

Advice Import & processing of GM soybean MON 94637 × MON 87751 × MON 87701 × MON 94313 × MON 89788

COGEM advice CGM/260205-03

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 94637 × MON 87751 × MON 87701 × MON 94313 × MON 89788 (GMFF-2025-35906, AP204), as submitted by Bayer Agriculture BV on behalf of Bayer CropScience LP (MA 250014_001).

GM soybean MON 94637 × MON 87751 × MON 87701 × MON 94313 × MON 89788 was produced by crossing the parental soybean lines MON 94637, MON 87751, MON 87701, MON 94313, and MON 89788 using traditional breeding methods.

All five GM soybean lines were originally generated by *Agrobacterium tumefaciens* mediated transformation. MON 94637, MON 87751, and MON 87701 contain genes which express insecticidal proteins, conferring resistance to certain lepidopteran insects (*cry1A.2* and *cry1B.2* genes in MON 94637, *cry1A.105* and *cry2Ab2* genes in MON 87751, and *cry1Ac* gene in MON 87701). 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 94637 × MON 87751 × MON 87701 × MON 94313 × MON 89788, see Table 1.

Table 1. Description of the introduced genes and traits.

Introduced genes	Encoded proteins	Regulatory elements	Traits
<i>cry1A.2</i> (MON 94637)	Chimeric protein with domains from different Cry1 proteins (Cry1A and Cry1C sub-classes) from <i>Bacillus thuringiensis</i> . ¹	Promoter, leader and intron of the polyubiquitin gene <i>ubq10</i> from <i>Arabidopsis thaliana</i> . 3'UTR sequence of the <i>Zfp-Mt1</i> gene from <i>Medicago truncatula</i> .	Resistance against certain lepidopteran insects.
<i>cry1B.2</i> (MON 94637)	Chimeric protein with domains from different Cry1 proteins (Cry1A and Cry1B and Cry1K subclasses) from <i>B. thuringiensis</i> . ¹	Promoter and leader of a chlorophyll a/b-binding (CAB) protein from <i>Cucumis melo</i> . 3' UTR sequence from the <i>Lox-Mt1</i> gene of <i>M. truncatula</i> .	Resistance against certain lepidopteran insects.
<i>cry1Ac</i> (MON 87701)	Codon optimized coding sequence of the Cry1Ac protein of <i>B. thuringiensis</i> var. <i>kurstaki</i> . ^{6,2,3}	Promoter from the <i>RbcS4</i> gene of <i>A. thaliana</i> and 3'region of the <i>sphas1</i> gene of <i>Glycine max</i> including 35 nucleotides of the carboxy-terminus of β-conglycinin coding region, termination codon and polyadenylation sequence.	Resistance against certain lepidopteran insects.
<i>cry1A.105</i> (MON 87751)	Chimeric protein with domains from different Cry1 proteins (Cry1Ab, Cry1F and Cry1Ac) from <i>B. thuringiensis</i> . ^{4,5}	Promoter from the <i>rbcS</i> gene family of <i>A. thaliana</i> and 3'UTR of the <i>PT1</i> gene from <i>M. truncatula</i> .	Resistance against certain lepidopteran insects.

Introduced genes	Encoded proteins	Regulatory elements	Traits
<i>cry2Ab2</i> (MON 87751)	Codon optimized coding sequence of the Cry2Ab2 protein from <i>B. thuringiensis</i> . ^{4,5,6}	Promoter from the <i>act2</i> gene of <i>A. thaliana</i> and 3'UTR of the Mt gene from <i>Oryza sativa</i> .	Resistance against certain lepidopteran insects.
<i>dmo</i> (MON 94313)	Dicamba mono-oxygenase (DMO), codon optimised coding sequence originally derived from <i>Stenotrophomonas maltophilia</i> . ^{7,8}	Promoter, leader and intron of the polyubiquitin gene <i>ubq3</i> from <i>A. 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>M. 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> . ⁹	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> . ^{10,11}	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>O. sativa</i> . ¹²	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.
<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. ¹³	P-FMV/Tsf1 promoter (chimeric promoter containing enhancer sequences of the promoter of the <i>A. thaliana</i> <i>Tsf1</i> 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 94637,¹⁴ MON 87751,^{15,16} MON 87701,¹⁷ MON 94313,¹⁸ and MON 89788¹⁹. Furthermore, COGEM also advised positively on several stacked GM soybean lines containing two or more of these events.^{20,21} Three of the GM soybean lines are authorised for placement on the market in the European Union since 2008 (MON 89788²²), 2012 (MON 87701²³), and 2019 (MON 87751²⁴). MON 94637 and MON 94313 have not yet received authorisation for placement on the EU market. EFSA published a positive assessment on MON 94637 in October of 2025,²⁵ and on MON 94313 in January of 2026.²⁶

Soybean (*Glycine max*) is cultivated worldwide, from equatorial to temperate zones. It is a predominantly self-pollinating species. Natural outcrossing rates are generally low.^{27,28} For growth, soybean requires an optimum temperature between 25 °C and 30 °C. It is sensitive to frost and does not survive freezing conditions.^{27,28} 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).²⁹ 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.^{27,28}

The application for market authorisation of GM soybean MON 94637 × MON 87751 × MON 87701 × 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. The bio-informatic analysis of each of the inserted elements and its 3' and 5' junctions in the genome of GM soybean MON 94637 × MON 87751 × MON 87701 × MON 94313 × MON 89788 was updated to assess protein sequence similarities, using up-to-date 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 94637 × MON 87751 × MON 87701 × MON 94313 × MON 89788 and noted that most agronomic characteristics were equivalent in the GM crop and the non-transgenic reference varieties. One exception is the 'early stand count', for which 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 94637 × MON 87751 × MON 87701 × 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 94637 × MON 87751 × MON 87701 × 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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