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KENMERK CGM/170418-01

ONDERWERP Advies import en verwerking van de genetisch gemodificeerde sojalijn DAS-68416-4xMON89788-1

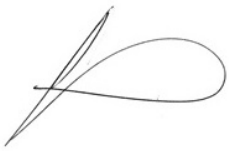
Geachte mevrouw Dijksma,

Naar aanleiding van de adviesvraag betreffende het dossier EFSA/GMO/NL/2013/115 over import en verwerking van genetisch gemodificeerde soja DAS-68416-4xMON89788-1 ingediend door Dow AgroSciences LLC, deelt de COGEM u het volgende mee.

Samenvatting:
De COGEM is gevraagd te adviseren over de milieurisico's van import en verwerking van de genetisch gemodificeerde (gg-) sojalijn DAS-68416-4xMON89788-1. Deze lijn brengt de genen *cp4 epsps*, *pat* en *aad-12* tot expressie, waardoor zij tolerant is voor glyfosaat, glufosinaat-ammonium en aryloxyalkanoate bevattende herbiciden.
Sojaboon DAS-68416-4xMON89788-1 is tot stand gekomen door de twee gg-ouderlijnen met elkaar te kruisen. De COGEM heeft eerder positief geadviseerd over alle twee de ouderlijnen. Hoewel het Nederlandse klimaat niet optimaal is, wordt Sojaboon op kleine schaal geteeld. Soja-opslagplanten komen in Nederland zeer zelden voor en hebben nooit geleid tot verwilderde populaties. De moleculaire karakterisering van DAS-68416-4xMON89788-1 is geactualiseerd en voldoet aan de criteria van de COGEM. Er zijn geen redenen om aan te nemen dat de geïntroduceerde eigenschappen tot verwildering van Sojaboon kunnen leiden. In Europa zijn geen wilde verwanten van Sojaboon aanwezig, zodat de ingebrachte sequenties zich niet naar andere soorten kunnen verspreiden. De COGEM acht de kans verwaarloosbaar klein dat incidenteel morsen van sojalijn DAS-68416-4xMON89788-1 leidt tot verspreiding van de gg-lijn in Nederland.
Concluderend acht de COGEM de milieurisico's van import en verwerking van sojalijn DAS-68416-4xMON89788-1 verwaarloosbaar klein. 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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Import and processing of genetically modified soybean DAS-68416-4xMON89788-1 with three herbicide tolerance traits

COGEM advice CGM/170418-01

- The present application (EFSA/GMO/NL/2013/115) concerns the authorisation for import and processing for use in feed and food of genetically modified (GM) soybean DAS-68416-4xMON89788-1;
- GM soybean DAS-68416-4xMON89788-1 expresses the *cp4 epsps*, *pat* and *aad-12* genes conferring tolerance to glyphosate, glufosinate-ammonium and aryloxyalkanoate containing herbicides;
- GM soybean DAS-68416-4xMON89788-1 was produced by conventional crossbreeding of DAS-68416-4 and MON89788-1;
- COGEM advised positively on import and processing of both parental lines;
- In the Netherlands, feral soybean populations do not occur and hybridisation of soybean with other species is not possible;
- The molecular characterisation of DAS-68416-4xMON89788-1 has been updated and meets the criteria of COGEM;
- There are no reasons to assume that the introduced traits will allow GM soybean DAS-68416-4xMON89788-1 to survive in the Dutch environment;
- There are no indications that the introduced traits altered the fitness of soybean DAS-68416-4xMON89788-1;
- The updated molecular characterisation does not give any indication of a potential environmental risk;
- COGEM is of the opinion that import and processing of soybean DAS-68416-4xMON89788-1 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/2013/115) filed by Dow AgroSciences LLC, concerns import and processing of genetically modified (GM) soybean line DAS-68416-4xMON89788-1. The line expresses the *pat* gene, the *cp4 epsps* gene and the *aad-12* gene, conferring tolerance to glufosinate-ammonium, glyphosate and aryloxyalkanoate containing herbicides. Soybean line DAS-68416-4xMON89788-1 was produced by conventional crossbreeding of GM soybean lines DAS-68416-4 and MON89788-1.

