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DATUM 10 mei 2019
KENMERK CGM/190510-01
ONDERWERP Advies import en verwerking gg-soja GMB151

Geachte mevrouw Van Nieuwenhuizen,

Naar aanleiding van een adviesvraag over de milieurisico's van import en verwerking van de genetisch gemodificeerde sojalin GMB151 (EFSA/GMO/NL/2018/153), ingediend door BASF Agricultural Solutions Seed US LLC, deelt de COGEM u het volgende mee.

Samenvatting:

De COGEM is gevraagd te adviseren over de mogelijke milieurisico's van import en verwerking van genetisch gemodificeerde (gg-) soja GMB151. In deze lijn komen de genen *cry14Ab-1.b* en *hppdPf-4Pa* tot expressie, waardoor het gewas resistent is tegen het sojacystenaaltje en tolerant is voor bepaalde herbiciden.

Hoewel het klimaat niet optimaal is, wordt Sojaboon op kleine schaal in Nederland geteeld. Soja-opslagplanten komen in Nederland zeer zelden voor en hebben nooit geleid tot verwilderde populaties. In Europa zijn geen wilde verwanten van Sojaboon aanwezig, zodat de ingebrachte sequenties zich niet naar andere soorten kunnen verspreiden.

De moleculaire karakterisering van sojalin GMB151 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-soja zou kunnen verwilderen.

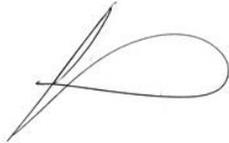
Alle aspecten in overweging nemende, acht de COGEM de milieurisico's voor Nederland bij import en verwerking van gg-soja GMB151 verwaarloosbaar klein.

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,



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Voorzitter COGEM

c.c. Dr. J. Westra, Hoofd Bureau ggo
 Mr. J.K.B.H. Kwisthout, Ministerie van IenW
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Import and processing of genetically modified soybean GMB151

COGEM advice CGM/190510-01

- The present application (EFSA/GMO/NL/2018/153) concerns the authorisation for import and processing for use in feed and food of genetically modified (GM) soybean GMB151;
- The GM soybean expresses the genes *cry14Ab-1.b* and *hppdPf-4Pa*, conferring resistance to soybean cyst nematode and tolerance to hydroxyphenylpyruvate dioxygenase (HPPD) inhibitor containing herbicides, respectively;
- In the Netherlands, feral soybean populations do not occur and hybridisation of soybean with other species is not possible;
- The molecular characterisation of GM soybean GMB151 meets the criteria of COGEM;
- There are no indications that the introduced traits alter the fitness of GM soybean GMB151;
- There is no reason to assume that the introduced traits will allow GM soybean GMB151 to survive in the Dutch environment;
- COGEM is of the opinion that import and processing of GM soybean GMB151 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 (EFSA/GMO/NL/2018/153), filed by BASF Agricultural Solutions Seeds US LLC, concerns import and processing of genetically modified (GM) soybean GMB151. This GM soybean line contains the genes *cry14Ab-1.b* and *hppdPf-4Pa*, conferring resistance to soybean cyst nematode and tolerance to hydroxyphenylpyruvate dioxygenase (HPPD) inhibitor containing herbicides, such as isoxaflutole.

2. Previous COGEM advice

COGEM has not previously advised on import and processing of GM soybean GMB151. COGEM did advise positively on GM soybean line FG72 and on GM cotton line GHB811, which both contain the gene *hppdPfW336*.^{1,2}

3. Environmental risk assessment

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.^{3,4,5} In the Netherlands, frost is common. On average 58 days a year have minimum temperatures below 0°C.^{6,7} Although the Dutch climate is not optimal, soybean is cultivated on a small scale (about 475 acres in 2018).⁸

The soybean plant is not weedy in character.^{4,5} To reduce yield losses during harvesting, soybean plants that have 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.^{4,9} Soybean volunteers are rarely observed throughout the world and do not effectively compete with other cultivated plants or primary colonisers.^{4,5} In addition, volunteers are easily controlled mechanically or chemically.⁵ Soybean volunteers are very uncommon in the Netherlands and have never resulted in establishment of wild populations.¹⁰ To the best of COGEM’s knowledge, there are no reports of feral soybean populations in Europe.

