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DATUM 16 juli 2014

KENMERK CGM/140716-01

ONDERWERP Advies import and processing of the genetically modified soybean line MON87769 x MON89788

Geachte mevrouw Mansveld,

Naar aanleiding van de adviesvraag betreffende het dossier EFSA/GMO/NL/2010/85 voor de import en verwerking van genetisch gemodificeerde soja MON87769 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 sojalijn MON87769 x MON89788 voor import en verwerking. Deze lijn brengt de genen *Pj.D6D* en *Nc.Fad3* tot expressie wat resulteert in sojabonen met een veranderde vetzuursamenstelling. Daarnaast brengt deze lijn het *cp4 epsps* gen tot expressie waardoor zij tolerant is voor glyfosaat bevattende herbiciden.

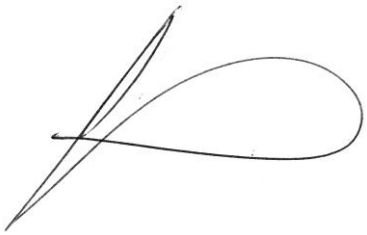
Het Nederlandse klimaat is niet optimaal voor de groei van soja. Soja is sterk koudegevoelig en heeft hoge temperaturen nodig voor kieming en ontwikkeling. In de zomer zijn de dagen lang, terwijl soja korte dagen nodig heeft voor de inductie van bloei. Soja wordt op dit moment niet geteeld in Nederland. Er zijn echter initiatieven voor de ontwikkeling van vroeg bloeiende sojarassen die geteeld kunnen worden in het gematigde Nederlandse klimaat.

Soja beschikt niet over eigenschappen die nodig zijn voor verwildering. Daarnaast worden opslagplanten wereldwijd zelden waargenomen. Er zijn geen redenen om aan te nemen dat de combinatie van geïntroduceerde eigenschappen in MON87769 x MON89788 het verwilderings-potentieel vergroten. In Europa zijn geen wilde verwanten van soja aanwezig, waardoor kruising niet mogelijk is. De COGEM acht daarom de kans verwaarloosbaar klein dat het incidenteel morsen van soja MON87769 x MON89788 leidt tot de verspreiding ervan in Nederland.

De COGEM acht de milieurisico's van import en verwerking van sojalijn MON87769 x MON89788 verwaarloosbaar klein. Omdat andere instanties een voedsel-veiligheidsbeoordeling 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
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Import and processing of the genetically modified soybean line MON87769 x MON89788

COGEM advice CGM/140716-01

Summary

The present application (EFSA/GMO/NL/2010/85) concerns import and processing for use in feed and food of the genetically modified soybean line MON87769 × MON89788. Cultivation is not part of this application.

Soybean line MON87769×MON89788 expresses the Pj.D6D *gene derived from* Primula juliae *and* Nc.Fad3 *derived from* Neurospora crassa *resulting in the production of stearidonic acid (SDA), an omega-3 fatty acid. Additionally, the line expresses a* cp4 epsps *gene conferring tolerance to glyphosate containing herbicides.*

MON87769×MON89788 was produced by means of conventional breeding with the two genetically modified parental soybean lines. Previously, COGEM issued positive advices 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. There is no reason to assume that the combination of introduced traits will increase the potential of soybean to establish feral populations.

COGEM considers the appended General Surveillance plan adequate for import of MON87769 × MON89788. However, the GS plan could be improved on a number of points.

In conclusion, COGEM is of the opinion that import and processing of soybean line MON87769×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 already carried out by other organisations.

Introduction

The scope of the present application (EFSA/GMO/NL/2010/85) filed by Monsanto Europe S.A., concerns import and processing of soybean line MON87769 × MON89788. This line expresses the *Pj.D6D* gene derived from *Primula juliae* and *Nc.Fad3* derived from *Neurospora crassa*. The introduction of these genes results in the seed specific production of stearidonic acid (SDA), an omega-3 fatty acid. Additionally, the line expresses the *cp4 epsps* gene conferring tolerance to glyphosate containing herbicides.

Soybean line MON87769×MON89788 was produced by conventional crossbreeding of genetically modified parental soybean lines MON87769 and MON89788. In May 2014, EFSA released a positive scientific opinion for the placing on the market of parental line MON87769 for food and feed uses, import and processing. The EFSA GMO Panel concluded that MON87769 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.[1]

Parental line MON89788 has an EU approval for import, food and feed since 2008.[2] In Canada and the United States MON89788 has been legalised for use in food and feed, and for environmental release.[3]

Previous COGEM advice

In 2010, COGEM advised positively on the import and processing of parental line MON87769.[4] 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.[5,6] 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.[7] COGEM also advised positively on import and processing of several MON89788 hybrid lines.[8,9,10]

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 frost intolerant and therefore does not survive freezing conditions.[11,12]

In the Netherlands, frost is common. On average 58 days in a year have a minimum temperature below 0°C.[13,14] 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.[15,16] 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 MON87769 × MON89788.

