Import and processing of genetically modified maize GA21xT25

COGEM advice CGM/170502-03

- The present application (EFSA/GMO/DE/2016/137) concerns the authorisation for import and processing for use in feed and food of genetically modified (GM) maize GA21xT25;
- Maize GA21xT25 was produced by conventional crossbreeding of the two GM parental maize lines GA21 and T25;
- The GM line expresses the *mepsps* and *pat* genes conferring tolerance to glyphosate and glufosinate-ammonium containing herbicides;
- COGEM advised positively on the import, processing and cultivation of the parental lines GA21 (2008, 2012) and T25 (2008, 2013).
- In the Netherlands, feral maize populations have never been observed and the appearance of volunteers is rare;
- In the Netherlands, wild relatives of maize have never been observed and hybridisation of maize with other species is therefore not possible;
- The molecular characterisation of maize GA21xT25 meets the criteria of COGEM;
- The updated molecular characterisation does not give any indication of a potential environmental risk;
- There are no indications that the introduced traits alter the fitness of maize GA21xT25;
- There are no reasons to assume that the introduced traits will allow GM maize GA21xT25 to survive in the Dutch environment;
- COGEM is of the opinion that import and processing of maize GA21xT25 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/DE/2016/137), filed by Syngenta, concerns import and processing of genetically modified (GM) maize GA21xT25, for use in feed and food. Maize GA21xT25 was produced by conventional crossbreeding of the two GM parental maize lines GA21 and T25. The stacked line contains the *mepsps* and *pat* genes conferring tolerance to glyphosate and glufosinate-ammonium containing herbicides.

Parental lines GA21 and T25 have been authorised for import and processing for use in food and feed in the European Union since 2008 and 1998, respectively.[1,2,3] In 2015 the European Commission renewed the authorisation for import and processing of T25.[3,4]

2. Previous COGEM advices

COGEM previously advised on the import, processing and cultivation of parental lines maize GA21 and T25.[5,6,7,8,9,10] In 2008 and 2012 COGEM advised positively on import and processing,

and cultivation of maize GA21.[6,7,8] In 2008 COGEM advised positively on cultivation of maize T25, and in 2013 positively on import and processing of maize T25.[9,10]

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,[11,12] and has both male and female flowers that are spatially separated. Female flowers are not attractive to insect pollinators, because they do not produce nectar. As insects do not visit the female flowers, insect pollination of maize is probably highly limited but cannot be excluded.[13]

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.[13,14] 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.[13]

Maize is very sensitive to weed competition.[15] During the long process of domestication, maize has lost the ability to persist in the wild.[12] A soil seed bank, small seeds, and an extended period of flowering and seed production are characteristics often observed in persistent weeds.[16] Maize lacks all these characteristics. After ripening, the seeds (the kernels) adhere to the cob and do not shatter naturally.[13,17] Consequently, seed dispersal is severely hampered.

During field observations in Austria some volunteers and maize plants were observed in non-agricultural habitats.[18] In the Netherlands, the appearance of volunteers is very rare, however, maize plants occasionally have been observed outside agricultural fields.[19] 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 genes and traits

Maize GA21xT25 contains a *mepsps* and *pat* expression cassette conferring tolerance to glyphosate and glufosinate-ammonium containing herbicides.

Introduced genes	Encoded proteins (enzymes)	Traits
mepsps	Modified 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) originating from *Zea mays*[20]	Tolerance to glyphosate containing herbicides, because of a decreased binding affinity for glyphosate
pat	Variant of phosphinothricin N-acetyltransferase (PAT) originating from *Streptomyces viridochromogenes* strain Tü 494[21,22]	Tolerance to glufosinate-ammonium containing herbicides
See references for a detailed description of the traits		

3.3 Molecular characterisation

GA21xT25 maize was produced by conventional crossbreeding of the GM maize lines GA21 and T25. The applicant confirmed by Southern blot analyses that the hybrid line contained both the parental transgenic inserts of GA21 and T25, and that no rearrangements of these inserts occurred. For each parental line, the applicant updated the bioinformatic analyses of the inserted elements and their 5' and 3' flanking regions using recent databases. According to the applicant, no essential endogenous genes were disrupted at the insertion site, and no biologically meaningful protein sequence similarities with allergens or toxic proteins were detected. The molecular characterisation was conducted according to the criteria previously laid down by COGEM.[23] The results from the updated molecular characterisation do not provide indications that GA21xT25 could pose a risk to the environment.

Conclusion: The molecular characterisation of maize GA21xT25 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 GA21xT25 and noted that most agronomic characteristics did not differ from those in the non-GM near-isogenic line. When differences were observed, they were within ranges considered to be normal for conventional maize. The results of the phenotypic evaluation do not give reason to assume that the GM maize line could pose an environmental risk.

In conclusion, COGEM is of the opinion that there are no indications to assume that the introduced traits in GA21xT25 allow the maize line to survive or establish in the Dutch environment.

Conclusion: GA21xT25 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 new general surveillance plan as part of the PMEM. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan,[24,25] but considers the current GS plan adequate for import and processing of maize GA21xT25.

6. Overall conclusion

COGEM is of the opinion that import and processing of maize GA21xT25 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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