

Aan de staatssecretaris van Openbaar Vervoer en Milieu
Ministerie van Infrastructuur en Waterstaat
De heer A.A. Aartsen
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KENMERK CGM/251104-01
ONDERWERP Advice on the import and processing of GM soybean DAS-44406-6 x FG72

Geachte heer Aartsen,

Naar aanleiding een adviesvraag over de milieurisico's van import en verwerking van gg-soja DAS-44406-6 x FG72 (GMFF-2025-34192/AP197), ontwikkeld door Syngenta Crop Protection, 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 DAS-44406-6 x FG72;
- DAS-44406-6 x FG72 is verkregen door conventionele kruising tussen de gg-soja ouderlijnen DAS-44406-6 en FG72;
- 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 sojaboonpopulaties 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 DAS-44406-6 x FG72 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 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*, *zmepsps*, 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 *zmepsps* 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
<i>pat</i> (DAS-44406-6)	Codon optimized variant of phosphinothricin N-acetyltransferase (PAT) originating from <i>Streptomyces viridochromogenes</i> ¹	CsVMV promoter from the cassava vein mosaic virus and <i>AtuORF1</i> terminator from <i>Agrobacterium tumefaciens</i>	Tolerance to glufosinate-ammonium containing-herbicides
<i>aad-12</i> (DAS-44406-6)	Codon optimized version of aryloxyalkanoate dioxygenase-12 (AAD-12) enzyme originating from <i>Delftia acidovorans</i> ²	<i>AtUbi10</i> constitutive promoter from the <i>Arabidopsis thaliana</i> polyubiquitin 10 (UBQ10) gene and <i>AtuORF23</i> terminator from <i>A. tumefaciens</i>	Tolerance to 2,4D containing-herbicides
<i>zmepsps</i> (DAS-44406-6)	The double mutant 5-enolpyruvylshikimate-3-phosphate synthase (2mEPSPS) enzyme originating from <i>Zea mays</i> ³	Promoter from the <i>A. thaliana</i> histone H4A748 gene, a TPotp C transit peptide-encoding sequence, and a transcription terminator of the <i>A. thaliana</i> H4A748 gene	Tolerance to glyphosate-containing herbicides

Introduced genes	Encoded proteins	Regulatory elements	Traits
<i>zmepsps</i> (FG72)	The double mutant 5-enolpyruvylshikimate-3-phosphate synthase (2mEPSPS) enzyme originating from <i>Zea mays</i> ³	Ph4a7q8 promoter of the <i>A.thaliana</i> H4 gene, Intron1 h3At (the first intron of gene II of the histone H3.III variant of <i>A. thaliana</i>), an optimised TPotp C transit peptide-encoding sequence, 3' untranslated region of the histone H4 gene of <i>A. thaliana</i> containing a transcription terminator	Tolerance to glyphosate-containing herbicides
<i>hppdPfw336</i> (FG72)	A modified 4-hydroxyphenylpyruvate dioxygenase (HPPD) originating from the ubiquitous bacterium <i>Pseudomonas fluorescens</i> ⁴	Ph4a7q8 ABBC sequence including the H4 histone gene promoter (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 <i>A. tumefaciens</i>	Tolerance isoxaflutole herbicides

COGEM has previously advised positively on the import and processing of the parental lines FG72^{5,6} and DAS-44406-6⁷, as well as stacked GM soybean lines containing DAS-44406-6^{8,9,10} or FG72¹¹. GM soybean FG72 and DAS-44406-6 were authorised for placement on the market in the European Union in 2016¹² and 2017¹³.

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 renewal of the market authorisation for 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

1. OECD (1999). Consensus document on general information concerning the genes and their enzymes that confer tolerance to phosphinothricin herbicide
2. Wright T et al. (2010). Robust crop resistance to broadleaf and grass herbicides provided by aryloxyalkanoate dioxygenase transgenes. *Proc. Natl. Acad. Sci USA*. 107: 20240-20245
3. Della-Cioppa GS et al. (1986). Translocation of the precursor of 5-enolpyruvylshikimate-3-phosphate synthase into chloroplasts of higher plants in vitro. *Proc. Natl. Acad. Sci USA* 83: 6873-6877
4. Boudec P et al (2001). Mutated hydroxyphenylpyruvate dioxygenase. DNA sequence and isolation of plants which contain such a gene and which are tolerant to herbicides. US Patent US6245968B1.
5. COGEM (2012). Import of genetically modified soybean FG72 with glyphosate and isoxaflutole herbicide tolerance. COGEM advice CGM/120104-02
6. COGEM (2025). Advice on the renewal of the import and processing of GM soybean FG72. COGEM advice CGM/250728-02
7. COGEM (2013). Import of genetically modified soybean DAS-44406-6 with three herbicide tolerance traits. COGEM advice CGM/130627-01
8. COGEM (2017). Import and processing of genetically modified soybean DAS-81419-2xDAS-44406-6. COGEM advice CGM/170515-01
9. COGEM (2024). Environmental risk assessment of import and processing of GM soybean GMB151 x DAS-44406-6. COGEM advice CGM/241127-01
10. COGEM (2025). Advice on the renewal of import and processing of GM soybean 305423xDAS-44406-6. COGEM advice CGM/250610-01
11. COGEM (2015). Import of genetically modified soybean FG72xA5547-127 with three herbicide tolerance traits. COGEM advice CGM/151104-01
12. Commission Implementing Decision (EU) 2016/1215 of 22 July 2016 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 (MST-FGØ72-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. OJEU L 199/16
13. Commission Implementing Decision (EU) 2017/2450 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. OJEU L 346/16
14. OECD (2006). "Section 2 - Soybean (GLYCINE MAX (L.) MARR.)", in *Safety Assessment of Transgenic Organisms*, Volume 1: OECD Consensus Documents, OECD Publishing, Paris
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
16. Centraal Bureau voor de Statistiek (CBS). <https://opendata.cbs.nl/#/CBS/nl/dataset/81302ned/table?searchKeywords=sojabonen> (accessed: 25 September 2025)