

Aan de staatssecretaris van
Infrastructuur en Milieu
Mevrouw W.J. Mansveld
POSTBUS 30945
2500 GX Den Haag

DATUM 7 januari 2013
KENMERK CGM/130107-01
ONDERWERP Advies import and processing of the genetically modified soybean line MON87705
x MON89788

Geachte mevrouw Mansveld,

Naar aanleiding van de adviesvraag betreffende het dossier EFSA/GMO/NL/2011/100 voor de import en verwerking van genetisch gemodificeerde soja MON87705 x MON89788, ingediend door Monsanto Europe S.A., deelt de COGEM u het volgende mee.

Samenvatting

De COGEM is gevraagd te adviseren over de toelating van sojalin MON87705 x MON89788 voor import en verwerking. In deze lijn is de expressie van de *FAD2-1A* en *FATB1-A* genen geremd wat resulteert in sojabonen met een veranderde vetzuursamenstelling. Het gehalte aan palmitinezuur, stearinezuur en linolzuur is verlaagd. Het gehalte aan oliezuur is verhoogd. Daarnaast brengt deze lijn twee *cp4 epsps* genen tot expressie waardoor zij tolerant is voor glyfosaat bevattende herbiciden.

Het Nederlandse klimaat is niet optimaal voor sojateelt. Tijdens de zomer zijn de dagen lang, terwijl soja een korte dagplant is die korte dagen nodig heeft voor bloei en ontwikkeling. Om die reden wordt soja op dit moment niet geteeld in Nederland. Er zijn echter initiatieven voor de ontwikkeling van extreem vroeg bloeiende sojarassen die kunnen groeien in het gematigde Nederlandse klimaat.

Soja beschikt niet over eigenschappen die nodig zijn voor verwildering. Opslagplanten worden wereldwijd zelden waargenomen. Er zijn geen redenen om aan te nemen dat de geïntroduceerde eigenschappen in MON87705 x MON89788 tot verwildering zouden kunnen leiden. Verder zijn er in Europa geen wilde verwanten van soja aanwezig, waardoor uitkruising niet mogelijk is. De COGEM acht daarom de kans dat incidenteel morsen in Nederland tot verspreiding van de sojalin leidt, verwaarloosbaar klein.

Op basis van de hierboven beschreven overwegingen acht de COGEM de risico's van import en verwerking van sojalin MON87705 x MON89788 verwaarloosbaar klein.

De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,



Prof. dr. ir. Bastiaan C.J. Zoeteman
Voorzitter COGEM

c.c. Drs. H.P. de Wijs, Hoofd Bureau GGO
Dr. I. van der Leij, Ministerie van IenM

Import and processing of the genetically modified soybean line MON87705 x MON89788

COGEM advisory report CGM/130107-01

Summary

The present application (EFSA/GMO/NL/2011/100) concerns import and processing for use in feed and food of the genetically modified soybean line MON87705 × MON89788. Cultivation is not part of this application.

Soybean line MON87705 × MON89788 line contains a FAD2-1A/FATB1-A suppression cassette resulting in an altered fatty-acid profile of the soybean seeds. Additionally, the line expresses two cp4 epsps genes conferring tolerance to glyphosate containing herbicides.

MON87705 × MON89788 was produced by means of conventional breeding with the two genetically modified parental soybean lines. Previously, COGEM issued positive opinions on the import and processing of both parental lines.

In Europe, there are no wild relatives of soybean and therefore, hybridisation with other species is not possible. Soybean does not possess any of the attributes commonly associated with problematic weeds such as seed shattering, dormancy and cold resistance. Establishment of feral soybean populations has never been observed in Europe. In addition, soybean volunteers are rarely observed throughout the world and do not effectively compete with other cultivated plants, weeds or primary colonisers.

COGEM considers the appended General Surveillance plan adequate for import of MON87705 × MON 89788. However, the GS plan could be improved on a number of points.

In view of the above, COGEM is of the opinion that incidental spillage of MON87705 × MON89788 poses a negligible risk to the environment. Since 2008, COGEM abstains from giving advice on the potential risks of incidental consumption in case a food/feed assessment is already carried out by other organisations.

