
6. Duff SMG et al. (2025). Optimizing the thermostability of triketone dioxygenase for engineering tolerance to mesotrione herbicide in soybean and cotton. *Front. Plant Sci.* 15: 1502454
7. Funke T et al. (2006). Molecular basis for the herbicide resistance of Roundup Ready crops. *PNAS* 103: 13010-13015
8. COGEM (2023). Environmental risk assessment of import and processing of GM herbicide tolerant soybean MON94313. COGEM advice CGM/230210-01
9. COGEM (2008). Molecular characterization of soybean MON89788 (EFSA/GMO/NL/2006/36). COGEM advice CGM/080827-01
10. COGEM (2026). Advice Import & processing of GM soybean MON 94637 × MON 87751 × MON 87701 × MON 94313 × MON 89788. COGEM advice CGM/260205-03
11. Commission Decision of 4 December 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. *OJEU* 333/7
12. European Food Safety Authorisation (EFSA, 2026). Assessment of genetically modified soybean MON 94313 (application GMFF-2022-6595). *EFSA Journal* 24: e9843
13. OECD (2006). "Section 2 - Soybean (GLYCINE MAX (L.) MARR.)", in *Safety Assessment of Transgenic Organisms*, Volume 1: OECD Consensus Documents, OECD Publishing, Paris
14. Andersson MS & de Vicente MC (2010). Soybean (Glycine max (L.) Merr.). In: *Gene flow between crops and their wild relatives*. Eds: Andersson MS et al., The Johns Hopkins University Press, Baltimore
15. Centraal Bureau voor de Statistiek (CBS). <https://opendata.cbs.nl/#/CBS/nl/dataset/81302ned/table?searchKeywords=sojabonen> (accessed: 12th of January 2026)