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Infrastructuur en Waterstaat
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DATUM 06 juli 2021
KENMERK CGM/210706-01
ONDERWERP Advies hernieuwing vergunning import en verwerking van gg-sojalijn A5547-127

Geachte mevrouw Van Nieuwenhuizen,

Naar aanleiding van een adviesvraag betreffende de hernieuwing van de vergunning voor import en verwerking van genetisch gemodificeerde soja A5547-127 (EFSA/GMO/RX/020), ingediend door BASF Agricultural Solutions Seed US LLC, vertegenwoordigd door BASF SE, deelt de COGEM u het volgende mee.

Samenvatting:

De COGEM is gevraagd om te adviseren over de hernieuwing van de vergunning voor import en verwerking van de genetisch gemodificeerde (gg-) sojalijn A5547-127. Deze lijn produceert het PAT eiwit waardoor de plant tolerant is voor herbiciden met als werkzame stof glufosinaat-ammonium. De eerdere vergunning is in 2012 voor een periode van 10 jaar afgegeven. De COGEM heeft in 2008 positief geadviseerd over de import en verwerking van sojalijn A5547-127.

De hernieuwingsaanvraag bevat onder meer geactualiseerde bioinformatische analyses, een recente literatuurstudie en de resultaten van de verplichte 'post-market environmental monitoring' die sinds 2012 is uitgevoerd.

Hoewel het klimaat niet optimaal is, wordt soja 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 soja aanwezig, waardoor de ingebrachte sequenties zich niet naar andere soorten kunnen verspreiden.

De geactualiseerde bioinformatische analyses van sojalijn A5547-127 voldoen aan de criteria van de COGEM. Uit de geactualiseerde bioinformatische analyses, literatuurstudie, aanvullende ongepubliceerde studies en de monitoringsrapporten komen geen nieuwe inzichten over mogelijke risico's voor mens en milieu naar voren.

Concluderend acht de COGEM de risico's van import en verwerking van gg-soja A5547-127 voor mens en milieu 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. Y. de Keulenaar, Hoofd Bureau ggo
 - Ministerie van IenW, Directie Omgevingsveiligheid en Milieurisico's
DG Milieu en Internationaal
 - Ing. M.A.C. Möllers, Food-Feed loket

Renewal of the authorisation for import and processing of genetically modified soybean A5547-127

COGEM advice CGM/210706-01

- The present application (EFSA/GMO/RX/020) concerns the renewal of the authorisation for import and processing of genetically modified (GM) soybean (*Glycine max*) A5547-127;
- GM soybean A5547-127 was previously authorised for import and processing in 2012;
- COGEM has advised positively on the import and processing of soybean A5547-127 in 2008;
- A5547-127 expresses the *pat* gene, which confers tolerance to herbicides containing the active ingredient glufosinate-ammonium;

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

- The updated bioinformatics analysis of soybean A5547-127 meets the criteria of COGEM;
- The updated bioinformatics analysis, literature review, several unpublished studies and monitoring reports do not give any indication of a potential environmental risk;

- COGEM is of the opinion that import and processing of soybean A5547-127 pose 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/RX/020), filed by BASF Agricultural Solutions Seed US LLC, as represented in the EU by BASF SE, concerns the renewal of the authorisation for import and processing of GM soybean (*Glycine max*) A5547-127. This authorisation was granted in 2012 (2012/81/EU).¹ Since import and processing authorisations remain valid for a period of 10 years, the applicant filed an application for the renewal of the authorisation granted in 2012. The application contains amongst others monitoring reports, updated bioinformatics analyses, and a systematic literature search.

2. Previous COGEM advice

In 2008 COGEM advised positively on the import and processing of soybean A5547-127.² In addition, COGEM also advised positively on the stacked event containing A5547-127: GM soybean FG72xA5547-127 in 2015.³

3. Environmental risk assessment

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.^{4,5,6} In the Netherlands frost is common, with an average of 51 days a year of minimum temperatures below 0°C.⁷ Although the Dutch climate is not optimal, soybean is cultivated on a small scale (about 476 acres in 2019 and 132 in 2020, according to provisional data).⁸