COGEM considers the environmental risks associated with import and processing of soybean line MON87705 × MON89788 to be negligible.

Introduction

The scope of the present application (EFSA/GMO/NL/2011/100) filed by Monsanto Europe S.A., concerns import and processing of soybean line MON87705 × MON89788. This line contains the soybean *FAD2-1A/FATB1-A* gene fragments down-regulating endogenous FAD2 and FATB enzymes resulting in an altered fatty acid profile of the soybean seeds. The level of the saturated fatty acids palmitic acid and stearic acid as well as the level of the polyunsaturated fatty acid linoleic acid has been decreased. The level of the monounsaturated acid oleic acid has been increased. Additionally, the line expresses two *cp4 epsps* genes conferring tolerance to glyphosate containing herbicides.

Soybean line MON87705 × MON89788 was produced by conventional crossbreeding of genetically modified parental soybean lines MON87705 and MON89788. Parental line MON89788 has an EU approval for import, food and feed since 2008.¹ In Canada and the United

States MON89788 has been legalised for use in food and feed, and for environmental release.² In October 2012, EFSA released a positive scientific opinion for the placing on the market of parental line MON87705 for food and feed uses, import and processing. The EFSA GMO Panel concluded that MON87705 is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment in the context of its intended uses as proposed by the applicant.³

Previous COGEM advice

Initially COGEM advised negatively on import and processing of parental soybean line MON89788 because its molecular characterization did not meet the criteria laid down by COGEM.^{4,5} Furthermore, COGEM questioned the general surveillance plan. After the applicant provided additional information on the molecular characterization and the general surveillance plan, COGEM advised positively.⁶ In 2010, COGEM also advised positively on import and processing of parental line MON87705 and hybrid line MON87701 x MON89788.^{7,8}

Aspects of the crop

Soybean (*Glycine max*) is a member of the genus *Glycine* and belongs to the *Fabaceae* (*Leguminosae*) family. Soybean is grown from equatorial to temperate zones. The optimum temperature for soybean growth is between 25°C and 30°C. Soybean seeds will germinate when the soil temperature reaches 10°C and under favourable conditions a seedling will emerge in a 5-7 day period. Soybean is sensitive to frost and therefore does not survive freezing conditions.^{9,10}

In the Netherlands, frost is common. On average 58 days in a year have a minimum temperature below 0°C.^{11,12} In the summer days are long, whereas soybean is a quantitative short-day plant that needs short days for induction of flowering. The Dutch climate is therefore not optimal for cultivation of soybean. However, field trials with a number of soybean varieties have shown that cultivation of soybean under temperate climatic conditions is possible.^{13,14} Further improvement of these varieties may result in soybean varieties suited for commercial cultivation in the Netherlands. Due to the characteristics of soybean, COGEM is of the opinion that this development does not affect the environmental risk assessment of MON87701 x MON89788.

The soybean plant is not weedy in character.⁹ As for all domesticated crops, soybean has been selected against seed shattering to reduce yield losses during harvesting. Soybean seeds rarely display dormancy and poorly survive in soil.¹⁵ Soybean volunteers are rare throughout the world and do not effectively compete with other cultivated plants or primary colonisers.⁹ In addition, volunteers are easily controlled mechanically or chemically.⁹ COGEM is not aware of any reports of feral soybean populations in Europe.

Soybean is predominantly a self-pollinating species. The cross-pollination rate of soybean is less than 1%.⁹ The dispersal of pollen is limited because the anthers mature in the bud and directly pollinate the stigma of the same flower. In Europe, hybridisation with other species is not possible because there are no wild relatives of soybean.⁹

Molecular characterization

MON87705 × MON89788 was produced by crossing the two genetically modified parental soybean lines MON87705 and MON89788. COGEM evaluated the molecular characterization in previous applications concerning import and processing of the genetically modified parental lines and concluded that the molecular characterization of the individual parental lines is adequate.^{7,8}

