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KENMERK CGM/260916-01
ONDERWERP Advies Import en verwerking van gg-soja DBN8205

Geachte mevrouw Bertram,

Naar aanleiding van een adviesvraag over de milieurisico's van import en verwerking van gg-soja DBN8205 (MA 260006_001; GMFF-2025-37290/AP205), ontwikkeld door Beijing DaBeiNong Biotechnology Co., vertegenwoordigd door Perseus BV, 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 om te adviseren over eventuele milieurisico's van import en verwerking van de genetisch gemodificeerde (gg-)sojalijn DBN8205. Deze sojalijn brengt de *Cry1Ac* en *Cry2Ab* genen tot expressie waardoor de plant beter beschermd is tegen vraat door vlinderachtigen. DBN8205 brengt daarnaast het *pat* gen tot expressie waardoor het tolerant is voor glufosinaat-ammonium bevattende herbiciden.

Hoewel het klimaat niet optimaal is, wordt soja op kleine schaal in Nederland geteeld. Opslagplanten worden hier zelden waargenomen en hebben nooit geleid tot verwildeerde populaties. Er zijn geen wilde verwanten van soja aanwezig in Europa, waardoor de ingebrachte genen zich niet naar andere soorten kunnen verspreiden. De moleculaire karakterisering van gg-soja DBN8205 voldoet aan de eisen van de COGEM. Er zijn geen redenen om aan te nemen dat expressie van de ingebrachte genen ervoor zorgt dat deze gg-sojalijn zich in Nederland zou kunnen vestigen.

Gezien het bovenstaande is de COGEM van oordeel dat de milieurisico's voor Nederland bij import en verwerking van gg-soja DBN8205 verwaarloosbaar klein zijn. Omdat andere instanties een voedselveiligheidsbeoordeling uitvoeren, heeft de COGEM de risico's van incidentele consumptie niet beoordeeld.



De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,

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c.c.

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Advice on the import and processing of GM soybean DBN8205

COGEM advice CGM/260916-01

- The present application (MA 260006_001; GMFF-2025-37290/AP205) concerns the authorisation for import and processing for use in food and feed of genetically modified (GM) soybean DBN8205;
- DBN8205 expresses the *Cry1Ac* and *Cry2Ab* genes, which confer resistance against certain lepidopteran species. It also contains the *pat* gene conferring tolerance to glufosinate-ammonium containing herbicides;
- The molecular characterisation of DBN8205 meets the criteria of COGEM, and no indications for potential environmental risks were identified;
- In the Netherlands, feral soybean populations do not occur;
- Hybridisation of soybean with other species is impossible in the Netherlands;
- There are no indications that the introduced traits allow GM soybean DBN8205 to survive in the Dutch environment;
- COGEM is of the opinion that import and processing of GM soybean DBN8205 poses a negligible risk to the environment in the Netherlands;
- COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is carried out by other organisations.

1. Introduction

The present application (MA 260006_001; GMFF-2025-37290/AP205), submitted by Perseus BV on behalf of Beijing DaBeiNong Biotechnology Co, concerns the import and processing of genetically modified (GM) soybean DBN8205. DBN8205 carries the *Cry1Ac* and *Cry2Ab* genes, which confer resistance against certain lepidopteran pests. It also expresses the *pat* gene conferring tolerance to glufosinate-ammonium containing herbicides.

2. Previous COGEM advice

COGEM has previously advised positively on GM soybean lines that express the *Cry1Ac* and/or *Cry2Ab2* genes from *Bacillus thuringiensis*, conferring resistance against certain lepidopteran pests.^{e.g.1,2,3,4} Soybean DBN8205 expresses a *Cry2Ab* gene. Different variants of the *Cry2Ab* gene, such as the gene variants *Cry2Ab1*, *Cry2Ab2* and *Cry2Ab3*, differ only by translationally silent nucleotide substitutions and encode an identical protein, collectively referred to as *Cry2Ab*.^{5,6} COGEM has also issued positive opinions on GM soybean express the *pat* gene from *Streptomyces viridochromogenes*1 conferring tolerance to glufosinate-ammonium containing herbicides.^{e.g.7,8}

3. Environmental risk assessment

The objective of an environmental risk assessment (ERA) is to identify and evaluate potential adverse effects of the genetically modified organism (GMO), direct or indirect, immediate, or delayed, on human health and the environment. This ERA involves the import and processing of GM soybean. Any concerns relating to cultivation, management or harvesting practices are beyond the scope of this advice. When assessing the environmental risk of incidental spillage of GM soybean COGEM first considers the likelihood that the event could establish itself in the Netherlands or could hybridise with related species. Other so-called 'areas of concern' (e.g. effects on non-target organisms) are addressed only if there is a possibility that the event could establish itself or if gene flow to other species might occur.

