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KENMERK CGM/180905-01
ONDERWERP Advies import en verwerking van gg-soja
MON87751xMON87701xMON87708xMON89788

Geachte mevrouw Van Veldhoven,

Naar aanleiding van een vergunningaanvraag voor import en verwerking van genetisch gemodificeerde soja MON87751xMON87701xMON87708xMON89788 (EFSA/GMO/NL/2016/128), ingediend door Monsanto Company, deelt de COGEM u het volgende mee.

Samenvatting:

De COGEM is gevraagd te adviseren over de mogelijke milieurisico's van import en verwerking van genetisch gemodificeerde (gg-) soja MON87751xMON87701xMON87708xMON89788. In deze gg-soja komen de genen *dmo* en *cp4 epsps* tot expressie, waardoor de plant tolerant is voor verschillende herbiciden. Ook bevat deze gg-soja de genen *cry1A.105*, *cry2Ab2* en *cry1Ac*, waardoor de plant resistent is tegen bepaalde plaaginsecten die behoren tot de vlinderachtigen.

Hoewel het klimaat niet optimaal is, wordt Sojaboon op kleine schaal in Nederland geteeld. Soja-opslagplanten komen in Nederland zeer zelden voor en hebben nooit geleid tot verwilderde populaties. In Europa zijn geen wilde verwanten van Sojaboon aanwezig, zodat de ingebrachte sequenties zich niet naar andere soorten kunnen verspreiden.

De moleculaire karakterisering van gg-soja MON87751xMON87701xMON87708xMON89788 voldoet aan de eisen van de COGEM. Er zijn geen redenen om aan te nemen dat expressie van de ingebrachte genen ervoor zorgt dat deze gg-soja zou kunnen verwilderen.

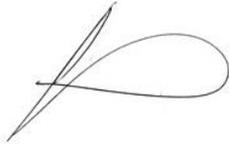
Gezien het bovenstaande acht de COGEM de milieurisico's van de import en verwerking van de gg-soja MON87751xMON87701xMON87708xMON89788, verwaarloosbaar klein.

Omdat een voedselveiligheidsbeoordeling door andere instanties wordt uitgevoerd, heeft de COGEM bij deze vergunningaanvraag 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 IenW
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Import and processing of genetically modified soybean MON87751xMON87701xMON87708xMON89788

COGEM advice CGM/180905-01

- The present application (EFSA/GMO/NL/2016/128) concerns the authorisation for import and processing for use in feed and food of genetically modified (GM) soybean MON87751xMON87701xMON87708xMON89788;
- Soybean MON87751xMON87701xMON87708xMON89788 was produced by conventional crossbreeding of the four GM parental soybean lines;
- Previously, COGEM advised positively on the import and processing of all four parental lines;
- The GM soybean expresses the genes *dmo* and *cp4 epsps*, conferring tolerance to dicamba-based herbicides and glyphosate containing herbicides;
- It also expresses the genes *cryIA.105*, *cry2Ab2* and *cryIAc*, resulting in resistance to certain lepidopteran insects.

- In the Netherlands, feral soybean populations do not occur and hybridisation of soybean with other species is not possible;

- The molecular characterisation of soybean MON87751xMON87701xMON87708xMON89788 has been updated and meets the criteria of COGEM;
- The updated bioinformatics analysis does not provide indications for potential environmental risks;
- There are no indications that the introduced traits allow soybean MON87751xMON87701xMON87708xMON89788 to survive in the Netherlands;
- There are no indications that soybean MON87751xMON87701xMON87708xMON89788 could establish feral populations in the Netherlands;

- COGEM is of the opinion that import and processing of soybean MON87751xMON87701xMON87708xMON89788 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/2016/128) filed by Monsanto Company concerns import and processing of soybean MON87751xMON87701xMON87708xMON89788. The GM soybean was produced by conventional crossbreeding of the four GM parental soybean lines. It expresses the *dmo* and *cp4 epsps* genes conferring tolerance to dicamba containing herbicides and glyphosate

containing herbicides. In addition, it expresses the genes *cryIA.105*, *cry2Ab2* and *cryIAc*, resulting in resistance to certain lepidopteran insects.

Parental lines MON87708¹, MON89788² and MON87701³ have been authorised for import and processing for use in food and feed in the European Union. Two stacked events have also been authorised for import and processing for use in food and feed in the European Union (MON87708xMON89788⁴ and MON87701xMON89788⁵).

The European Commission has not yet authorized import and processing for use in feed and food of soybean line MON87751. Also, the opinion of the European Food Safety Authority (EFSA) on the application concerning import of MON87751 (EFSA/GMO/NL/2014/121) has not been issued yet.

2. Previous COGEM advice

COGEM has previously advised positively on import and processing of all four parental lines: MON87751⁶, MON87701⁷, MON87708⁸ and MON89788^{9,10}. COGEM also advised positively on the import and processing of MON87708xMON89788¹¹ and of MON87701xMON89788¹². The environmental risks associated with import and processing were considered negligible.

3. Environmental risk assessment

Potential environmental risks of soybean MON87751xMON87701xMON87708xMON89788 are assessed as part of the environmental risk assessment carried out by COGEM.

3.1 Characteristics of soybean

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, soybean is cultivated on a small scale (about 1000 acres in 2017).¹⁸

The soybean plant is not weedy in character.^{14,15} To reduce yield losses during harvesting, soybean plants that have minimal seed scattering were selected for further breeding. 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 Soybean volunteers are very uncommon in the Netherlands and have never resulted in establishment of wild populations.²⁰ To the best of COGEM's knowledge, there are no reports of feral soybean populations in Europe.

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%.^{14,15,21,22,23,24,25} 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.

