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KENMERK CGM/160419-01
ONDERWERP Advies import en verwerking van de genetisch gemodificeerde sojalinj
MON87705xMON87708xMON89788

Geachte mevrouw Dijkma,

Naar aanleiding van de adviesvraag betreffende het dossier EFSA/GMO/NL/2015/126 over import en verwerking van genetisch gemodificeerde soja MON87705xMON87708xMON89788 ingediend door Monsanto Europe S.A., 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-) sojalinj MON87705xMON87708xMON89788. In deze lijn is de expressie van de *fad2* en *fatb* genen geremd waardoor de sojabonen een veranderde vetzuursamenstelling hebben. Daarnaast brengt deze lijn twee *cp4 epsps* genen en een *dmo* gen tot expressie waardoor zij tolerant is voor glyfosaat en dicamba bevattende herbiciden.

Sojaboon MON87705xMON87708xMON89788 is tot stand gekomen door de drie gg-ouderlijnen met elkaar te kruisen. De COGEM heeft eerder positief geadviseerd over alle drie 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 MON87705xMON87708xMON89788 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 sojalinj MON87705xMON87708xMON89788 leidt tot verspreiding van de lijn in Nederland.

Concluderend acht de COGEM de milieurisico's van import en verwerking van sojalinj MON87705xMON87708xMON89788 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,

Prof. dr. ing. Sybe Schaap
Voorzitter COGEM

c.c. Drs. H.P. de Wijs, Hoofd Bureau ggo
 Mr. J.K.B.H. Kwisthout, Ministerie van IenM

Import and processing of the genetically modified soybean MON87705xMON87708xMON89788 with an altered fatty acid profile

COGEM advice CGM/160419-01

- This application (EFSA/GMO/NL/2015/126) concerns import and processing for use in feed and food of genetically modified (GM) soybean MON87705xMON87708xMON89788;
- This GM soybean MON87705xMON87708xMON89788 was produced by conventional crossbreeding of MON87705, MON87708 and MON89788;
- COGEM advised positively on import and processing of all three parental lines;
- The GM soybean contains the expression cassettes for *cp4 epsps* and *dmo* conferring tolerance to glyphosate and dicamba containing herbicides;
- MON87705xMON87708xMON89788 contains a suppressor cassette for *fatb* and *fad2* resulting in a modified fatty acid composition;
- The molecular characterization of MON87705xMON87708xMON89788 is updated and meets the criteria of COGEM;
- The chance that a feral soybean population will establish in the Netherlands is negligible;
- Soybean cannot hybridise with other species in the Netherlands;
- Import and processing of soybean MON87705xMON87708xMON89788 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/2015/126) filed by Monsanto Europe S.A., concerns import and processing of genetically modified (GM) soybean line MON87705xMON87708xMON89788. It contains a *FAD2-1A/ FATB1-A* suppression cassette resulting in an altered fatty acid profile of the soybean seeds. Additionally, the line expresses the *dmo* gene and two copies of the *cp4 epsps* gene, conferring tolerance to dicamba and glyphosate containing herbicides. Soybean line MON87705xMON87708xMON89788 was produced by conventional crossbreeding of GM soybean lines MON87705, MON87708 and MON89788.

EFSA issued positive opinions on import, food and feed uses and processing of all three parental lines.^{1,2,3} Also positive opinions were issued for import, food and feed uses of the soybean lines MON87705xMON89788 and MON87708xMON89788.^{4,5} In 2008 MON89788 was authorised for food and feed uses in Europe.⁶ In Canada and the United States MON89788 was authorised for use in food and feed, and for environmental release since 2007.⁶

Previous COGEM advice

COGEM advised positively on import and processing of parental lines MON87705, MON87708 and MON89788.^{7,8,9} COGEM also advised positively on the import and processing of the soybean lines MON87705xMON89788, MON87708xMON89788 and MON87769x MON89788.^{10,11,12}

2. Environmental risk assessment

2.1 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.^{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 for cultivation of soybean, soybean is cultivated on a small scale.¹⁸

The soybean plant is not weedy in character.^{14,15} 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.^{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 To the best of COGEM's knowledge there are no reports of feral soybean populations in Europe. Soybean volunteers are uncommon in the Netherlands and have never led to wild populations.

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%.^{14,15,20,21,22,23,24} Pollen disperses only over short distances. In Europe, hybridisation with other species is not possible because there are no wild relatives of soybean.^{14,15}

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

2.2 Description of the introduced genes and traits

MON87705xMON87708xMON89788 soybean was produced by conventional crossbreeding of the GM soybean lines MON87705, MON87708 and MON89788. In its previous opinions issued in 2010, 2011 and 2008, COGEM evaluated the molecular characterization of all parental lines and considered them adequate.^{7,8,9} The bioinformatics analyses of soybean MON87705xMON87708xMON89788 were updated using recent databases. COGEM is of the opinion that the molecular characterization is performed correctly.

Inserted expression cassettes	Encoded protein/elements	Trait
<i>dmo</i>	Dicamba mono-oxygenase enzyme (DMO) from <i>Stenotrophomonas maltophilia</i> ⁸	Tolerance to dicamba containing herbicides
Codon optimized <i>cp4 epsps</i>	Variant of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme originating from <i>Agrobacterium tumefaciens</i> strain CP4 ⁹	Tolerance to glyphosate containing herbicides
FAD2-1A/FATB1-A suppression cassette	Endogenous FATB1-A and FAD2-1A sense and antisense gene segments generating an inverted repeat ⁷	Altering fatty acid profile in soybean seeds by suppression of the endogenous <i>FATB</i> and <i>FAD2</i> RNA levels
For a detailed description of the introduced genes and traits see references.		

Altered fatty acid composition

MON87705xMON87708xMON89788 contains a *FAD2-1A/FATB1-A* suppression cassette. *FATB1-A* and *FAD2-1A* are thioesterases and desaturases respectively, and both are involved in fatty acid metabolism. Changing the expression of these proteins leads to an altered fatty acid profile of the soybean seeds. An altered fatty acid composition can influence the seed predation rate. However, predation is only one of the factors involved in seed survival and not a determining factor in survival of soybean in Northwest Europe. The seed will germinate when the soil temperature reaches 10°C and will emerge in a 5-7 day period under favourable conditions.¹⁵ Soybean can under certain environmental conditions grow as a volunteer in the year following cultivation. However, soybean is not frost tolerant, and does not survive freezing winter conditions.^{14,15,25} Volunteers do not compete well with other cultivated or wild plants and can be controlled mechanically or chemically.^{14,15}

Conclusion: The molecular characterization of soybean MON88705xMON88708xMON89788 is adequate. There are no indications that expression of the introduced sequences will increase the potential of soybean MON88705xMON88708xMON89788 to establish feral populations.

2.3 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.²⁶ The

outcome of the assessment by other organisations (EFSA, RIKILT) was not known when this advice was completed.

3. General Surveillance

COGEM has published several recommendations for further improvement of the general surveillance (GS) plan,^{27,28} but considers the current GS plan adequate for import and processing of soybean MON87705xMON87708xMON89788.

4. Overall conclusion

Import and processing of soybean MON87705xMON87708xMON89788 poses a negligible risk to the environment in the Netherlands. COGEM abstains from giving advice on potential risks of incidental consumption since a food/feed assessment is already carried out by other organizations.

5. References

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