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DATUM 19 november 2007
KENMERK CGM/071119-02
ONDERWERP Advies teelt van maïslijn 1507x59122

Geachte mevrouw Cramer,

Naar aanleiding van een adviesvraag betreffende de teelt van genetisch gemodificeerde maïs 1507x59122 (dossier EFSA/GMO/NL/2005/28) van Mycogen Seeds c/o Dow AgroSciences LLC, adviseert de COGEM als volgt:

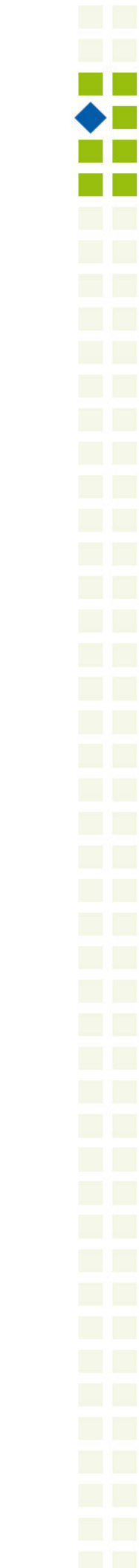
Samenvatting:

De COGEM is gevraagd te adviseren over een vergunningaanvraag voor de teelt van de genetisch gemodificeerde maïslijn 1507x59122. Deze maïslijn bezit twee kopieën van het *pat* gen, waardoor de plant tolerant is voor glufosinaat-ammonium bevattende herbiciden. Daarnaast bevat de maïslijn het *cry34Ab1*, *cry35Ab1* en *cry1F* gen, waardoor de plant resistent is tegen bepaalde kevers en vlinderachtigen.

Eerder dit jaar heeft de COGEM geadviseerd over de teelt van de maïslijnen 59122 en 59122xNK603x1507. In beide gevallen was de COGEM van mening dat de gegevens betreffende eventuele effecten op niet-doelwitorganismen onvoldoende waren. Zowel de laboratoriumexperimenten als de gegevens van de veldexperimenten waren onvoldoende van kwaliteit om een volledige risico-analyse te kunnen uitvoeren. Aangezien deze aanvraag geen nieuwe gegevens bevat ten opzichte de eerdere aanvragen zijn dezelfde bezwaren ook op de huidige aanvraag van toepassing.

Daarnaast acht de COGEM het 'general surveillance' plan te vrijblijvend en onvoldoende beschreven om zekerheid te bieden omtrent detectie van mogelijk onverwachte effecten. In het plan zou de methode waarop gegevens over onverwachte effecten worden verkregen en gerapporteerd verder moeten worden uitgewerkt.

In het licht van bovenstaande bezwaren kan de COGEM niet positief adviseren over de teelt van maïslijn 1507x59122.



De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,



Prof. dr. ir. Bastiaan C.J. Zoeteman
Voorzitter COGEM

c.c. Dr. D.C.M. Glandorf
Dr. I. van der Leij

Cultivation of genetically modified maize line 1507x59122

COGEM advice CGM/071119-02

Summary

*This notification concerns the cultivation of the genetically modified maize line 1507x59122. The maize line harbors two copies of the same *pat* gene, which confers tolerance to herbicides containing glufosinate-ammonium. In addition, the maize line contains the *cry34Ab1*, *cry35Ab1* and *cry1F* genes. These *cry* genes make the maize line resistant to certain butterflies, moths and beetles.*

Previously, COGEM advised on the application for cultivation of the maize lines 59122 and 59122xNK603x1507. Based on the provided studies on non-target organisms (NTOs) COGEM expressed serious concerns about the substantiation of the conclusion that the indicated maize lines exert no negative effects on NTOs. These previously mentioned concerns remain, since the current notification does not contain any additional information regarding possible effects on NTOs. Furthermore, COGEM poses reservations with respect to the general surveillance plan. In the opinion of COGEM the surveillance plan proposed is too limited.

As a result of the concerns mentioned regarding the NTO studies and the general surveillance plan, COGEM cannot issue a positive advice on the cultivation of maize line 1507x59122.