Properties of the introduced genes resulting in an altered fatty acid profile

MON87705 × MON89788 contains a *FAD2-1A/FATB1-A* suppression cassette. *FATB1-A* and *FAD2-1A* are thioesterase and desaturase enzymes respectively, and both are involved in the fatty acid metabolism. The suppression cassette consists of endogenous *FATB1-A* and *FAD2-1A* sense and antisense gene segments generating an inverted repeat. Due to the presence of the inverted repeat, transcription of the *FAD2-1A/FATB1-A* cassette generates double stranded RNA (dsRNA). Via the RNA interference (RNAi) pathway, the dsRNA mediates suppression of the endogenous *FATB* and *FAD2* RNA levels in soybean seeds resulting in a decrease in the level of *FAD2* and *FATB* enzymes. This leads to an altered fatty acid profile of the soybean seeds in particular lower levels of palmitic, stearic, and linoleic acid, as well as an increase in the level of oleic acid. According to the applicant, the assembled gene transcript does not encode a functional protein.

Properties of the introduced genes conferring herbicide tolerance

Soybean line MON87705 × MON89788 also expresses two 5-enolpyruvylshikimate-3-phosphate synthase (*cp4 epsps*) genes. The *cp4 epsps* gene encodes the CP4 EPSPS protein. EPSPS is an enzyme involved in the biosynthesis of aromatic amino acids. Glyphosate inhibits EPSPS, resulting in a lack of amino acids essential for growth and development of plants. In contrast to EPSPS, the CP4 EPSPS protein is not inhibited by glyphosate and therefore the plant is tolerant to glyphosate containing herbicides.¹⁶

Environmental risk assessment

The current application concerns import and processing of soybean line MON87705 × MON 89788. In case of spillage, soybean seed may be released into the environment. Soybean seeds rarely display dormancy, poorly survive in soil and do not survive freezing winter conditions. The Dutch climatic conditions are not optimal for growth of soybean. In the summer, days are long, whereas soybean is a quantitative short-day plant that needs short days for induction of flowering.

Soybean volunteers are rare throughout the world and do not effectively compete with other cultivated plants, weeds or primary colonisers.⁹ In addition, volunteers are easily controlled mechanically or chemically.⁹

There is no reason to assume that soybean line MON87705 × MON 89788 has an increased potential to survive or establish feral populations in case of incidental spillage.

Since 2008 COGEM abstains from giving advice on the potential risks of incidental consumption in case a food/feed assessment is already carried out by other organisations.¹⁷ 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. Regarding the risks for food and feed, the outcome of the assessment by other organisations (EFSA, RIKILT) was not known at the moment of the completion of this advice.

General surveillance plan

General surveillance (GS) has been introduced to be able to observe unexpected adverse effects of genetically modified (GM) crops on the environment. The setting or population in which these effects might occur is either not, or hardly predictable. The GS plan is required for every application for market authorisation. The current GS plan states that unanticipated adverse effects will be monitored by the authorisation holder and operators involved in the handling and use of viable soybean MON87705 × MON 89788.

In 2010, COGEM published a report on the principles that, according to COGEM, should be followed for general surveillance.¹⁸ COGEM considers the submitted GS plan adequate for import of MON87705 × MON 89788. However, the GS plan could be improved on the following points.

In the present GS plan, the authorization holder states that the operators have agreed to provide information relevant to the monitoring of MON87705 × MON 89788 to the authorisation holder. The GS plan could be improved by a guarantee that operators will monitor for unanticipated effects. This is in line with the criteria laid down by COGEM.

The GS plan further states that if the authorisation holder identifies an unexpected adverse effect caused by the GM plant, he will inform the European Commission immediately. COGEM is of the opinion that Member States should also be directly informed of these effects by the authorisation holder, to ensure that appropriate measures for protection of humans and the environment can be implemented immediately.

In the EFSA guidance document, EFSA states that raw data and analysis of monitoring data should be made available by the applicant to the Competent Authorities and the European Commission.¹⁹ COGEM agrees with this request and points out that the General Surveillance plan of soybean MON87705 × MON 89788 could be improved by a statement of the applicant on this point.²⁰

Advice

COGEM has been asked to advice on import and processing for use in food and feed of soybean line MON87705 × MON 89788. This line contains the soybean *FAD2-1A/FATB1-A* gene fragments resulting in an altered fatty acid profile of the soybean seeds. Additionally, the line expresses two *cp4 epsps* genes conferring tolerance to glyphosate containing herbicides.

