

Aan de minister van
Volkshuisvesting, Ruimtelijke
Ordening en Milieubeheer
Mevrouw dr. J.M. Cramer
Postbus 30945
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DATUM 25 maart 2008
KENMERK CGM/080325-02
ONDERWERP Advice cultivation of maize variety 1507x59122

Geachte mevrouw Cramer,

Naar aanleiding van een adviesvraag betreffende de teelt van genetisch gemodificeerde maïs 1507x59122 van Pioneer Hi-Bred International, deelt de COGEM u het volgende mee.

Samenvatting:

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

In haar eerdere advies over teelt van maïslijn 1507x59122 concludeerde de COGEM dat de gegevens betreffende de effecten op niet-doelwitorganismen onvoldoende waren. Daarnaast plaatste de COGEM kanttekeningen bij het geleverde monitoringplan. Naar aanleiding van de opmerkingen van de COGEM is de aanvrager verzocht om aanvullende informatie te leveren. De aanvrager heeft aanvullende informatie geleverd over de statistische betekenis van eerder uitgevoerde laboratoriumstudies, de relevantie van de geteste niet-doelwitorganismen, de methodologie van de veldproeven en over het monitoringplan. Daarnaast zijn resultaten van nieuwe laboratoriumexperimenten en veldstudies aangeleverd. De COGEM is van mening dat de aanvullende informatie haar eerdere bezwaren wegneemt. Op grond van de aangeleverde gegevens komt de COGEM tot de conclusie dat de risico's voor mens en milieu bij de teelt van maïslijn 1507x59122 verwaarloosbaar klein zijn.

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

Hoogachtend,

A handwritten signature in black ink, consisting of a large loop on the left and a long horizontal stroke extending to the right.

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

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

Cultivation of genetically modified maize line 1507x59122

COGEM advice CGM/080325-02

This notification concerns the cultivation of the genetically modified maize line 1507x59122. The maize line harbors the cry34Ab1, cry35Ab1, cry1F genes and two copies of the pat gene conferring tolerance to glufosinate-ammonium-containing herbicides and resistance to certain butterflies, moths and beetles.

In Europe, wild relatives of maize are not present and establishment of maize plants in the wild has never been observed. There are no reasons to assume that the inserted traits will increase the potential of the maize line to establish feral populations. In addition, the appearance of volunteers is very rare under Northwest European agronomical conditions.

In her previous advice on cultivation of maize line 1507x59122 COGEM expressed concerns about the substantiation of the conclusion that maize line 1507x59122 exerts no negative effects on non-target organisms (NTOs). In addition, in COGEMs view the proposed general surveillance plan was too limited. Because of these concerns COGEM could not issue a positive advice on the cultivation of maize line 1507x59122. The applicant was asked to provide more detailed and confirmatory data to underpin the conclusion that maize line 1507x59122 exerts no adverse effects on NTOs and to provide more information about the implementation of general surveillance.

The applicant provided additional information regarding the statistical relevance of existing laboratory studies, the representativeness of the selected NTO test species for the European situation, the methodology used to examine possible effects on NTOs and the general surveillance plan. In addition, data from additional laboratory experiments and field tests was provided.

Based on the additional information provided by the applicant and the considerations put forward in this advice, COGEM is of the opinion that the cultivation of maize line 1507x59122 poses a negligible risk to human health and the environment.

Introduction

The present notification by Pioneer Hi-Bred International concerns the cultivation of maize line 1507x59122. This maize line expresses the cry34Ab1, cry35Ab1 and cry1F genes conferring resistance to certain coleopteran and lepidopteran insects such as the corn rootworm (*Diabrotica* spp.) and the European corn borer (*Ostrinia nubilalis*). The cry34Ab1 and cry35Ab1 proteins are synergistic. Expression of the cry34Ab1 gene confers an average resistance to the corn rootworm, while expression of only the cry35Ab1 gene confers no resistance at all. Expression of both genes in the same plant,

however, results in a maximum resistance to the corn rootworm. Maize line 1507x59122 also contains two copies of the *pat* gene, conferring tolerance to glufosinate-ammonium containing herbicides.

Previous COGEM advices

Previously, COGEM advised positively on the import of maize line 1507x59122 (1). In Europe, wild relatives of maize are not present and establishment of maize plants in the wild has never been observed. There are no reasons to assume that the inserted traits will increase the potential of the maize line to establish feral populations. In addition, the appearance of volunteers is very rare under Northwest European agronomical conditions. Furthermore, it was concluded that the molecular characterization was adequate.