3.1 Characteristics of soybean

Soybean (*Glycine max*) belongs to the *Leguminosae* (*Fabaceae*) family and is cultivated from equatorial to temperate zones. The optimum temperature for soybean growth is between 25 °C and 30 °C. Soybean is sensitive to frost and therefore does not survive freezing conditions.^{9,10,11} The soybean plant is not weedy in character.^{10,11} To reduce yield losses during harvest, soybean plants with minimal seed scattering were selected for breeding. Soybean seeds rarely display dormancy, poorly survive in soil, and do not form a persistent soil seed bank.^{10,12} Soybean volunteers are rarely observed throughout the world and do not compete effectively with other cultivated plants or primary colonisers.^{10,11} In addition, volunteers are easily controlled mechanically or chemically.¹¹ Soybean is a predominantly self-pollinating species. The anthers mature in the bud and directly pollinate the stigma of the same flower.^{10,11} The cross-pollination rate of soybean is low and on average between 1 to 3%.^{10,11,13,14,15,16,17} Soybean pollen disperses almost only over short distances.

3.2 Receiving environment

As mentioned previously, soybean is sensitive to frost. Frost is common in the Netherlands, with an average of 51 days a year of minimum temperatures below 0 °C.¹⁸ Although the Dutch climate is not optimal, soybean is cultivated on a small scale (179 hectares or approximately 441 acres in 2026, preliminary data).¹⁹ Soybean volunteers are very uncommon in the Netherlands and have never resulted in establishment of wild populations.^{20,21} To the best of COGEM's knowledge, there are no reports of feral soybean populations in Europe. Additionally, in Europe, hybridisation with other species is not possible because there are no wild relatives of soybean.^{10,11}

Conclusion: In the Netherlands feral soybean populations do not occur and hybridisation of soybean with other species is not possible.

3.3 Description of the introduced genes and traits

The GM soybean DBN8205 was generated by *Agrobacterium tumefaciens* (strain EHA101) mediated transformation of the conventional soybean variety 'Jack' with the pDBN4031 plasmid. This plasmid is 17.3 kb and contains one T-DNA region, consisting of the *Cry1Ac*, the *Cry2Ab* and the *pat* expression cassette. Outside the T-DNA, pDBN4031 contains the *spec* gene: the *aadA* gene from *Escherichia coli*. The *aadA* gene encodes an enzyme conferring tolerance to spectinomycin and streptomycin, and is used as a selectable marker for the plasmid in bacteria.

A description of the inserted genetic elements is listed in the table below. The list is limited to information on the introduced genes, corresponding traits, and regulatory elements (promoters and terminators).

Introduced genes	Encoded proteins	Regulatory elements	Traits
<i>cry1Ac</i>	Codon-modified coding sequence of the Cry1Ac protein of <i>Bacillus thuringiensis</i> ^{22,23,24}	Promoter from the RbcS4 gene of <i>Arabidopsis thaliana</i> ²⁵ and 3' region of the Nos gene from <i>Agrobacterium tumefaciens</i> ²⁶	Resistance to certain lepidopteran insects
<i>cry2Ab</i>	The Cry2Ab protein from <i>B. thuringiensis</i> ²⁷	Promoter from the act2 gene of <i>A. thaliana</i> ²⁸ and terminator sequence PsEg <i>Pisum sativum</i> ²⁹	Resistance to certain lepidopteran insects
<i>pat</i>	Codon optimized variant of phosphinothricin Nacetyltransferase (PAT) originating from <i>Streptomyces viridochromogenes</i> strain Tü 494 ^{30,31,32}	35S promoter ³³ and 35S terminator ³⁴ from <i>Caulimovirus tessellobrassicae</i> (cauliflower mosaic virus)	Tolerance to glufosinate-ammonium containing herbicides
See references for a detailed description of the traits			