3.2 Description of the introduced genes, traits and regulatory elements

Soybean MON87751xMON87701xMON87708xMON89788 was created by conventional crossbreeding of the parental lines. For a detailed description of the parental lines, see previous COGEM advises.^{6,7,8,9} A description of the inserted genetic elements is listed in the table below. The list is limited to information on the introduced genes, corresponding traits, and regulatory elements (promoters and terminators).

| Introduced genes | Encoded proteins | Traits | Regulatory elements |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>dmo</i> (MON87708) | Dicamba mono-oxygenase enzyme (DMO) from <i>Stenotrophomonas maltophilia</i> ^{8,26,27} | Tolerance to dicamba containing herbicides | <i>Peanut chlorotic streak caulimovirus</i> (PC1SV) promoter and the E9 3' non-translated region from the <i>rbcS2</i> gene of <i>Pisum sativum</i> |
| Codon optimized <i>cp4 epsps</i> (MON89788) | Variant of 5-enolpyruvulshikimate-3-phosphate synthase (EPSPS) enzyme originating from <i>Agrobacterium</i> sp. strain CP4 ^{9,28} | Tolerance to glyphosate containing herbicides | P-FMV/Tsf1 promoter (chimeric promoter containing enhancer sequences of the promoter of the <i>Arabidopsis thaliana</i> <i>Tsf1</i> gene and of the 35S promoter of <i>Figwort mosaic virus</i> (FMV)) and E9 3' non-translated region from the <i>rbcS2</i> gene of <i>P. sativum</i> |
| <i>cryIA.105</i> (MON87751) | The Cry1A.105 protein is a chimeric protein with domains from different Cry1 proteins from <i>Bacillus thuringiensis</i> ^{6,29,30} | Resistance to certain lepidopteran insects | Promoter from the <i>rbcS</i> gene family of <i>A. thaliana</i> and <i>PT1</i> gene 3'UTR from <i>Medicago trunculata</i> |
| <i>cry2Ab2</i> (MON87751) | Variant of the Cry2Ab2 protein from <i>B. thuringiensis</i> ^{6,29,30,31} | Resistance to certain lepidopteran insects | Promoter from the <i>act2</i> gene of <i>A. thaliana</i> and <i>Mt</i> gene 3'UTR from <i>Oryza sativa</i> |
| <i>cryIAc</i> (MON87701) | Codon-modified coding sequence of the Cry1Ac protein of <i>B. thuringiensis</i> var. <i>kurstaki</i> ^{12,31,32,33} | Resistance to certain lepidopteran insects | Promoter from the <i>RbcS4</i> gene of <i>A. thaliana</i> and 3'region of the <i>sphas1</i> gene of <i>Glycine max</i> including 35 nucleotides of the carboxy-terminus of β -conglycinin |

| Introduced genes | Encoded proteins | Traits | Regulatory elements |
|----------------------------------------------------------------|------------------|--------|----------------------------------------------------------------|
| | | | coding region, termination codon and polyadenylation sequence. |
| <i>See references for a detailed description of the traits</i> | | | |

3.3 Molecular characterisation

Previously, COGEM has evaluated the molecular characterisation of each parental line and considered these to be adequate.^{6,7,8,9}

The applicant compared the inserted sequences in MON87751xMON87701xMON87708xMON89788 and the previously determined sequences for MON87751, MON87701, MON87708 and MON89788. According to the applicant the DNA sequences of the MON87751, MON87701, MON87708 and MON89788 inserts and flanking sequences in MON87751xMON87701xMON87708xMON89788 are identical to the DNA sequences determined for the respective single events.

The applicant also updated the bioinformatics analyses of the inherited inserted elements, and the sequences spanning the insertion sites and the 5' and 3' flanking regions using recent databases.

According to the applicant, no essential endogenous genes were disrupted at the insertion sites, and the putative products of the open reading frames (ORFs) spanning the 5' and 3' junctions of the inserts, did not show significant protein sequence similarity with known allergens, toxins or other biologically active proteins.

The molecular characterisation was conducted according to the criteria previously laid down by COGEM. The results from the updated molecular characterisation do not provide indications that import of soybean MON87751xMON87701xMON87708xMON89788 could pose a risk to the environment.

Conclusion: The molecular characterisation of soybean MON87751xMON87701xMON87708xMON89788 is adequate and no indications for potential environmental risks were identified.

3.4 Phenotypic and agronomic characteristics

The applicant analysed the phenotypic and agronomic characteristics of soybean MON87751xMON87701xMON87708xMON89788 and noted that most agronomic characteristics were comparable with those in the non-GM near-isogenic control line. When differences were observed, they were within ranges considered to be normal for conventional commercial reference soybean. The results of the phenotypic evaluation do not give reason to assume that the GM soybean could pose an environmental risk.

In conclusion, COGEM is of the opinion that there are no reasons to assume that the introduced traits in MON87751xMON87701xMON87708xMON89788 allow the GM soybean to survive or establish in the Dutch environment.

Conclusion: There are no indications that the introduced traits allow soybean MON87751xMON87701xMON87708xMON89788 to survive in the Netherlands. Soybean MON87751xMON87701xMON87708xMON89788 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, RIKILT carries out a food and/or feed assessment for Regulation (EC) 1829/2003 applications. The outcome of the assessment by other organisations (EFSA, 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,^{34,35} but considers the current GS plan adequate for the import and processing of soybean MON87751xMON87701xMON87708xMON89788.

6. Overall conclusion

There are no indications that expression of the introduced traits will alter the fitness of soybean MON87751xMON87701xMON87708xMON89788 under natural conditions. COGEM is of the opinion that import and processing of soybean MON87751xMON87701xMON87708xMON89788 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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