The soybean plant is not weedy in character.^{5,6} To reduce yield losses during harvest, soybean plants that have minimal seed scattering were selected for breeding. Soybean seeds rarely display dormancy, poorly survive in soil, and do not form a persistent soil seed bank.^{5,9} Soybean volunteers are rarely observed throughout the world and do not effectively compete with other cultivated plants or primary colonisers.^{5,6} In addition, volunteers are easily controlled mechanically or chemically.⁶ Soybean volunteers are very uncommon in the Netherlands and have never resulted in establishment of wild populations.¹⁰ 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.^{5,6} The cross-pollination rate of soybean is low and on average between 1 to 3%.^{5,6,11,12,13,14,15} Soybean pollen disperses only over short distances. In Europe, hybridisation with other species is not possible because there are no wild relatives of soybean.^{5,6}

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 gene, trait and regulatory elements

A5547-127 was developed using particle bombardment with plasmid pB2/35SAcK (derivative of plasmid pUC19). The inserted sequence also contains part of the plasmid backbone, consisting of two truncated non-functional sequences of the beta-lactamase (*bla*) gene on the 3' and 5' side of the expression cassette, but these fragments do not constitute a functional gene.^{2,16} 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>pat</i>	Phosphinothricin-N-acetyl transferase (PAT) originating from <i>Streptomyces viridochromogenes</i> ¹⁷	Tolerance to glufosinate-ammonium containing herbicides	35S promoter and 35S terminator sequence from <i>Cauliflower mosaic virus (CaMV)</i> ^{18,19}

3.3 Updated bioinformatics analyses

To confirm the sequence of A5547-127 soybean, the applicant has re-sequenced relevant plant material. Pairwise alignment of the new transgenic locus sequence and previously provided sequence shows 100% nucleotide identity. The bioinformatic analyses have been reconducted using updated databases. The sequences spanning the insertion site at the 5' and 3' flanking regions and the entire insert were screened to identify all open reading frames (ORFs) between stop codons. According to the applicant, the putative products of the ORFs do not generate any relevant protein sequence similarities with known allergens or toxins. In addition, assessment of the amino acid sequence identity of the PAT protein did not reveal similarities to known allergens or toxic proteins.

Considering the above, COGEM is of the opinion that the molecular characterisation of soybean A5547-127 has been performed correctly and meets the requirements of COGEM.²⁰ No new elements that would invalidate the conclusions of the initial risk assessment were identified.

Conclusion: The bioinformatics analyses of soybean A5547-127 have been updated and are adequate. No indications for potential environmental risks were identified.

3.4 Systematic literature search and unpublished studies

The applicant performed a literature search using several bibliographic databases and additional sources of information (e.g., web pages of regulatory authorities for food and feed safety, agriculture and biotechnology) covering a publication period from October 1st 2011 to June 26th 2020. The literature search identified 899 unique publications, of which one was rated as relevant. No adverse effects were reported in this publication. In addition, an overview was provided of unpublished studies (produced, controlled or sponsored by the applicant or provided to the applicant by a third party that were not previously submitted to the EU within the authorisation period) on soybean A5547-127. No studies were identified with new data relevant to the risk assessment. Overall, no adverse effects on human and animal health, or the environment were identified in the literature search and unpublished studies of the applicant.

Conclusion: The systematic literature search and unpublished studies do not give any indication of potential environmental risks resulting from import and/or processing of soybean A5547-127.

3.5 Annual monitoring reports

The applicant supplied annual reports on the monitoring carried out between February 2012 and June 2019. Monitoring was performed by operators involved in the import, handling and processing of viable soybean A5547-127 i.e., COCERAL, UNISTOCK and FEDIOL. To monitor the safety of soybean A5547-127, the applicant performed also a yearly review of the scientific literature. The monitoring results and literature search do not provide indications of adverse health or environmental effects associated with import or use of soybean A5547-127.

Conclusion: The information in the annual monitoring reports gives no indication of adverse effects or incidents resulting from import and processing of soybean A5547-127.

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, WFSR carries out a food and/or feed assessment for Regulation (EC) 1829/2003 applications. The outcome of the assessment by other organisations (EFSA, WFSR) was not known when this advice was completed.

5. Post-market environmental monitoring (PMEM)

The applicant does not consider it necessary to change the post-market environmental monitoring (PMEM) plan of the initial authorisation. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan^{21,22} but considers the initial GS plan adequate for import and processing of soybean A5547-127.

6. Overall conclusion

COGEM is of the opinion that import and processing of soybean A5547-127 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.

References

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