In 2007, COGEM was asked to advice on the cultivation of maize line 1507x59122. COGEM was of the opinion that the studies on possible effects of cultivation of maize line 1507x59122 on non-target organisms (NTOs) contained some serious shortcomings. In addition, the proposed general surveillance plan was too limited. Because of these concerns COGEM could not issue a positive advice on cultivation of maize line 1507x59122 (2).

Aspects of the crop

Maize (*Zea mays* L.) is a member of the grass family *Poaceae*. Maize was domesticated in Central America and is nowadays cultivated throughout the world (3). Although insect pollination can not be completely excluded, maize is predominantly wind pollinated (4, 5). According to literature, pollen viability varies between 30 minutes and 9 days (5, 6, 7). In Europe, hybridization with other species cannot occur since wild relatives of maize are not present in Europe (3).

The appearance of volunteers is very rare under Dutch conditions. Grains exhibit no germination dormancy, resulting in a short persistence. In addition, only few seeds remain on the field after harvesting of fodder maize (4). In the Netherlands, establishment of feral maize populations has never been observed.

Molecular characterization

The molecular characterization of maize 1507x59122 was previously evaluated by COGEM in an application concerning import and processing for the use in feed and food of maize line 1507x59122. It was concluded that the molecular characterization is adequate and that the risk of formation of toxic or allergenic products with the modification of maize 1507x59122 is negligible (1).

Environmental risk assessment

In her previous advice, COGEM formulated a series of questions to the applicant concerning the statistical power of certain laboratory studies, the representativeness of the selected NTO test species for the European situation, the methodology used to examine possible effects on NTOs, the possible synergistic effects of the Cry34Ab1, Cry35Ab1 and Cry1F proteins on NTOs and the implementation of general surveillance. Furthermore, COGEM asked for more confirmatory data from field tests. In response to these questions the applicant provided additional information.

Recently, COGEM issued an advice on cultivation of maize variety 59122 (8). In this advice COGEM considered additional information on the statistical power of certain laboratory studies, the representativeness of the selected NTO test species for the European situation and the methodology used to examine possible effects on NTOs. This information also applies to the studies performed for maize line 1507x59122. In the current advice COGEM will focus on the additional information provided by the applicant that applies specifically to cultivation of 1507x59122 and was not considered in COGEMs advice on cultivation of maize line 59122. This information concerns possible synergistic effects of the Cry34Ab1, Cry35Ab1 and Cry1F proteins on NTOs, additional field studies and General Surveillance.

Synergistic effects

In her previous advice on cultivation of maize line 1507x59122 COGEM asked the applicant to examine whether the Cry34Ab1, Cry35Ab1 and Cry1F proteins exert a synergistic effect on NTO's. In response to this question the applicant provided several additional studies (both laboratory and field studies).

Laboratory studies

The applicant conducted several additional laboratory experiments. Experiments in which pollen was fed to the monarch butterfly (*Danaus plexippus*) and the lady beetle (*Coleomegilla maculata*) were performed to evaluate the effect of 1507x59122 pollen on non-target insects. Newly hatched larvae of the monarch butterfly were fed milkweed leaves to which 1507x59122 pollen, pollen derived from a respective isolate and no pollen was applied in six densities. Survival, development, weight gain and leaf consumption were measured. Adverse effects were not observed.

In addition, neonate *C. maculata* larvae were fed a 1:1 mixture of lyophilized ground corn earworm eggs and 1507x59122 pollen or control pollen. Development, adult weight and mortality were measured and adverse effects were not observed.

In another experiment microbe-produced Cry1F protein, Cry34Ab1 + Cry35Ab1 proteins, Cry34Ab1+Cry35Ab1+Cry1F proteins or a buffer control were applied to the diet of the southern corn rootworm (*Diabrotica undecimpunctata howardi*) and the European corn borer (*Ostrinia nubilalis*). The southern corn rootworm is susceptible to the Cry34Ab1/Cry35Ab1 proteins, whereas the European corn borer is susceptible to the Cry1F protein. The applicant compared the effect of a diet supplemented with Cry34Ab1/Cry35Ab1 proteins to the effect of a diet supplemented with the Cry34Ab1/Cry35Ab1/Cry1F proteins on larval weight and stated that no synergistic or antagonistic effect was observed. In COGEMs view this study contains weaknesses with respect to the supplied statistics and statistical power. However, both the southern corn rootworm and the European corn borer are target organisms. No adverse effects were observed when the monarch butterfly and a lady beetle were fed 1507x59122 pollen, which indicates that the Cry34Ab1, Cry35Ab1 and Cry1F proteins do not exert an adverse synergistic effect on non-target insects.