Introduction

This notification concerns the cultivation of the genetically modified maize line 1507x59122. The maize line harbors two copies of the same *pat* gene, which confers tolerance to herbicides containing glufosinate-ammonium. In addition, the maize line contains the *cry34Ab1*, *cry35Ab1* and *cry1F* genes. These *cry* genes make the maize line resistant to certain butterflies, moths and beetles.

COGEM advised several times on the import and cultivation of genetically modified maize lines, like maize line 59122, 59122xNK603 and 1507xNK603x1507 (1-5).

Maize originates from Central America and is cultivated as an agricultural crop. Although insect pollination cannot be excluded completely, maize is predominantly wind pollinated (6, 7). Pollen viability varies between 30 minutes and nine days according to literature (7-9). In Europe, no wild relatives of maize are present, which eliminates the possible risk of hybridization with other species.

The appearance of volunteers is very rare under Dutch conditions. The grains exhibit no germination dormancy, resulting in a short persistence in Northern European climate conditions. Furthermore, only few seeds remain on the field after harvesting of fodder maize (6). Establishment of maize plants in the wild has never been observed in the Netherlands. In addition, there is no reason to assume that the inserted traits will increase the now absent potential of maize to establish feral populations.

Recently, COGEM evaluated the application for import of the maize line 1507x59122 (10). The commission concluded that the molecular characterization of this maize line was adequate and that no allergenic or toxic products are expected to be formed. Consequently, COGEM was of the opinion that the import of this maize line posed a negligible risk to the human health and the environment.

Effects of genetically modified maize on non-target organisms

Previously, COGEM advised on the application for cultivation of the maize lines 59122 and 59122xNK603x1507 (4, 5). Based on the provided studies on non-target organisms (NTOs) COGEM expressed serious concerns about the substantiation of the conclusion that the indicated maize lines exert no negative effects on NTOs. These previously mentioned concerns remain, since the current notification does not contain any additional information regarding possible effects on NTOs. In short, COGEM is of the opinion that an appropriate laboratory study should include a relevant statistical approach and a clear substantiated methodology. In addition, it should address the question whether the combination of three *Bt* genes poses a synergistic effect on NTOs. Additional data from laboratory experiments and field studies that apply to European field conditions should be supplied. Furthermore, NTOs should be studied which are representative of the insects present in maize fields in Europe. In the opinion of COGEM, a relevant study is a field study which is comparable to the current agricultural practice. A field experiment should have a clear methodological setup and should be performed at the time of year that maize is normally cultivated. Otherwise, no relevant statistically significant conclusions can be drawn regarding the effects of the genetically modified maize line.

General surveillance plan

Apart from the stated issues with the NTO studies, COGEM also poses reservations with respect to the general surveillance plan. In the judgement of COGEM the surveillance plan proposed is too limited. The applicant refers to a pre-defined format as the most appropriate method to collect data on unanticipated adverse effects. A specification of this format, describing how the unexpected effects are monitored and how data is collected and reported is missing. Furthermore, the surveillance plan relies solely on the

expertise of the users of this maize line. In COGEM's view this is too limited to ascertain that unanticipated adverse effects are observed and reported. In an advice on the monitoring of genetically modified crops in the Netherlands, COGEM suggested to include existing monitoring systems in the general surveillance (11). In respect of the Dutch situation, the Network Ecological Monitoring (NEM), the 'Monitoring van de Waterstaatkundige Toestand des Lands' (MWTL) and FLORON have been mentioned as potential agencies.

Additional remark

With respect to the monitoring of Bt resistance development in the target organisms, COGEM notes that the monitoring plan proposed will only be adequate in case of recessive inheritance of Bt resistance in the target pest population. However, literature shows that Bt resistance in the European corn borer can be partly dominant (12). Under selective circumstances, such as the presence of Bt toxin, a dominant resistance allele may quickly increase in frequency. However, this aspect is not a part of the environmental risk analysis and does not contribute to the final opinion of the COGEM on this application.

Conclusion

As a result of the concerns mentioned regarding the NTO studies and the general surveillance plan, COGEM cannot issue a positive advice on the cultivation of maize line 1507x59122.

References

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