Advice on the import and processing of GM soybean DAS-44406-6 x FG72

COGEM advice CGM/251104-01

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 DAS-44406-6 x FG72 (GMFF-2025-34192), as submitted by Syngenta Crop Protection NV/SA on behalf of Syngenta Crop Protection AG.

GM soybean DAS-44406-6 x FG72 was produced by crossing the parental soybean lines DAS-44406-6 and FG72 using traditional breeding methods. DAS-44406-6 was initially produced by *Agrobacterium tumefaciens*-mediated transformation. FG72 was produced using biolistic transformation. GM soybean DAS-44406-6 x FG72 expresses the *aad-12, 2mepsps,* and *pat* genes derived from DAS-44406-6, which respectively confer tolerance to 2,4-D, glyphosate and glufosinate-ammonium containing herbicides. It also expresses the *2mepsps* and *hppdPf W336* genes derived from FG72 which confer tolerance to respectively glyphosate and HPPD-containing herbicides (see Table 1 for a description of introduced genes and traits).

Table 1. Description of the introduced genes and traits

Introduced genes	**Encoded proteins**	**Regulatory elements**	**Traits**
pat (DAS-44406-6)	Codon optimized variant of phosphininothricin N-acetyltransferase (PAT) originating from *Streptomyces viridochromogenes*[1]	CsVMV promoter from the cassava vein mosaic virus and AtuORF1 terminator from *Agrobacterium tumefaciens*	Tolerance to glufosinate-ammonium containing-herbicides
aad-12 (DAS-44406-6)	Codon optimized version of aryloxyalkanoate dioxygenase-12 (AAD-12) enzyme originating from *Delftia acidovorans*[2]	AtUbi10 constitutive promoter from the *Arabidopsis thaliana* polyubiquitin 10 (UBQ10) gene and AtuORF23 terminator from *A. tumefaciens*	Tolerance to 2,4D containing-herbicides
2mepsps (DAS-44406-6)	The double mutant 5-enolpyruvylshikimate-3-phosphate synthase (2mEPSPS) enzyme originating from *Zea mays*[3]	Promoter from the *A. thaliana* histone H4A748 gene, a TPotp C transit peptide-encoding sequence, and a transcription terminator of the *A. thaliana* H4A748 gene	Tolerance to glyphosate-containing herbicides

Introduced genes	Encoded proteins	Regulatory elements	Traits
2mepsps (FG72)	The double mutant 5-enolpyruvylshikimate-3-phosphate synthase (2mEPSPS) enzyme originating from *Zea mays*[3]	Ph4a748 promoter of the *A.thaliana* H4 gene, Intron1 h3At (the first intron of gene II of the histone H3.III variant of *A. thaliana*), an optimised TPotp C transit peptide-encoding sequence, 3' untranslated region of the histone H4 gene of *A. thaliana* containing a transcription terminator	Tolerance to glyphosate-containing herbicides
hppdPfW336 (FG72)	A modified 4-hydroxyphenylpyruvate dioxygenase (HPPD) originating from the ubiquitous bacterium *Pseudomonas fluorescens*[4]	Ph4a748 ABBC sequence including the H4 histone gene promotor (which contains an internal duplication), 5' TEV leader sequence from tobacco etch virus, ; TPotp Y transit peptide-encoding sequence, and the 3' nos terminator from *A. tumefaciens*	Tolerance isoxaflutole herbicides

COGEM has previously advised positively on the import and processing of the parental lines FG72[5,6] and DAS-44406-6[7], as well as stacked GM soybean lines containing DAS-44406-6[8,9,10] or FG72[11]. GM soybean FG72 and DAS-44406-6 were authorised for placement on the market in the European Union in 2016[12] and 2017[13].

Soybean (*Glycine max*) is cultivated worldwide, from equatorial to temperate zones. It is a predominantly self-pollinating species. Natural outcrossing rates are generally low.[14,15] For growth, soybean requires an optimum temperature between 25 °C and 30 °C. It is sensitive to frost and does not survive freezing conditions.[14,15] 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).[16] 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.[14,15]

The bio-informatic analysis of each of the inserted elements and its 3' and 5' junctions in GM soybean DAS-44406-6 x FG72 were updated, using up-to-date databases of allergens, toxins, and general proteins to assess protein sequence similarities. No indications for potential environmental risks were identified.

The applicant analysed the phenotypic and agronomic characteristics of DAS-44406-6 x FG72 and noted that most agronomic characteristics were equivalent in the GM crop and the non-transgenic reference varieties. One exception is the 100-seed weight, for which non-equivalence to reference varieties was more likely than not. Further assessment by the applicant indicated that the non-equivalence was not biologically relevant, and 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 DAS-44406-6 x FG72 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 of DAS-44406-6 x FG72 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.

References

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15. 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
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