Field studies

In its previous advice, COGEM expressed serious concerns on the quality of the field study from Spain (2005). The maize in this study was planted too late in season, and therefore no relevant conclusions could be drawn regarding the effects of cultivation of maize 1507x59122 on NTOs. In addition, COGEM concluded that the quality of this study was not sufficient to draw conclusions about the absence of effects from cultivation of maize line 1507x59122 on NTOs. Moreover, since maize line 1507x59122 is a newly developed variety which has entered the market only recently, results from earlier experiments are not available.

The applicant provided two additional field studies performed in Spain (2006) and Hungary (2006). These studies examined the impact of cultivation of maize line 1507x59122 on non-target arthropod populations. The abundance of non-target arthropods was monitored using pitfall traps (rove beetles, spiders, centipedes/millipedes, ground beetles, springtails), sticky traps (rove beetles, leafhoppers, aphids, thrips, flower bugs, parasitic hymenoptera) and visual observations (flower bugs, damsel bugs, spiders, lacewings, ladybird beetles, ground beetles). The field studies show no significant harmful effects on the NTOs present in maize 1507x59122 compared to the non-gm maize control, which confirms the results from laboratory feeding studies in which 1507x59122 pollen did not exert an adverse effect on non-target insects.

General surveillance

In her previous advice on cultivation of maize 1507x59122 COGEM requested information on the approach used for monitoring, data collection and reporting of

unanticipated effects. In response to these questions the applicant provided the format used to collect data on unanticipated adverse effects and stated that existing infrastructures will be used to distribute and collect this format. In addition, the applicant indicated that they will consider requesting appropriate access to suitable data obtained from future surveys of conservation goals. In COGEMs view, the general surveillance plan supplied for cultivation of maize 1507x59122 is too informal and gives no guarantees that data is obtained. The general surveillance plan relies mostly on the expertise of the users of this maize line. In her previous advice COGEM stated that in her opinion this is too limited to ascertain that unanticipated adverse effects are observed and reported. COGEM suggested to include existing monitoring systems in general surveillance. The Netherlands is in the process of implementing such as system. COGEM underlines the importance of using existing monitoring systems in other countries in general surveillance and including these monitoring systems in general surveillance. In addition, COGEM is of the opinion that the general surveillance plan should mention that information about the distribution of the form and the percentage of returned forms is included in the monitoring report.

Furthermore, in her previous advice on cultivation of maize line 59122 COGEM stated that during monitoring extra attention should be paid to lady beetles (8). Since lady beetles were not present in high numbers during the field studies of maize line 1507x59122 COGEM is of the opinion that during cultivation of maize line 1507x59122 extra attention should be paid to monitoring of lady beetles.

Advice

The present application concerns the cultivation of maize line 1507x59122. This maize line expresses the *cry34Ab1*, *cry35Ab1* and *cry1F* genes conferring resistance to certain coleopteran and lepidopteran insects such as the corn rootworm (*Diabrotica* spp.) and the European corn borer (*Ostrinia nubilalis*). In addition, maize line 1507x59122 contains two copies of the *pat* gene conferring tolerance to glufosinate-ammonium-containing herbicides. In the past, COGEM advised positively on import of this particular maize line.

There are no wild relatives of maize in the Netherlands and the appearance of volunteers under Dutch conditions is very rare. Furthermore, there are no reasons to assume that the inserted traits will increase the now absent potential of the maize line to establish feral populations. COGEM is of the opinion that the molecular characterization of this maize line is adequate.

In her previous advice on cultivation on maize line 1507x59122, COGEM formulated a series of questions to the applicant concerning the statistical power of certain laboratory studies, the representativeness of the selected NTO test species for the European

situation, the methodology used to examine possible effects on NTOs, possible synergistic effects of the Cry34Ab1, Cry35Ab1 and Cry1F proteins on NTOs and the implementation of general surveillance. In response to these questions, the applicant provided additional information regarding the statistical relevance of existing laboratory studies, representativeness of the selected NTO test species for the European situation, the methodology used to examine possible effects on NTOs and data from additional laboratory experiments and field tests. Furthermore, extra information regarding the general surveillance plan was provided. COGEM is of the opinion that during cultivation of maize line 1507x59122 additional attention should be paid to the monitoring of lady beetles. Since the additional experiments did not reveal adverse effects from the cultivation of maize line 1507x59122 on NTOs, COGEM is of the opinion that the cultivation of maize line 1507x59122 poses a negligible risk to human health and the environment.

References

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