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Onderwerp
Advies Marktdossier EFSA/GMO/NL/2005/12
Maïs 59122

Geachte heer Van Geel,

Naar aanleiding van de adviesvraag betreffende het dossier EFSA/GMO/NL/2005/12, 'maïslijn 59122' voor de import en verwerking van genetisch gemodificeerde maïs door Pioneer Hi-Bred International, adviseert de COGEM als volgt.

**Samenvatting:**
De COGEM is gevraagd te adviseren over de import en verwerking van een genetisch gemodificeerde maïslijn (59122). Teelt van deze lijn maakt geen deel uit van de vergunningaanvraag. In de maïslijn zijn de genen c*ry34Ab1*, *cry35Ab1* en *pat* ingebouwd waardoor de plant minder gevoelig is voor de larven van de maïswortelkevers en daarnaast tolerant is voor glufosinaat-ammonium herbicides.

De vergunningaanvraag betreft alleen import. De enige wijze waarop maïs in het milieu verspreid kan worden is door morsen van maïskorrels. 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 is geen reden om aan te nemen dat de modificaties het verwilderingspotentieel vergroten. De COGEM is gezien het bovenstaande van mening dat het incidenteel morsen van de genetisch gemodificeerde maïs in Nederland geen risico's voor het milieu met zich meebrengt.

De COGEM acht derhalve de risico's voor mens en milieu bij de import en verwerking van onderhavige maïslijn verwaarloosbaar klein.

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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. ir. B.P. Loos
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# Title: Import and processing of maize variety 59122 (EFSA/GMO/NL/2005/12)

**COGEM advice: CGM/051122-01**

*The present application concerns the commercial import and processing for use in feed and food of a genetically modified maize line. Cultivation is not part of the application. The maize line 59122 is genetically modified containing genes (cry34Ab1, cry35Ab1 and pat) conferring resistance to certain coleopteran insects, and tolerance to glufosinate-ammonium herbicides.*

*The application only comprehends the import of maize. Therefore, release in the environment can only occur by spillage of maize kernels. 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 now absent potential of the maize line to establish feral populations. Therefore, COGEM is of the opinion that incidental spillage of the hybrid maize line will not pose a risk to the environment in the Netherlands.*

*In view of the aforementioned, COGEM is of the opinion that the risks for the environment and human health associated with the import and processing of maize line 59122 are negligible.*

## Introduction

The present application by Pioneer Hi-Bred International concerns the commercial import and processing for use in feed and food of a genetically modified maize line.

The maize line 59122 is modified by the introduction and expression of the c*ry34Ab1* and *cry35Ab1* genes. These genes confer resistance to certain coleopteran insect pests, the corn rootworm larvae (*Diabrotica* spp.) is one of them. The insertion and expression of the gene *pat* confers tolerance to the application of glufosinate-ammonium herbicides.

During the last few years, COGEM was asked repeatedly to issue advice on applications concerning the commercial import and processing of various genetically modified (gm) maize variants. Environmental risk analyses focuses on 1) the potential of the gm maize variety to establish feral populations, 2) its potential to outcross with wild relatives and the effects of outcrossing on the environment, and 3) risks associated with incidental consumption by humans and animals. Therefore, the crop characteristics, the molecular characterization of the gm plant (e.g. location of the insert and characteristics of the inserted genes), and the environment in which the

plant is introduced (e.g. wild relatives, geographical and climatological conditions) are taken into account.
In the case of maize, COGEM has repeatedly stated that maize is not able to run wild, and that no wild relatives are present in Europe.

*Previous COGEM advices*
The use of the *pat* gene in maize 1507 and Bt11 has been assessed earlier by the Netherlands with respect to safety for human health and the environment (C/NL/00/10 and C/GB/96/M4/1). The COGEM has advised positively on the import of maize 1507 and on the cultivation of Bt11 maize (CGM/030115-01 and CGM/050816-01). The Bt11 maize line has been previously approved for import in the E.U..

**Aspects of the crop**
Maize (*Zea mays* L.) is a member of the grass family *Poaceae* and cultivation of maize, as an agricultural crop, originated in Central America. Maize is predominantly wind pollinated, although insect pollination can not be completely excluded (1;2). Pollen viability varies between 30 minutes and nine days according to literature (2;3;4). In Europe, no wild relatives of maize are present and, therefore, hybridisation with other species will not occur.

The appearance of volunteers is very rare under Dutch conditions. Maize kernels exhibit no germination dormancy, resulting in a short persistence. Furthermore, during harvesting of fodder maize only few seeds remain on the field (1). Establishment of maize plants in the wild has never been observed in the Netherlands. There are no reasons to assume that inserted traits will increase the potential of the maize line to run wild.

