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
dmo (**MON 94313**)	Dicamba mono-oxygenase (DMO), codon optimised coding sequence originally derived from *Stenotrophomonas maltophilia.*[1,2]	Promoter, leader and intron of the polyubiquitin gene *ubq3* from *Arabidopsis thaliana.* Chloroplast targeting sequence of the *APG6* gene from *A. thaliana.* 3'UTR sequence of the *Sali3-2* gene from *Medicago truncatula.*	Tolerance to dicamba-containing herbicides.
pat (**MON 94313**)	Phosphinothricin N–acetyltransferase (PAT), codon optimised coding sequence originally derived from *Streptomyces viridochromogenes.*[3]	Synthetic promoter and 5'UTR based on multiple promoter and 5'UTR sequences from *A. thaliana.* Synthetic intron based on multiple intron sequences from *A. thaliana.* 3'UTR sequence of a putative *Hsp20* gene from *M. truncatula*	Tolerance to glufosinate-ammonium-containing herbicides.
ft_t.1 (**MON 94313**)	FOPs and 2,4-D dioxygenase (FT_T.1), a modified version of the R-2,4 dichlorophenoxypropionate dioxygenase (*rdpA*) gene of *Sphingobium herbicidovorans*.[4,5]	Promoter, leader and intron of the polyubiquitin gene *ubq10* from *A. thaliana.* 3' UTR sequence from an expressed gene of unknown function from *M. truncatula.*	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.)
tdo (**MON 94313**)	Triketone dioxygenase (TDO), codon optimised coding sequence originally derived from *Oryza sativa*.[6]	Synthetic promoter and 5'UTR based on multiple promoter and 5'UTR sequences from *A. thaliana.* Synthetic intron based on multiple intron sequences from *A. thaliana.* Synthetic 3'UTR based on multiple 3'UTR sequences from *Zea mays.*	Tolerance to β-triketone herbicides, such as mesotrione.

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

COGEM has previously advised positively on the import and processing of the parental lines MON 94313[8] and MON 89788[9]. 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

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