Import and processing of genetically modified soybean DAS-81419-2xDAS-44406-6

COGEM advice CGM/170515-01

- The present application (EFSA/GMO/NL/2016/132) concerns the authorisation for import and processing for use in feed and food of genetically modified (GM) soybean DAS-81419-2xDAS-44406-6;
- GM soybean DAS-81419-2xDAS-44406-6 expresses the *cry1F*v3, *cry1Ac*(synpro), *pat*, *2mepsps*, and *aad-12* genes, conferring tolerance to glyphosate, glufosinate-ammonium and 2,4D containing herbicides, and providing resistance to certain lepidopteran insects;
- GM soybean DAS-81419-2xDAS-44406-6 was produced by conventional crossbreeding of DAS-81419-2 and DAS-44406-6;
- COGEM advised positively on the 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-81419-2xDAS-44406-6 has been updated and meets the criteria of COGEM;
- There are no reasons to assume that the introduced traits will allow GM soybean DAS-81419-2xDAS-44406-6 to survive in the Dutch environment;
- There are no indications that the introduced traits alter the fitness of soybean DAS-81419-2xDAS-44406-6;
- 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-81419-2xDAS-44406-6 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/2016/132) filed by Dow AgroSiences LLC., concerns import and processing of genetically modified (GM) soybean line DAS-81419-2xDAS-44406-6. The line expresses the *cry1F*v3, *cry1Ac*(synpro) genes, providing resistance against certain lepidopteran insects; the *pat* gene, conferring tolerance to glufosinate-ammonium containing herbicides; the *2mepsps* gene, conferring tolerance to glyphosate containing herbicides; and the *aad-12* gene, conferring tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) herbicides. Soybean line DAS-81419-2xDAS-44406-6 is produced by conventional crossbreeding of GM soybean lines

DAS-81419-2 and DAS-44406-6. EFSA issued positive opinions on import, food and feed uses and processing of both parental lines.[1,2]

2. Previous COGEM advice

COGEM advised positively on import and processing of the parental lines DAS-81419-2 and DAS-44406-6.[3,4]

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.[5,6,7] In the Netherlands, frost is common. On average 58 days a year have minimum temperatures below 0°C.[8,9] Although the Dutch climate is not optimal, soybean is cultivated on a small scale.[10]

The soybean plant is not weedy in character.[6,7] 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.[6,11] Soybean volunteers are rarely observed throughout the world and do not effectively compete with other cultivated plants or primary colonisers.[6,7] In addition, volunteers are easily controlled mechanically or chemically.[7] 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 resulted in the rise of wild populations.[12]

Soybean is predominantly a self-pollinating species. The anthers mature in the bud and directly pollinate the stigma of the same flower.[6,7] The cross-pollination rate of soybean is low and on average between 1 to 3%.[6,7,13,14,15,16,17] Pollen disperses only over short distances. In Europe, hybridisation with other species is not possible because there are no wild relatives of soybean.[6,7]

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-81419-2xDAS-44406-6 soybean was produced by conventional crossbreeding of the GM soybean lines DAS-81419-2 and DAS-44406-6. In its previous COGEM advice in 2013 and 2014, COGEM evaluated the molecular characterisation of the parental lines and considered them adequate.[3,4] The bioinformatic analyses of soybean DAS-81419-2xDAS-44406-6 were updated using recent databases. COGEM is of the opinion that the molecular characterisation has been performed correctly and meets the requirements of COGEM.[18]

Conclusion: The molecular characterisation of soybean DAS-81419-2xDAS-44406-6 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
*cry1F*v3	The Cry1F protein originating from *Bacillus thuringiensis* subsp. Aizawa strain PS811[3]	Resistance to certain lepidopteran insects
*cry1Ac(*synpro*)*	The Cry1Ac protein originating from *B. thuringiensis* subsp. kurstaki strain HD73[3]	Resistance to certain lepidopteran insects
pat	Variant of phosphininothricin N-acetyltransferase (PAT) originating from *Streptomyces viridochromogenes*[3,4]	Tolerance to glufosinate-ammonium containing herbicides
2mepsps	The double mutant 5-enolpyruvylshikimate-3-phosphate synthase (2mEPSPS) enzyme originating from *Zea mays*[4]	Tolerance to glyphosate containing herbicides
aad-12	Aryloxyalkanoate dioxygenase-12 (AAD-12) enzyme originating from *Delftia acidovorans*[4]	Tolerance to 2,4D 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-81419-2xDAS-44406-6 in comparison to a non-transgenic control and reference varieties. According to the applicant, the days to maturity, yield and seed weight were found to be lower in DAS-81419-2xDAS-44406-6 than the isoline. The applicant claims that differences in seed weight can be attributed to inter-varietal variation, but the reference that is provided does not fully support this claim. However, this incongruence does not affect the outcome of the environmental risk assessment. The results of the phenotypic and agronomic characterisation do not give reasons to assume that this GM soybean line could pose an environmental risk. Therefore, COGEM is of the opinion that there are no indications to assume that the introduced traits in DAS-81419-2xDAS-44406-6 allow soybean to survive or establish in the Dutch environment.

Conclusion: DAS-81419-2xDAS-44406-6 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.[19] 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 general surveillance plan as part of the PMEM. 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 DAS-81419-2xDAS-44406-6.

6. Overall conclusion

COGEM is of the opinion that import and processing of soybean DAS-81419-2xDAS-44406-6 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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