Domesticated soybean does not evince weedy traits, is not found outside cultivated areas and does not compete well with other cultivated or wild plants.[11] 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.

Soybean volunteers are rare throughout the world. Since soybean is frost intolerant, volunteers are likely to be frost killed during autumn or early winter in the year they were produced.[11] In addition, volunteers are easily controlled mechanically or chemically. COGEM is not aware of any reports of feral soybean populations in Europe.

Soybean is predominantly a self-pollinating species. 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.[11] The cross-pollination rate of soybean is less than 1% and decreases quickly as distance increases.[11] A recent study in China showed that the farthest distance at which outcrossing was still observed was 15 metres with a rate of 0.012%.[17]

Molecular characterization

MON87769×MON89788 was produced by crossing the two genetically modified parental soybean lines MON87769 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. [4,7]

Properties of the genes resulting in production of stearidonic acid

MON87769×MON89788 contains the *P. juliae Pj.D6D* gene and the *N. crassa Nc.Fad3* gene. Expression of these genes results in the seed-specific production of the PjΔ6 en NcΔ15 desaturase proteins.

Δ6 desaturase is responsible for the conversion of α-linolenic acid (ALA) into stearidonic acid (SDA). SDA is an omega-3 fatty acid, which is a normal metabolic precursor to the longchain, poly-unsaturated omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in humans and animals. Longchain poly-unsaturated omega-3 fatty acids have been linked to reductions in cardiovascular disease, cancer, inflammation and neurological disorders.[18] Δ6 desaturase may also convert linoleic acid (LA) into γ–linolenic acid (GLA). The addition of Δ15 desaturase increases ALA levels, allowing greater flux to SDA accumulation in MON87769. It also lowers the LA levels (by conversion of LA into ALA) and hence lowers the substrate pool for GLA production.

Properties of the introduced gene conferring herbicide tolerance

Soybean line MON87769×MON89788 also expresses the 5-enolpyruvylshikimate-3-phosphate synthase (*cp4 epsps*) gene. 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.[19]

Environmental risk assessment

The current application concerns import and processing of soybean line MON87769 × MON89788. 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.[11] In addition, volunteers are easily controlled mechanically or chemically.[11] There is no reason to assume that soybean line MON87769×MON89788 has an increased potential to survive or establish feral populations in case of incidental spillage.

In conclusion, COGEM is of the opinion that soybean line MON87769×MON89788 is not able to establish itself and form feral populations in the Netherlands.

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.[20] 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

General surveillance (GS) has been introduced to be able to observe unexpected adverse effects of GM crops on the environment. A GS plan is required for every application for market authorisation.

The current GS plan states that unanticipated adverse effects will be monitored by existing monitoring systems, which include the authorization holder and operators involved in the handling and use of viable soybean. The third parties (operators) involved in GS will report adverse effects to the authorization holder.

In 2010, COGEM published a report on the principles that, according to COGEM, should be followed for general surveillance.[21] COGEM considers the submitted GS plan adequate for import of MON87769×MON89788 however, the 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 MON87769×MON89788 to the authorisation holder. The GS plan could be improved by a guarantee that operators will monitor for unanticipated effects. In particular a statement is lacking that the authorisation holder will give evidence that the operators collect this information.

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 the applicant should make raw data and analysis of monitoring data available to the Competent Authorities and the European Commission.[22] COGEM agrees with this requerement and points out that the applicant should include a statement on this point.[23]

Advice

COGEM has been asked to advice on import and processing for use in food and feed of soybean line MON87769 × MON89788. This line expresses the *Pj.D6D* and *Nc.Fad3* genes resulting in the production of stearidonic acid (SDA), an omega-3 fatty acid. Additionally, the line expresses a *cp4 epsps* gene 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.

Soybean line MON87769×MON89788 was produced by conventional crossbreeding of the genetically modified parental soybean lines MON87769 and MON89788. There is no reason to assume that the combination of the introduced traits 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 MON87769×MON89788 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 cannot occur. COGEM considers the current GS plan sufficient for import and processing of soybean line MON87769 × MON89788. 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 MON87769×MON89788 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.

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