EFSA issued a positive opinion on import, food and feed uses and processing of parental line MON-89788-1.[1] Recently, EFSA also issued a positive opinion on import, food and feed uses and processing of DAS-68416-4.[2] Parental line MON089788-1 has been authorised for food and feed uses in Europe, Canada and the United States.[3] DAS-68416-4 has been authorised for use in food and feed in the United States and Canada, and for environmental release since 2011 and 2012 respectively.[4]

2. Previous COGEM advice

COGEM advised positively on import and processing of both parental lines MON89788-1 and DAS-68416-4.[5,6] COGEM also advised positively on import and processing of several other MON89788 hybrid lines.[7,8,9,10,11]

3. Environmental risk assessment

3.1 Aspects of the wild-type 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.[12,13,14] In the Netherlands, frost is common. On average 58 days a year have minimum temperatures below 0°C.[15,16] Although the Dutch climate is not optimal, soybean is cultivated on a small scale.[17]

The soybean plant is not weedy in character.[13,14] To reduce yield losses during harvesting, soybean has been selected for minimal seed scattering. Soybean seeds rarely display dormancy, poorly survive in soil and do not form a persistent soil seed bank.[13,18] Soybean volunteers are rarely observed throughout the world and do not effectively compete with other cultivated plants or primary colonisers.[13,14] In addition, volunteers are easily controlled mechanically or chemically.[14] To the best of COGEM's knowledge there are no reports of feral soybean populations in Europe. Soybean volunteers are very uncommon in the Netherlands and have never led to wild populations.[19]

Soybean is predominantly a self-pollinating species. The anthers mature in the bud and directly pollinate the stigma of the same flower.[13,14] The cross-pollination rate of soybean is low and on average between 1 to 3%.[13,14,20,21,22,23,24] Pollen disperses only over short distances. In Europe, hybridisation with other species is not possible because there are no wild relatives of soybean.[13,14]

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

3.2 Molecular characterisation

DAS-68416-4xMON89788-1 soybean was produced by conventional crossbreeding of the GM soybean lines MON89788 and DAS-68416-4. In its previous opinions issued in 2008 and 2011,

COGEM evaluated the molecular characterisation of the parental lines and considered them adequate.[5,6] The bioinformatic analyses of soybean DAS-68416-4xMON89788-1 were updated using recent databases. The applicant confirmed by Southern blot analysis that the hybrid line contained both the parental transgenic inserts of MON89788 and DAS-68416-4, and that no rearrangements of these inserts occurred. COGEM is of the opinion that the molecular characterisation has been performed correctly and meets the requirements of COGEM.[25]

Conclusion: The molecular characterisation of soybean DAS-68416-4xMON89788-1 is adequate and no indications for potential environmental risks were identified.

3.3 Description of the introduced genes and traits

Introduced genes	Encoded proteins	Traits
aad-12	Variant of aryloxyalkanoate dioxygenase-12 (AAD-12) enzyme originating from *D. acidovorans*[6,26]	Tolerance to aryloxyalkanoate based herbicides including phenoxy auxin (e.g., 2,4-D, MCPA) and pyridyloxy auxins (e.g., fluroxypyr, triclopyr)
Codon optimized *cp4 epsps*	Variant of 5-enolpyruvulshikimate-3-phosphate synthase (EPSPS) enzyme originating from *Agrobacterium* sp. strain CP4[27,28]	Tolerance to glyphosate containing herbicides
pat	Variant of phosphinothricin-N-acetyl transferase (PAT) from *S. viridochromogenes*[29,30]	Tolerance to glufosinate-ammonium containing herbicides
For a detailed description of the introduced genes and traits see references.		

3.4 Phenotypic and agronomic characterisation

The applicant evaluated the phenotype of soybean DAS-68416-4xMON89788-1 in comparison to its conventional counterparts, as well to commercial reference soybean varieties. The results of the phenotypic evaluation do not give reasons to assume that this GM soybean line poses an environmental risk.

The applicant also evaluated whether DAS-68416-4xMON89788-1 differed from its conventional counterpart in its response to abiotic stress, disease and arthropod damage. According to the applicant no differences were observed. Therefore, COGEM is of the opinion that there are no indications to assume that the introduced traits in DAS-68416-4xMON89788-1 allow soybean to survive or establish in the Dutch environment.

Conclusion: DAS-68416-4xMON89788-1 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, a food and/or feed assessment for Regulation (EC) 1829/2003 applications is carried out by RIKILT. COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is already carried out by other organisations.[31] The outcome of the assessment by other organisations (RIKILT) was not known when this advice was completed.

5. Post-market environmental monitoring (PMEM)

The applicant supplied a new 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 import and processing of soybean DAS-68416-4xMON89788-1.

6. Overall conclusion

COGEM is of the opinion that import and processing of soybean DAS-68416-4xMON89788-1 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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