Although field trials have indicated that it might be possible to develop soybean varieties for cultivation in the Netherlands, the Dutch climate is not optimal for soybean growth. Soybean volunteers are rare throughout the world and do not effectively compete with other cultivated plants or primary colonisers. Modern soybean cultivars do not possess any of the characteristics commonly associated with problematic weeds. There is no reason to assume that expression of the

introduced suppression cassette will increase the potential of soybean to establish feral populations. In addition, establishment of feral soybean populations in Europe has never been observed.

COGEM is of the opinion that the risk of spread of soybean MON87705 × MON 89788 within the Netherlands due to incidental spillage of this soybean is negligible. Wild relatives of soybean are not present in Europe and therefore introgression of the inserted suppression cassette into closely related species can not occur. COGEM considers the current GS plan sufficient for import and processing of soybean line MON87705 × MON 89788. However, the GS plan could be improved on a number of points.

Based on the aspects discussed, COGEM is of the opinion that import and processing of soybean line MON87705 × MON 89788 poses a negligible risk to the environment. A food/feed safety assessment is carried out by other organisations. Therefore, COGEM abstains from advice on the potential risks of incidental consumption.

References

1. Commission Decision of 4 December 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2008/933/EC). Official Journal of the European Union Documentno. C(2008) 7517
2. Center for Environmental Risk Assessment – GM Crop Database. http://cera-gmc.org/index.php?action=gm_crop_database&mode=ShowProd&data=MON89788 (November 2012)
3. EFSA (2012). Scientific Opinion on application (EFSA-GMO-NL-2010-78) for the placing on the market of herbicide-tolerant, increased oleic acid genetically modified soybean MON 87705 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2012;10(10):2909
4. COGEM (2007). Import and processing of glyphosate tolerant soybean MON 89788 (EFSA/GMO/NL/2006/36). Advisory report CGM/070807-01
5. COGEM (2008). Heroverweging criteria voor de moleculaire karakterisering bij markttoelatingen van gg-gewassen. Signalering CGM/081219-01
6. COGEM (2008). Molecular characterization of soybean MON89788 (EFSA/GMO/NL/2006/36). Advisory report CGM/080827-01
7. COGEM (2010). Import and processing of genetically modified soybean MON87701xMON89788. Advisory report CGM/100202-01
8. COGEM (2010). Import and processing of genetically modified glyphosate tolerant soybean MON87705 with an altered fatty acid profile. Advisory report CGM/101013-03
9. OECD (2000). Consensus document on the biology of *Glycine max* (L.) Merr. (Soybean)
10. Bramlage WJ *et al.* (1978). Chilling stress to soybeans during imbibition. Plant Physiol 61:525-529

11. Koninklijk Nederlands Meteorologisch Instituut (KNMI), maand- en seizoenoverzichten.
http://www.knmi.nl/klimatologie/maand_en_seizoenoverzichten/ (November2012)
12. Compendium voor de leefomgeving, meteorologische gegevens 1990-2010.
<http://www.compendiumvoordeleefomgeving.nl/indicatoren/nl0004-Meteorologische-gegevens-in--Nederland.html?i=9-54> (November 2012)
13. Paauw JGM (2006). Rassenonderzoek sojabonen op lössgrond 2004-2006. Projectrapport
Praktijkonderzoek Plant en Omgeving b.v.
14. Biobred: www.biobred.eu/ (November 2012)
15. OECD (1993). Traditional crop breeding practices: An historical review to serve as baseline for
assessing the role of modern biotechnology
16. Funke T *et al.* (2006). Molecular basis for the herbicide resistance of Roundup Ready crops. Proc.
Natl. Acad. Sci. USA. 103: 13010-13015
17. COGEM (2008). Toelichting advies GA21. Brief CGM/080117-02
18. COGEM (2010). General Surveillance. Topic report CGM/100226-01
19. EFSA Panel on Genetically Modified Organisms (2011). Guidance on the Post-Market
Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 9:2316
20. COGEM (2011). Comments on the European Food Safety Authority draft version of the revised
'Guidance on the post-market environmental monitoring (PMEM). Advisory report CGM/110520-01