COMMISSIE
COGEM
GENETISCHE
MODIFICATIE

BEZOEKADRES:
A. VAN LEEUWENHOEKLAAN 9
3721 MA BILTHOVEN

POSTADRES:
POSTBUS 578
3720 AN BILTHOVEN

TEL.: 088 689 2777
INFO@COGEM.NET
WWW.COGEM.NET

Aan de staatssecretaris van Openbaar Vervoer en Milieu
Ministerie van Infrastructuur en Waterstaat
Ch.A. Jansen
Postbus 20901
2500 EX Den Haag

DATUM 9 oktober 2024
KENMERK CGM/241009-01
ONDERWERP Advies hernieuwing vergunning voor import gg-soja MON87769

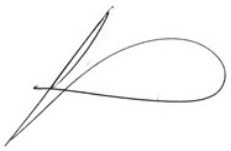
Geachte heer Jansen,

Naar aanleiding van een adviesvraag over hernieuwing van de vergunning voor import en verwerking van genetisch gemodificeerde soja MON87769 (GMFF-2023-21253), ontwikkeld door Bayer CropScience LP, vertegenwoordigd door Bayer Agriculture BV, deelt de COGEM u het volgende mee.

Samenvatting:
De COGEM is gevraagd om te adviseren over de hernieuwing van de vergunning voor import en verwerking van de genetisch gemodificeerde (gg-) sojalijn MON87769. Deze lijn brengt de genen *Pj.D6D* en *Nc.Fad3* tot expressie, wat resulteert in sojabonen met een veranderde vetzuursamenstelling. De eerdere vergunning is in 2015 afgegeven voor een periode van 10 jaar. De COGEM heeft in 2010 positief geadviseerd over de import en verwerking van de sojalijn MON87769.
De hernieuwingsaanvraag bevat o.a. geactualiseerde bio-informatische analyses, een recente literatuurstudie en de resultaten van de verplichte 'post-market environmental monitoring' die sinds 2015 is uitgevoerd. Hieruit komen geen nieuwe inzichten over mogelijke risico's voor mens en milieu naar voren. Hoewel het klimaat niet optimaal is, wordt soja op kleine schaal in Nederland geteeld. Opslagplanten worden hier zelden waargenomen en hebben nooit geleid tot verwilderde populaties. Er zijn in Europa geen wilde verwanten van soja, waardoor de ingebrachte genen zich niet naar andere soorten kunnen verspreiden.
Alle aspecten in overweging nemende, acht de COGEM de milieurisico's voor Nederland bij de import en verwerking van gg-soja MON87769 verwaarloosbaar klein. Omdat andere instanties een voedselveiligheidsbeoordeling uitvoeren, heeft de COGEM bij deze vergunningaanvraag 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,



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

Renewal of the authorisation for import and processing of genetically modified soybean MON87769

COGEM advice CGM/241009-01

- The present application (GMFF-2023-21253) concerns the renewal of the authorisation for import and processing for use in feed and food of genetically of genetically modified (GM) soybean (*Glycine max*) MON87769;
- GM soybean MON 87769 was previously authorised for import and processing in 2015;
- COGEM has advised positively on the import and processing of GM soybean MON87769 in 2010;

- MON87769 expresses the *Pj.D6D* gene derived from *Primula juliae* and *Nc.Fad3* derived from *Neurospora crassa* resulting in the production of stearidonic acid (SDA), an omega3 fatty acid;

- In the Netherlands, feral soybean populations do not occur;
- Hybridisation of soybean with other species is not possible in the Netherlands, as there are no wild relatives of soybean;

- The molecular characterisation of GM soybean MON87769 has been updated and meets the criteria of COGEM;
- The updated bioinformatics analyses, literature review and monitoring reports do not give any indication of a potential environmental risk;

- COGEM is of the opinion that import and processing of GM soybean MON87769 poses a negligible risk to the environment in the Netherlands;
- As other organisations carry out a food/feed assessment, COGEM abstains from giving advice on the potential risks of incidental consumption.