**Molecular characterisation**

*Origin and function of the introduced genes*
Maize line 59122 is genetically modified via Agrobacterium-mediated transformation. The introduced genes c*ry34Ab1* and *cry35Ab1* act together to control certain coleopteran insect pests, among others the larvae of the Western corn rootworm (*Diabrotica virgifera virgifera*), Northern corn rootworm (*Diabrotica barberi*) and the Southern corn rootworm (*Diabrotica undecimpunctata howardi*). By inserting the *pat* gene, the plant acquires tolerance to glufosinate-ammonium herbicides.

An overview of the introduced sequences is given below:

- *Ubi*1ZM promotor, derived from the *Zea mays*
- *cry34Ab1* gene, from *Bacillus thuringiensis* strain PS149B1; confers resistance to coleopteran insects
- PINII, terminator sequence from *Solanum tuberosum* proteinase inhibitor II gene
- TA peroxidase promotor, derived from *Triticum aestivum*
- *cry35Ab1* gene, from *Bacillus thuringiensis* strain PS149B1; confers resistance to coleopteran insects
- CaMV 35S promotor, derived from *Cauliflower mosaic virus*
- *pat*, from *Streptomyces viridochromogenes*; confers tolerance to glufosinate-ammonium herbicide
- CaMV 35 terminator, derived from *Cauliflower mosaic virus*

*Properties of the introduced genes*

Insect resistance

The genes *cry34Ab1* and *cry35Ab1* are derived from *Bacillus thuringiensis* strain PS149B1. By inserting the genes, plants will produce δ-endotoxins (Bt-toxins). These toxins are insecticidal to larvae of certain coleopteran insects. The toxins selectively bind to receptors located in the midgut, resulting in gut perforation causing death of the insect within 48 to 72 hours (5).

The corn rootworm is an economically important pest insect, causing major crop losses. Larvae of this insect feed on roots, resulting in the interference of the plant's ability to absorb water and nutrients and in the reduction of the stability of the plant. As a consequence, damaged plants may lodge, making harvesting difficult.

The corn rootworm was accidentally introduced in the mid-nineties in Bosnia by military air traffic and became established shortly after introduction. The pest is still spreading at a regular rate of about 40 km per year, but is infamous for rapid spread over large distances by (air) traffic. In 2003 this insect was first discovered near Schiphol airport in the Netherlands, but eradicated successfully. In 2005, incidental outbreaks of this pest have been reported and eradicated (6;7). The COGEM notes that in case the corn rootworm is able to establish and spread itself in the Netherlands, large damage to crops can be expected (8;9). Successful introduction by (air) traffic might occur anytime in the near future.

The Cry3Ab1 and Cry35Ab1 proteins do not exhibit amino acid homology to known allergens or toxins.

Selectable marker

Maize line 59122 was genetically modified by the introduction of the gene *pat*, encoding for the enzyme phosphinothricin acetyltransferase protein (PAT). Expression of PAT confers tolerance to glufosinate-ammonium herbicides.

The active ingredient in glufosinate-ammonium herbicide is L-phosphinothricin (L-PPT), which binds to glutamine synthetase in plants. The detoxification of excess ammonia is thereby prevented, leading to plant death. Maize line 59122 expresses the *pat* gene which catalyses the conversion of L-PPT to an inactive form, which does not bind glutamine synthetase. The application of glufosinate-ammonium herbicides to maize line 59122 will therefore be ineffective since ammonia is detoxified.

The PAT protein does not exhibit amino acid homology to known allergens or toxins.

*Molecular analysis*

Based on southern blot analysis, the integration patterns of the introduced genes in the parental lines remain stable and unchanged in the upcoming generations. Furthermore, the genome does not contain fragments from the vector backbone.

The information provided by the applicant sufficiently proves that no novel ORF's potentially encoding new proteins or fusion proteins are present. Furthermore, identified genes in *Zea mays* do not appear to be disrupted by the insert.

Furthermore, the COGEM notes that the applicant has provided evidence that incidental consumption of Cry3A and PMI will not have adverse effects. In addition, interactions between the different recombinant gene products are not expected in the maize line because the proteins have a different mode of action.

**Advice**

The present application concerns the import, processing for feed and food use of a genetically modified maize line. Cultivation of the present line is not part of the application.

There are no reasons to assume that the inserted traits will increase the now absent potential of the maize line to establish feral populations. Therefore, COGEM is of the opinion that incidental spillage of maize kernels 59122 will pose no risk in the Netherlands.

In view of the above, COGEM is of the opinion that the risks for the environment and human health associated with the import and processing of the maize line 59122 are negligible.

## References


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