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KENMERK CGM/180802-01

ONDERWERP Advies import en verwerking van gg-soja DP305423xMON87708xMON89788

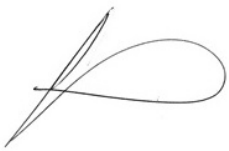
Geachte mevrouw Van Veldhoven,

Naar aanleiding van een vergunningaanvraag voor import en verwerking van genetisch gemodificeerde soja DP305423xMON87708xMON89788 (EFSA/GMO/NL/2018/148), ingediend door Pioneer Hi-Bred International, Inc., 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 DP305423xMON87708x MON89788. In deze gg-soja komen de genen *gm-hra*, *dmo* en *cp4 epsps* tot expressie, waardoor de plant tolerant is voor verschillende herbiciden. Ook bevat deze gg-soja een fragment van het *fad2-1* gen, waardoor de plant een verhoogd oliezuurgehalte heeft.
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 gg-soja DP305423xMON87708xMON89788 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.
Gezien het bovenstaande acht de COGEM de milieurisico's van de import en verwerking van de gg-soja DP305423xMON87708xMON89788, verwaarloosbaar klein.
Omdat een voedselveiligheidsbeoordeling door andere instanties wordt uitgevoerd, 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

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Import and processing of genetically modified soybean DP305423xMON87708xMON89788

COGEM advice CGM/180802-01

- The present application (EFSA/GMO/NL/2018/148) concerns the authorisation for import and processing for use in feed and food of genetically modified (GM) soybean DP305423xMON87708xMON89788;
- Soybean DP305423xMON87708xMON89788 was produced by conventional crossbreeding of the three GM parental soybean lines;
- Previously, COGEM advised positively on the import and processing of all three parental lines;
- The GM soybean expresses the genes *gm-hra, dmo* and *cp4 epsps*, conferring tolerance to acetolactate synthase (ALS) inhibiting herbicides, dicamba-based herbicides and glyphosate containing herbicides;
- It also expresses a fragment of the *fad2-1* endogenous gene, resulting in a high-oleic acid phenotype;

- In the Netherlands, feral soybean populations do not occur and hybridisation of soybean with other species is not possible;

- The molecular characterisation of soybean DP305423xMON87708xMON89788 has been updated and meets the criteria of COGEM;
- The updated bioinformatics analysis do not provide indications for potential environmental risks;

- There are no indications that the introduced traits allow soybean DP305423xMON87708x MON89788 to survive in the Netherlands;
- There are no indications that soybean DP305423xMON87708xMON89788 could establish feral populations in the Netherlands;

- COGEM is of the opinion that import and processing of soybean DP305423xMON87708x MON89788 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/2018/148) filed by Pioneer concerns import and processing of soybean DP305423xMON87708xMON89788. The GM soybean was produced by

conventional crossbreeding of three GM parental soybean lines. It expresses the *gm-hra*, *dmo*, and *cp4 epsps* genes conferring tolerance to acetolactate synthase (ALS) inhibiting herbicides, dicamba containing herbicides and glyphosate containing herbicides. In addition, it expresses a fragment of the endogenous *fad2-1* gene, resulting in an increased level of oleic acid and decreased levels of linoleic acid, linolenic acid, and, to a lesser extent, palmitic acid.

Parental lines MON87708[1], MON89788[2], and DP305423[3] have been authorised for import and processing for use in food and feed in the European Union. Two stacked events have also been authorised for import and processing for use in food and feed in the European Union (MON87708xMON89788[4] and DP305423x40-3-2[5]).

2. Previous COGEM advice

COGEM has previously advised positively on import and processing of all three parental lines: MON87708[6], MON89788[7,8,9], and (DP)305423[10]. COGEM also advised positively on the import and processing of MON87708xMON89788[11], and (DP)305423x40-3-2.[12] The environmental risks associated with import and processing were considered negligible.

3. Environmental risk assessment

Potential environmental risks of soybean DP305423xMON87708xMON89788 are assessed as part of the environmental risk assessment carried out by COGEM.