1. Introduction

The present application (GMFF-2023-21253), filed by Bayer Agriculture BV on behalf of Bayer CropScience LP, concerns the renewal of the authorisation for import and processing for use in feed and food of genetically of genetically modified (GM) soybean (*Glycine max*) MON87769. This authorisation was granted in 2015.[1] As import and processing authorisations remain valid for a period of 10 years, the applicant has filed an application for the renewal of the authorisation granted in 2015. The application contains – among other things – monitoring reports, updated bioinformatics analyses, and a systematic literature search. The soybean MON87769 expresses the *Pj.D6D* gene derived from *Primula juliae* and *Nc.Fad3* derived from *Neurospora crassa*, resulting in the production of stearidonic acid (SDA), an omega3 fatty acid.

2. Previous COGEM Advice

The COGEM advised on the import and processing of GM soybean MON87769 in 2010, and concluded that it poses a negligible risk to the environment.[2] In addition, COGEM also advised positively on a stacked event containing MON87769: GM soybean MON87769 x MON89788 in 2014.[3]

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 chance that the event could establish itself or if gene flow to other species might occur.

3.1 Characteristics of the crop

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.[4,5,6] The soybean plant is not weedy in character.[5,6] To reduce yield losses during harvest, soybean plants with minimal seed scattering have been selected for breeding. Soybean seeds rarely display dormancy, survive poorly in soil, and do not form a persistent soil seed bank.[5,7] Soybean volunteers are rarely observed throughout the world and do not compete effectively with other cultivated plants or primary colonisers.[5,6] In addition, volunteers are easily controlled mechanically or chemically.[6]

Soybean is a predominantly self-pollinating species. The anthers mature in the bud and directly pollinate the stigma of the same flower.[5,6] Pollinators such as honeybees (*Apis mellifera* L.) may improve the distribution of pollen on the stigmatic surface, which is known to increase seed set in many crops, and may as well facilitate transfer of soybean pollen and enable cross-pollination.[8,9,10,11] The cross-pollination rate of soybean is low and on average between 1 to 3%.[5,6,12,13,14,15,16] Usually, soybean pollen only disperse over short distances.

3.2 Receiving environment

As mentioned previously, soybean is sensitive to frost. Temperatures below 0 °C are common in the Netherlands, with an average of 51 frost days a year between 1991 and 2020.[17] Although the Dutch climate is not optimal, soybean is cultivated on a small scale (442 hectares in 2023).[18] Soybean volunteers are very uncommon in the Netherlands and have never resulted in establishment of wild populations.[19,20] 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.[5,6]

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

3.3 Description of the introduced genes and traits

MON87769 was developed by *Agrobacterium*-mediated transformation of the conventional soybean line A3525 with the binary vector PV-GMPQ1972. PV-GMPQ1972 contains two T-DNA regions (T-DNA I and II). T-DNA I contains the *Pj.D6D* and *Nc.Fad3t* expression cassettes, resulting in the production of stearidonic acid (SDA), an omega-3 fatty acid. T-DNA-II contains the cassette that expresses the *cp4 epsps* gene derived from *Agrobacterium* sp., conferring tolerance to glyphosate containing herbicides.[21] Glyphosate tolerance was used as a tool to select transformed plants. This cassette was subsequently removed from the line by conventional breeding and selection, resulting in MON87769 soybean which is tolerant to dicamba herbicides, but sensitive to herbicides containing glyphosate.[22]

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 (promotors and terminators). For a more detailed description, see the previous COGEM advise.[2]

Introduced gene	**Encoded protein**	**Regulatory elements**	**Traits**
Pj.D6D	Delta-6 desaturase from *Primula juliae* (PjΔ6D)	7Sα' seed-specific promoter and leader sequence from the *Sphas1* gene of *Glycine max* The tml 3' non-translated region of the *tml* gene from *Agrobacterium tumefaciens* octopine-type Ti plasmid	Seed specific production of the PjΔ6 desaturase proteins
Nc.Fad3t	Delta-15 desaturase from *Neurospora crassa* (NcΔ15D)	7Sα promotor and leader sequence from the *Sphas2* gene from *G. max* The E9 3' non-translated region from the *rbcS2* gene of *Pisum sativum* for polyadenylation of the mRNA.	Seed specific production of the NcΔ15 desaturase proteins