3.4 Molecular characterisation

The applicant performed a Sanger sequencing analysis of the DBN8205 genome to determine the sequence of the insertion site, insert and flanking regions. Analysis of the sequencing data shows the inserted sequence in DBN8002 to be identical to the T-DNA of the transformation plasmid pDBN4006. Southern blot experiments demonstrate the absence of the plasmid backbone sequence in DBN8205. In addition, these experiments demonstrate that DBN8205 contains a single intact insert, with single copies of the *cry1Ac*, *cry2Ab* and *pat* genes, which remain stable across five generations.

The applicant analysed the integrity of the site of insertion by comparing its sequence to the sequence of the corresponding region of the reference genome of soybean. Bio-informatic analysis of about 1,000 base pairs of the 5' and 407 base pairs of the 3' flanking regions show the T-DNA to be inserted at a single location on chromosome 1. A 280 bp deletion was found at the T-DNA insertion site. The applicant states that the deleted region corresponds to an intergenic region, and did not disrupt any known gene or annotated sequence of the soybean genome. According to analysis of the insertion site, no endogenous genes were disrupted by the T-DNA insert.

The applicant screened the 3' and 5' junctions of the insert and its flanking regions, as well as the entire insert, for potential newly created open reading frames (ORFs). According to the applicant, the putative products of the identified ORFs did not generate any protein sequence similarity with known allergens or toxins.

Overall, the molecular characterisation was conducted according to the criteria previously laid down by COGEM.³⁵ The results from the molecular characterisation do not provide indications that DBN8205 soybean could pose a risk to the environment.

Conclusion: The molecular characterisation of soybean DBN8205 is adequate and no indications for potential environmental risks were identified.

3.5 Phenotypic and agronomic characteristics

The applicant evaluated the phenotypic and agronomic characteristics of DBN8205 at multiple field sites across the China during the 2021 growing season, comparing it to both the conventional counterpart (soybean 'Jack') and several commercial non-GMO reference varieties. The applicant analysed the phenotypic and agronomic characteristics of DBN8205. Some of the assessed characteristics were observed to differ from the conventional counterpart. In DBN8205 soybean plants differences were observed with regard to 'plant height' (lower than control), 'final plant stand' (number of plants per m², lower than control), 'lodging' (lower than control) and '1000 seeds weight' (lower than control). The above mentioned characteristics, and all other parameters, were equivalent to the non-GM soybean reference varieties, taking into account natural variation.

Based on these findings, COGEM concludes that – aside from the introduced herbicide tolerance and insect resistance trait – the agronomic and phenotypic characteristics of DBN8205 are comparable to those of conventional soybean varieties. There is no evidence to suggest that DBN8205 would have an increased ability to survive or establish in the Dutch environment.

Conclusion: There are no indications that soybean DBN8205 would be able to survive or establish in the Netherlands.

4. Food/feed assessment

This application is submitted under Regulation (EC) 1829/2003, therefore a food/feed assessment is carried out by EFSA and national organisations involved in the assessment of food safety. In the Netherlands, WFSR carries out a food and/or feed assessment for Regulation (EC) 1829/2003 applications. The outcome of the assessment by other organisations (EFSA, WFSR) was not known when this advice was completed.

5. Post-market environmental monitoring

The applicant supplied a post-market environmental monitoring (PMEM) plan, following the standard PMEM template that has been developed by the European Commission in cooperation with relevant operators.³⁶ The purpose of PMEM plan is to detect any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs after they have been placed on the market. The PMEM plan must include general surveillance for unanticipated adverse effects and, where relevant, case-specific monitoring. COGEM has previously published several recommendations for further improvement of PMEM plans^{37,38}, but considers the supplied PMEM plan adequate for the import and processing of soybean DBN8205.

Conclusion: The current PMEM plan of GM soybean DBN8205 is sufficient for import and processing.

6. Overall conclusion

Conclusion: COGEM is of the opinion that import and processing of soybean DBN8205 poses a negligible risk to the environment in the Netherlands. COGEM abstains from giving advice on the potential risks of incidental consumption since other organisations carry out a food/feed assessment.

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