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KENMERK CGM/170629-01

ONDERWERP Advies hernieuwing vergunning voor import en verwerking van de gg-maïslijn GA21

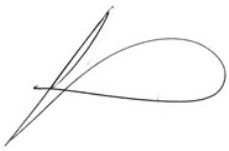
Geachte mevrouw Dijksma,

Naar aanleiding van een adviesvraag betreffende een hernieuwing van de vergunning voor import en verwerking van genetisch gemodificeerde maïs GA21 (EFSA/GMO/RX/005), ingediend door Syngenta, 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-) maïslijn GA21. De eerdere vergunning is in 2008 voor een periode van 10 jaar afgegeven. De lijn brengt het *mepsps* gen tot expressie, waardoor de plant tolerant is voor glyfosaat bevattende herbiciden. De COGEM heeft in 2008 positief geadviseerd over de import, verwerking en teelt van gg-maïslijn GA21.
De hernieuwingsaanvraag bevat onder meer nieuwe sequentiegegevens, geactualiseerde bioïnformatische analyses, een recente literatuurreview en de resultaten van de verplichte 'post-market environmental monitoring' die sinds 2008 is uitgevoerd.
Verwildering van maïsplanten is in Nederland nooit waargenomen. Planten uit gemorst maïszaad (opslagplanten) worden hier nauwelijks aangetroffen. Bovendien zijn er in Nederland geen wilde verwanten van maïs aanwezig, zodat de ingebrachte sequenties zich niet naar andere soorten kunnen verspreiden.
Uit de geactualiseerde moleculaire karakterisering, literatuurstudie en monitoringsrapporten zijn geen nieuwe inzichten over mogelijke risico's voor mens en milieu naar voren gekomen.
Gezien het bovenstaande acht de COGEM de risico's van import en verwerking van gg-maïs GA21 voor mens en milieu verwaarloosbaar klein.
Omdat een voedselveiligheidsbeoordeling door andere instanties wordt uitgevoerd, 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,



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Renewal of the authorisation for import and processing of genetically modified maize GA21

COGEM advice CGM/170629-01

- The present application (EFSA/GMO/RX/005) concerns the renewal of the authorisation for import and processing for use in feed and food of genetically modified maize GA21;
- Maize GA21 has been authorised for import and processing in 2008;
- In 2008, COGEM advised positively on the import, processing and cultivation of maize GA21;
- Maize GA21 expresses the *mepsps* gene conferring tolerance to glyphosate containing herbicides;
- In the Netherlands, feral maize populations have never been observed and the appearance of volunteers is rare to absent;
- In the Netherlands, wild relatives of maize have never been observed and hybridisation of maize with other species is not possible;
- The molecular characterisation (bioinformatic analysis) of maize GA21 has been updated and meets the criteria of COGEM;
- There are no indications that the introduced trait will alter the fitness of maize GA21;
- The updated molecular characterisation, literature review and monitoring reports do not give any indication of a potential environmental risk;
- COGEM is of the opinion that import and processing of maize GA21 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/RX/005) filed by Syngenta, concerns the renewal of the authorisation for import and processing of genetically modified (GM) maize GA21 for use in feed and food. Maize GA21 contains the *mepsps* gene, conferring herbicide tolerance to glyphosate containing herbicides. The GM maize line has been authorised for import, food, feed and processing in Europe on March 28th in 2008 (2008/280/EC).[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 for import and processing. The application contains, amongst others, monitoring reports, an updated molecular characterisation and an updated literature search.

2. Previous COGEM advices

In 2008 COGEM advised positively on the import and processing of maize GA21.[2] Additionally, in 2008 and in 2012 (following the publication of the EFSA opinion), COGEM advised positively on

the cultivation of maize GA21.[3,4] Recently, COGEM advised positively on the import and processing of GM stacked maize line GA21xT25.[5]

3. Environmental risk assessment

3.1 Aspects of the wild-type crop

Maize (*Zea mays*) is a member of the grass family *Poaceae*. It is a highly domesticated crop originating from Central America, but nowadays cultivated globally. Maize is wind pollinated, and has both male and female flowers that are spatially separated.[6,7] Female flowers are not attractive to insect pollinators, because they do not produce nectar. Insect pollination of maize is probably highly limited but cannot be excluded.[8]

In the Netherlands, no wild relatives of maize are present and hybridisation with other species cannot occur. Maize requires warm conditions in order to grow and does not tolerate prolonged cold and frost.[8,9] In cultivation areas with warmer climatic conditions, the appearance of volunteers can occur the year following maize cultivation due to spilled cobs or kernels. However, these volunteers are usually killed by common mechanical pre-planting soil preparation practices.[8]

Maize is very sensitive to weed competition.[10] During the long process of domestication, maize has lost the ability to persist in the wild.[7] A soil seed bank, small seeds, and an extended period of flowering and seed production are characteristics often observed in persistent weeds.[11] Maize lacks all these characteristics. After ripening, the seeds (the kernels) adhere to the cob and do not shatter naturally.[8,12] Consequently, seed dispersal is severely hampered.

During field observations in Austria some volunteers and maize plants were observed in non-agricultural habitats.[13] In the Netherlands, the appearance of volunteers is very rare, however, maize plants occasionally have been observed outside agricultural fields.[14] COGEM is not aware of any reports of feral maize populations in the Netherlands or elsewhere in Europe.

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

3.2 Description of the introduced gene and trait

Transformation event GA21 was produced via particle bombardment of maize suspension culture cells.

Introduced genes	Encoded proteins (enzymes)	Traits
mepsps	Modified 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) originating from *Zea mays*[15]	Tolerance to glyphosate containing herbicides, because of a decreased binding affinity for glyphosate
See reference for a detailed description of the trait		

3.3 Updated molecular characterisation

The applicant provided additional sequence information. Using recent databases the applicant updated the bioinformatic analyses of the inserted element and the sequences spanning the 5' and

3' junctions of the insert and its flanking regions. According to the applicant, no essential endogenous genes were disrupted at the insertion site, and the putative reading frames did not generate any protein sequence similarities with known allergens, toxins or other biologically active proteins. COGEM is of the opinion that the molecular characterisation of maize GA21 has been performed correctly and meets the requirements of COGEM.[16] The results from the updated bioinformatic analyses do not provide indications that maize GA21 could pose a risk to the environment.

Conclusion: The molecular characterisation of maize GA21 is adequate and no indications for potential environmental risks were identified.

3.4 Systematic literature search

The applicant performed a systematic literature search using a broad collection of bibliographic databases, covering a publication period from 2005 to 2016 to monitor the safety of maize GA21. The scientific publications contained no reports on adverse effects or incidents.

Conclusion: The systematic literature review gives no indication of adverse effects or incidents resulting from import and/or processing of maize GA21.

3.5 Annual monitoring reports

The applicant supplied annual monitoring reports carried out between March 2008 and July 2016. Monitoring was performed by operators involved in the import, handling and processing of maize GA21, i.e. COCERAL, UNISTOCK and FEDIOL. As part of the monitoring reports, the applicant also performed a yearly review of scientific publications to monitor the safety of maize GA21. The monitoring reports and the scientific publications contained no reports on adverse effects or incidents.

Conclusion: The information in the annual monitoring reports gives no indication of adverse effects or incidents resulting from import and processing of maize GA21.

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 new post-market environmental monitoring (PMEM) plan. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan,[17,18] but considers the current GS plan adequate for import and processing of maize GA21.

6. Overall conclusion

There are no indications that expression of the introduced traits will alter the fitness of maize GA21. COGEM is of the opinion that import and processing of maize GA21 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

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