3.4 Updated bioinformatic analyses

The bioinformatic analysis performed for the previous application regarding MON87769 was repeated with updated databases – assembled in 2023 – containing sequences from allergens, toxins, and proteins. According to the applicant there were no biologically relevant amino acid sequence similarities to

known allergens, toxins, or other biologically active proteins with adverse effects for human or animal health.

COGEM is of the opinion that the molecular characterisation of GM soybean MON87769 has been performed correctly and meets the requirements of COGEM.[23]

Conclusion: The bioinformatics analyses of GM soybean MON87769 been updated and performed adequately. No indications for potential environmental risks were identified.

3.5 Systematic literature search and unpublished studies

The applicant performed a literature search using several bibliographic databases and internet pages of relevant key organisations involved in the risk assessment of GM plants covering a publication period from 1 January 2014 to 4 January 2024. The literature search was performed for multiple GM soybean events at once and addressed the question "Does the Bayer GM soybean products, derived food/feed products and the introduced improved fatty acid profile and dicamba tolerance traits have adverse effects on human and animal health and the environment?". The applicant states that they are not in possession of unpublished studies that could influence the risk assessment of GM soybean MON87769.

The literature search identified 1865 publications in electronic databases and 520 records of internet pages of relevant key organisations. Four studies were considered relevant for soybean MON87769.[24,25,26,i] According to the applicant, none of these studies were found to contain new data relevant to the risk assessment. Overall, no adverse effects on human and animal health, or the environment were identified in the literature searches of the applicant.

Conclusion: The systematic literature search did not provide any indications that import and processing of soybean MON87769 poses an environmental risk.

3.6 Annual monitoring reports

The applicant supplied annual reports of the post-market monitoring (PMEM) conducted between October 2015 and November 2023. These reports contain, amongst other things, information on the monitoring that is conducted by operators involved in import, handling, and processing of viable GM soybean. These operators are members of the European trade associations COCERAL, UNISTOCK or FEDIOL, and have agreed to participate in the PMEM. They are expected to report any occurrence of unanticipated adverse effects arising from soybean MON87769, including adventitious populations

[i] Out of the four identified relevant studies one was not accessible to the COGEM. This concerns the reference: Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) (2014) ステアリドン酸産生ダイズ, MON87769 https://www.maff.go.jp/j/syouan/nouan/carta/torikumi/attach/pdf/index-53.pdf. This is described by the applicant as a weblink dedicated to a list of approved genetically modified agricultural crops. The applicant states that no adverse effects on human and animal health, or the environment were identified in this document.

resisting routine eradication procedures. No adverse health or environmental effects were reported by the trade associations involved in the monitoring of import and processing of MON87769 soybean.

According to the monitoring reports, no relevant publications that invalidate the initial conclusions on the risk assessment of MON87769 soybean were identified in the annual literature search.

Conclusion: The information in the annual monitoring reports gives no indication of adverse effects or incidents resulting from import and/or processing of MON87769.

4. Food/feed assessment

This application is submitted under Regulation (EC) 1829/2003[27], therefore a food/feed assessment is conducted by European Food Safety Authority (EFSA) and national organisations involved in the assessment of food safety. In the Netherlands, Wageningen Food Safety Research (WFSR) conducts 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 did not propose any changes to the existing post-market environmental monitoring (PMEM) plan for soybean MON87769. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan[28,29] – which is part of a PMEM plan – but considers the current GS plan adequate for import and processing of soybean MON87769.

Conclusion: The current PMEM plan is sufficient for the import and processing of GM soybean MON87769.

6. Overall conclusion

Overall, COGEM is of the opinion that import and processing of soybean MON87769 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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