Soybean is predominantly a self-pollinating species. The anthers mature in the bud and directly pollinate the stigma of the same flower.^{4,5} The cross-pollination rate of soybean is low and on average between 1 to 3%.^{4,5,11,12,13,14,15} Pollen disperses only over short distances. In Europe, hybridisation with other species is not possible because there are no wild relatives of soybean.^{4,5}

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

3.2 Description of the introduced genes and traits

GMB151 was developed using *Agrobacterium tumefaciens* mediated transformation. 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	Traits	Regulatory elements
<i>cry14Ab-1.b</i>	Cry14Ab-1 from <i>Bacillus thuringiensis</i> ¹⁶	Resistance to soybean cyst nematode	Pubi10At promoter from <i>Arabidopsis thaliana</i> and 35S terminator from <i>Cauliflower mosaic virus (CaMV)</i>
<i>hppdPf-4Pa</i>	Modified 4-hydroxy-phenylpyruvate dioxygenase (HPPD-4) from <i>Pseudomonas fluorescens</i> ¹⁷	Tolerance to hydroxy-phenylpyruvate dioxygenase inhibitor containing herbicides	Double enhanced promoter from CaMV and 3’ untranslated region of the 35S transcript from CaMV
For a detailed description of the introduced genes and traits, see references			

3.3 Molecular characterisation

The applicant performed Next Generation Sequencing (NGS) and Junction Sequence Analysis (JSA). According to the applicant the results of these analyses show that the GMB151 soybean transgenic locus contains one copy of the T-DNA, comprising the complete *cry14Ab-1.b* gene cassette and the *hppdPf-4Pa* gene cassette which lacks the 5' part of the P2x35S promoter. GMB151 contains a 39 bp insert at the 3' end of the inserted T-DNA. 21 bp of this DNA show sequence identity to a region containing ORIpVS1 from the transforming plasmid pSZ8832 and 17 bp have sequence identity to the 3' flanking genomic sequence. Besides these 21 bp no backbone sequences are present in GMB151.

During the integration of the T-DNA, a fragment of 63 bp was deleted from the soybean genome. According to the applicant, the insertion of the T-DNA is located in the 3' untranslated region of a putative endogenous gene annotated as a BON1-associated protein 1-like protein. The applicant states that based on literature, the BON1-associated protein 1 has a function in a signal transduction cascade in *Arabidopsis thaliana*. At present, the biological function of the BON1-associated protein 1-like protein in soybean remains uncharacterized.

One base pair difference between the 3' flanking genomic sequence of the GMB151 soybean transgenic locus and the GMB151 insertion locus was found. According to the applicant, sequence differences between plants are commonly found and are due to natural genetic variation.¹⁸

The applicant screened the junctions between the T-DNA insert and the flanking soybean genomic DNA as well as the entire insert (from stop to stop codon) for potential newly created open reading frames (ORFs). According to the applicant, no significant sequence similarities between the putative products of these ORFs and no known or putative allergenic or toxic proteins were detected in bioinformatics analyses.

The molecular characterisation was conducted according to the criteria previously laid down by COGEM.¹⁹

Conclusion: The molecular characterisation of soybean GMB151 is adequate and no indications for potential environmental risks were identified.

3.4 Phenotypic and agronomic characteristics

The applicant analysed the phenotypic and agronomic characteristics of soybean GMB151 and noted that these, except for the introduced traits, are not different from the non-GM conventional counterpart, and are equivalent to the reference varieties, taking into account natural variation. The introduced traits do not give reason to assume that GMB151 has an altered fitness compared to conventional counterpart. COGEM is of the opinion that there are no indications that soybean GMB151 will be able to survive or establish in the Dutch environment.

Conclusion: There are no indications that the introduced traits allow the event GM soybean GMB151 to survive in the Netherlands. GMB151 does not have an increased potential for the establishment of feral populations 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, RIKILT carries out a food and/or feed assessment for Regulation (EC) 1829/2003 applications. The outcome of the assessment by other organisations (EFSA, RIKILT) was not known when this advice was completed.

5. Post-market environmental monitoring (PMEM)

The applicant supplied a post-market environmental monitoring (PMEM) plan. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan^{20,21} but considers the current GS plan adequate for import and processing of soybean GMB151.

6. Overall conclusion

COGEM is of the opinion that import and processing of soybean GMB151 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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