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.[13,14,15] In the Netherlands, frost is common. On average 58 days a year have minimum temperatures below 0°C.[16,17] Although the Dutch climate is not optimal, soybean is cultivated on a small scale (about 1000 acres in 2017).[18]

The soybean plant is not weedy in character.[14,15] To reduce yield losses during harvesting, soybean plants that have minimal seed scattering were selected for further breeding. Soybean seeds rarely display dormancy, poorly survive in soil, and do not form a persistent soil seed bank.[14,19] Soybean volunteers are rarely observed throughout the world and do not effectively compete with other cultivated plants or primary colonisers.[14,15] In addition, volunteers are easily controlled mechanically or chemically.[15] Soybean volunteers are very uncommon in the Netherlands and have never resulted in establishment of wild populations.[20] 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.[14,15] The cross-pollination rate of soybean is low and on average between 1 to 3%.[14,15,21,22,23,24,25] Pollen disperses only over short distances. In Europe, hybridisation with other species is not possible because there are no wild relatives of soybean.[14,15]

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, traits and regulatory elements

Soybean DP305423xMON87708xMON89788 was created by conventional crossbreeding of the parental lines. For a detailed description of the parental lines, see previous COGEM advises.[6,7,8,10] A description of the inserted genetic elements are listed in the table below. The list is limited to information on the introduced genes, corresponding traits, and regulatory elements (promotors and terminators).

Introduced genes	**Encoded proteins**	**Traits**	**Regulatory elements**
dmo	Dicamba mono-oxygenase enzyme (DMO) from *Stenotrophomonas maltophilia*[6,26,27]	Tolerance to dicamba containing herbicides	*Peanut chlorotic streak caulimovirus* (PC1SV) promoter and the E9 3' non-translated region from the *rbcS2* gene of *Pisum sativum*
Codon optimized *cp4 epsps*	Variant of 5-enolpyruvulshikimate-3-phosphate synthase (EPSPS) enzyme originating from *Agrobacterium* sp. strain CP4[8,28]	Tolerance to glyphosate containing herbicides	P-FMV/Tsf1 promoter (chimeric promoter containing sequences of the *Arabidopsis thaliana Tsf1* gene enhancer and *Figwort mosaic virus* (FMV) 35S promoter) and E9 3' non-translated region from *P. sativum*
gm-hra	Acetolactate synthase (ALS or GM-HRA) from *Glycine max*[10,29]	Tolerance to acetolactate synthase (ALS) inhibiting herbicides	S-adenosyl-L-methionine synthetase (SAMS) promoter, and the acetolactate synthase (*als*) gene terminator from *G. max*
Fragment of the coding region of *gm-fad2-1*	Does not code for a functional protein[10,30]	Transcription of the *gm-fad2-1* fragment silences the endogenous *fad2-1* gene which results in the inhibition of the conversion of oleic acid to linoleic acid, resulting in decreased levels of linoleic acid and increased levels of oleic acid	Seed preferred promoter (1000-fold less active in leaf tissue) and terminator from soybean Kunitz trypsin inhibitor gene 3 (*KTi3*)
See references for a detailed description of the traits			

3.3 Molecular characterisation

The applicant compared the inserted sequences in DP305423xMON87708xMON89788 with the previously determined sequences of the single events. According to the applicant, the DNA sequences of the DP305423, MON87708, and MON89788 inserts and flanking sequences in DP305423xMON87708xMON89788 are identical to the DNA sequences determined for the respective single events.

The applicant also updated the bioinformatics analyses of the inherited inserted elements, and the sequences spanning the insertion sites and the 5' and 3' flanking regions. According to the applicant no essential endogenous genes were disrupted, and the putative products of the open reading frames (ORFs) spanning the 5' and 3' junctions of the inserts, did not show significant protein sequence similarity with known allergens, toxins or other biologically active proteins.

The molecular characterisation was conducted according to the criteria previously laid down by COGEM.[31] The results from the updated bioinformatics analyses do not provide indications that import of soybean DP305423xMON87708xMON89788 could pose a risk to the environment.

Conclusion: The molecular characterisation of soybean DP305423xMON87708xMON89788 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 DP305423x MON87708xMON89788 and noted that the agronomic characteristics were comparable with those in the non-GM near-isogenic control line. The results of the phenotypic evaluation do not give reason to assume that the GM soybean could pose an environmental risk.

In conclusion, COGEM is of the opinion that there are no reasons to assume that the introduced traits in DP305423xMON87708xMON89788 allow the GM soybean to survive or establish in the Dutch environment.

Conclusion: There are no indications that the introduced traits allow soybean DP305423xMON87708xMON89788 to survive in the Netherlands.
Soybean DP305423xMON87708xMON89788 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 general surveillance plan as part of the PMEM. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan,[32,33] but considers the current GS plan adequate for the import and processing of soybean DP305423xMON87708xMON89788.

6. Overall conclusion

There are no indications that expression of the introduced traits will alter the fitness of soybean DP305423xMON87708xMON89788 under natural conditions. COGEM is of the opinion that import and processing of soybean DP305423xMON87708xMON89788 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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