



COMMISSIE
COGEM

GENETISCHE
MODIFICATIE

Aan de minister van
Volkshuisvesting, Ruimtelijke
Ordening en Milieubeheer
Mevrouw dr. J.M. Cramer
Postbus 30945
2500 GX Den Haag

DATUM 17 augustus 2007
KENMERK CGM/070817-02
ONDERWERP Advies Import van maïslijn 59122 x NK603

Geachte mevrouw Cramer,

Naar aanleiding van een adviesvraag betreffende de import en verwerking van genetisch gemodificeerde maïs 59122 x NK603 van Pioneer Hi-Bred International Inc., deelt de COGEM u het volgende mee.

Samenvatting:

De COGEM is gevraagd te adviseren over de mogelijke risico's voor mens en milieu bij import en verwerking van de genetisch gemodificeerde (gg) maïslijn 59122 x NK603. Teelt van deze lijn maakt geen deel uit van de vergunningaanvraag.

In de maïslijn zijn de genen *pat* en *cp4epsps* ingebouwd waardoor de plant tolerant is voor respectievelijk glufosinaat-ammonium en glyfosaat bevattende herbiciden. Daarnaast bevat de maïslijn de genen *cry34Ab1* en *cry35Ab1* waardoor de plant resistent is voor bepaalde kevers en vlinders.

Maïs heeft in Nederland geen wilde verwanten en opslag van maïsplanten is in Nederland nagenoeg uitgesloten. Verwildering van de maïsplant is in Nederland nooit waargenomen. Er zijn geen redenen om aan te nemen dat de modificaties het verwilderingspotentieel vergroten. De COGEM acht daarom de kans verwaarloosbaar klein dat incidenteel morsen leidt tot verspreiding van 59122 x NK603 binnen Nederland.

De COGEM is van mening dat de moleculaire karakterisering van de maïslijn 59122 x NK603 volledig is en dat de aanvrager voldoende heeft aangetoond dat er geen nieuwe allergeene of toxische producten gevormd worden als gevolg van de kruising van de lijnen. Bovendien wordt maïslijn NK603 sinds 2000 geteeld in de Verenigde Staten en diverse andere landen zonder rapportages over nadelige effecten.

De COGEM is van mening dat de risico's voor mens en milieu verwaarloosbaar klein zijn bij markttoelating voor import en verwerking van de maïslijn 59122 x NK603.

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. B.P. Loos
Dr. I. van der Leij

Import of genetically modified maize 59122 x NK603

COGEM advice CGM/070817-02

Summary

*This notification concerns the import and processing of the genetically modified maize line 59122 x NK603 for use in feed and food. Cultivation is not part of the application. The hybrid maize line harbors a *pat* and a *cp4epsps* gene and two *cry* genes; *cry34Ab1* and *cry35Ab1*. The *pat* and *cp4epsps* genes confer tolerance to herbicides containing glufosinate-ammonium and glyphosate, respectively. The *cry34Ab1* and *cry35Ab1* genes are responsible for resistance to certain coleopteran insects such as the corn rootworm (*Diabrotica virgifera*).*

Previously, COGEM advised positively on the import of maize lines 59122 and NK603. COGEM has also given a positive advice on the cultivation of maize line NK603.

In the Netherlands, no wild relatives of maize are 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 Dutch conditions.

COGEM is of the opinion that the molecular analysis is adequate. The applicant has sufficiently proven that no toxic or allergenic products are formed as a result of the modification of maize line 59122 x NK603. Based on these considerations, COGEM is of the opinion that the import of maize line 59122 x NK603 poses a negligible risk to human health and the environment.

Introduction

The present notification by Pioneer Hi-Bred International, Inc. concerns the import and processing of the hybrid maize line 59122 x NK603 for use in feed and food.

The maize line is produced by traditional crossing of maize lines 59122 and NK603. Maize line 59122 expresses the *pat* gene conferring tolerance to glufosinate-ammonium containing herbicides and the two *cry* genes *cry34Ab1* and *cry35Ab1* conferring insect resistance to certain coleopteran insects such as the corn rootworm (*Diabrotica virgifera*). The other parental maize line, NK603 expresses *cp4epsps*, conferring tolerance to glyphosate containing herbicides.

Previous COGEM advices

Previously, COGEM advised positively on the import of maize lines 59122 and NK603 (1, 2). COGEM has also given a positive advice on the cultivation of maize line NK603 (3).

Aspects of the crop

Maize (*Zea mays L.*) is a member of the grass family *Poaceae*. Maize is originating from Central America. 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, no wild relatives of maize are present and, therefore, hybridization with other species can not occur.

The appearance of volunteers is very rare under Dutch conditions. Generally, only few kernels remain on the field after harvesting of fodder maize (4). Kernels exhibit no dormancy, resulting in a short persistence under Northern European climate conditions.. Establishment of maize plants in the wild has never been observed in the Netherlands.

Molecular characterization

The genetically modified maize line 59122 x NK603 was produced by crossing two parental maize lines 59122 and NK603. The characterization of these parental lines will be briefly discussed. A more detailed description can be found in previous COGEM advices on the single parental maize lines (1,2).

Description of the introduced genes

Maize line 59122 expresses the *cry34Ab1*, *cry35Ab1* and a *pat* gene. Besides these three genes, regulatory components necessary to regulate gene expression were inserted as part of the vector.

The genetically modified maize line NK603 contains two *cp4 epsps* expression cassettes. The *cp4epsps* gene was isolated from the CP4 strain of the soil bacterium *Agrobacterium tumefaciens*.

Molecular analysis

Previously, the molecular aspects of parental maize line 59122 as well as NK603 have been thoroughly analyzed (1,2). COGEM is of the opinion that the molecular analysis of the two parental maize lines 59122 and NK603 was sufficient and it is unlikely that toxic or allergenic products are formed as a consequence of the modifications.

Advice

The present application concerns the commercial import and processing of maize line 59122 x NK603 for the use in food and feed. Maize line 59122 x NK603 expresses the genes *pat*, *cp4epsps*, *cry34Ab* and *cry35Ab1*, providing the plant with a herbicide tolerance trait as well as resistance to certain coleopteran insects. In the past, COGEM advised positively on the import of maize lines with these traits and hybrid maize lines with a combination of these traits.

There are no wild relatives of maize in the Netherlands and the appearance of volunteers is very rare under Dutch conditions. Furthermore, there are no reasons to assume that the inserted traits will enable the maize line to run wild.

In the opinion of COGEM, the molecular analysis for 59122 as well as NK603 is adequate. In addition, maize line NK603 has been already commercially grown and consumed from 2000 on in the U.S.A and several other countries without any reports of adverse effects.

In view of these considerations, COGEM is of the opinion that the proposed import and processing of maize line 59122 x NK603 poses a negligible risk to human health and the environment.

References

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NK603.doc
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Creation Date: 8/17/2007 10:24 AM
Change Number: 3
Last Saved On: 8/17/2007 4:38 PM
Last Saved By: van Keulen
Total Editing Time: 11 Minutes
Last Printed On: 8/24/2007 10:42 AM
As of Last Complete Printing
Number of Pages: 5
Number of Words: 1.065 (approx.)
Number of Characters: 6.075 (approx.)