

Aan de staatssecretaris van Openbaar Vervoer en Milieu
Ministerie van Infrastructuur en Waterstaat
Drs. S.Th.M. Hermans
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DATUM 10 juni 2025
KENMERK CGM/250610-01
ONDERWERP Advice on the import and processing of GM soybean 305423xDAS-44406-6

Geachte mevrouw Hermans,

Samenvatting:

- De COGEM is gevraagd te adviseren over de mogelijke milieurisico's van import en verwerking van de genetisch gemodificeerde (gg-)soja 305423xDAS-44406-6;
- De gg-soja 305423xDAS-44406-6 is verkregen door conventionele kruising tussen de gg-sojalijnen 305423 en DAS-44406-6;
- De COGEM heeft eerder positief geadviseerd over import en verwerking van beide ouderlijnen;
- In deze lijn worden genen tot expressie gebracht die zorgen voor tolerantie tegen verschillende herbiciden en een aangepaste vetzuursamenstelling;
- Er zijn geen verwilderde sojapopulaties in Nederland 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 verwilderen;
- Gezien het bovenstaande acht de COGEM de milieurisico's van de import en verwerking van de gg-soja 305423xDAS-44406-6 verwaarloosbaar klein.

Op verzoek van het Food-Feed loket voor ggo markttoelatingen is het advies in het Engels geschreven.

COGEM has been requested to evaluate the environmental risks associated with the authorisation for import of genetically modified (GM) soybean 305423xDAS-44406-6 (GMFF-2024-29150) for use in food and feed, as submitted by Corteva Agriscience Belgium B.V. on behalf of Corteva Agriscience LLC.

This GM soybean was produced by crossing the two parental soybean lines 305423 and DAS-44406-6 using traditional crossing methods. 305423 was produced using microprojectile bombardment and DAS-44406-6 was produced by *Agrobacterium*-mediated transformation. The GM soybean 305423xDAS-44406-6 expresses the *gm-hra*-, *pat*-, *aad-12*-, and *2mepsps*-genes, which respectively confer tolerance to acetolactate synthase-inhibitors, glufosinate-ammonium, 2,4-D, and glyphosate-containing herbicides. It also expresses the *gm-fad2-1* gene resulting in an altered fatty acid composition (Table 1).

Table 1. Description of the introduced genes and traits

Introduced genes	Encoded proteins	Regulatory elements	Traits
<i>gm-hra</i> (305423)	Acetolactate synthase (ALS or GM-HRA) from <i>Glycine max</i> ¹	S-adenosyl-L-methionine synthetase (SAMS) promoter, and the acetolactate synthase (<i>als</i>) gene terminator from <i>G. max</i>	Tolerance to acetolactate synthase (ALS) inhibiting herbicides
<i>Pat</i> (DAS-44406-6)	Codon optimized variant of phosphininothricin N-acetyltransferase (PAT) originating from <i>Streptomyces viridochromogenes</i> ²	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> ³	<i>AtUbio</i> constitutive promoter from the <i>A. thaliana</i> polyubiquitin 10 (UBQ10) gene and <i>AtuORF23</i> terminator from <i>A. tumefaciens</i>	Tolerance to 2,4D containing-herbicides
<i>2mepsps</i> (DAS-44406-6)	The double mutant 5-enolpyruvylshikimate-3-phosphate synthase (2mEPSPS) enzyme originating from <i>Zea mays</i> ⁴	Histone H4A748 promoter from <i>Arabidopsis thaliana</i> including an intron from the histone 3 gene from <i>A. thaliana</i> and Histone H4A748 terminator from <i>A. thaliana</i>	Tolerance to glyphosate-containing herbicides

Introduced genes	Encoded proteins	Regulatory elements	Traits
Fragment of the coding region of <i>gm-fad2-1</i> (305423)	Does not code for a functional protein ⁵	Seed preferred promoter (1000-fold less active in leaf tissue) and terminator from soybean Kunitz trypsin inhibitor gene 3 (KTI3)	Transcription of the <i>gm-fad2-1</i> fragment silences the endogenous <i>fad2-1</i> gene, which results in the inhibition of the conversion of oleic acid to linoleic acid, leading to decreased levels of linoleic acid and palmitic acid, and increased levels of oleic acid

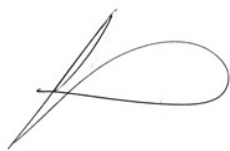
COGEM has previously advised positively on the import and processing of both parental lines 30542^{6,7} and DAS-44406-6⁸ and these GM soybeans were authorised for the placing on the market in the European Union.^{9,10}

Soybean (*Glycine max*) is cultivated worldwide, from equatorial to temperate zones. It is a predominantly self-pollinating species. Natural outcrossing rates are generally low.^{11,12} For growth, soybean requires an optimum temperature between 25 °C and 30 °C. It is sensitive to frost and does not survive freezing conditions.^{11,12} 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).¹³ 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.^{11,12}

The bio-informatic analysis of the inserted elements and its 3' and 5' junctions in GM soybean 305423xDAS-44406-6 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 305423xDAS-44406-6 and noted that these, except for the introduced traits, are not different compared to the conventional counterpart and are equivalent to the reference varieties. There are no indications of unexpected interactions between the introduced traits from the parental lines. The introduced traits in GM soybean 305423xDAS-44406-6 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 305423xDAS-44406-6 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.

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

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