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KENMERK CGM/071120-01
ONDERWERP Advies import en verwerking van maïslijn MON89034xMON88017 (EFSA/GMO/NL/
2007/39)

Geachte mevrouw Cramer,

Naar aanleiding van de adviesvraag betreffende het dossier EFSA/GMO/NL/2007/39, getiteld "Import and processing of MON89034xMON88017" voor de import en verwerking van genetisch gemodificeerde maïs door Monsanto Europe S.A. adviseert de COGEM als volgt:

Samenvatting:

De COGEM is gevraagd te adviseren over toelating voor import en verwerking van de genetisch gemodificeerde hybride maïslijn MON89034xMON88017. De maïslijn bevat de genen *cry1A.105*, *cry2Ab2* en *cry3Bb1*, waardoor de plant resistent is voor bepaalde insecten. Daarnaast bevat deze maïslijn het gen *cp4 epsps*, waardoor de plant tolerant is voor herbiciden met als werkzame stof glyfosaat.

Verwildering van maïsplanten is in Nederland nooit waargenomen. Daarnaast is opslag van maïsplanten in Nederland nagenoeg uitgesloten. Er zijn geen redenen om aan te nemen dat expressie van de geïnserteerde genen het verwilderingspotentieel van maïs vergroot. Bovendien zijn er in Europa geen wilde verwantten van maïs aanwezig waardoor uitkruising niet mogelijk is.

De COGEM heeft eerder positief geadviseerd over import van ouderlijn MON88017. Recent heeft de COGEM geadviseerd over import van de ouderlijn MON89034 en geconcludeerd dat de moleculaire karakterisatie van deze lijn niet volledig was.

De COGEM wijst erop dat het General Surveillanceplan onvoldoende in detail is uitgewerkt waardoor het onduidelijk is of onverwachte effecten effectief gerapporteerd zullen worden.

De COGEM acht de kans zeer klein dat import en verwerking van MON89034xMON88017 tot risico's voor mens en milieu zal leiden, maar door de onvolledige moleculaire karakterisatie van ouderlijn MON89034 kan zij vooralsnog niet positief adviseren over import en verwerking van MON89034xMON88017.

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

Import and processing of maize MON89034xMON88017

COGEM advice CGM/071120-01

Summary

The present application by Monsanto Europe S.A. (file EFSA/GMO/NL/2007/39) ‘Import and processing of MON89034xMON88017’, concerns the import and processing for use in feed and food of a genetically modified maize line. Cultivation is not part of this application.

The hybrid maize line MON89034xMON88017 contains the genes cry1A.105, cry2Ab2 and cry3Bb1, conferring resistance to certain insects. In addition, this maize line contains the cp4 epsps gene, resulting in tolerance to glyphosate containing herbicides.

Previously, COGEM issued a positive advice on the import and processing of maize line MON88017. But, COGEM is also of the opinion that molecular data provided for parental maize line MON89034 are incomplete. Therefore, COGEM could not issue a positive advice on maize lines MON89034 and MON89034xNK603.

During the long domestication process, maize has lost its ability to survive in the wild. In the Netherlands, the appearance of maize volunteers is rare and establishment of volunteers in the wild has never been reported. There are no reasons to assume that the traits introduced will increase the potential of maize to establish feral populations. The genes introduced in MON89034xMON88017 cannot spread to closely related species since wild relatives of maize are not present in Europe.

In view of the above, COGEM is of the opinion that incidental spillage of MON89034xMON88017 most likely poses negligible risks to man and the environment. However, because of the incomplete molecular analysis of MON89034, COGEM cannot advice positively on import and processing of maize line MON89034xMON88017.

In addition, COGEM is of the opinion that the applicant should describe in more detail how the general surveillance plan will be organized and which organizations are involved. Furthermore, the applicant should ensure that direct and indirect effects are reported annually.

Introduction

The present application by Monsanto S.A., file EFSA/GMO/NL/2007/39, concerns the import and processing of hybrid maize line MON89034xMON88017 for use in feed and food. This line contains the cry1A.105, cry2Ab2, cry3Bb1 and cp4 epsps genes, which are constitutively expressed. As a result MON89034xMON88017 is resistant to certain lepidopteran and coleopteran insects and tolerant to glyphosate containing herbicides.

Previous COGEM advices

In 2007, COGEM issued a positive advice on the import and processing of maize line MON88017 (1). COGEM also advised on maize lines MON89034 and MON89034xNK603. As the molecular data concerning MON89034 contained flaws, COGEM did not advice positively on import and processing of these lines (2,3).

Aspects of the crop

Maize (*Zea mays*) is a member of the *Poaceae* family (grasses). Maize was domesticated in Central America and is nowadays cultivated throughout the world (4). In Europe, hybridization with other species cannot occur since wild relatives of maize are not present in Europe (4). The appearance of volunteers is very rare under Dutch conditions. Grains exhibit no germination dormancy, resulting in a short persistence. Establishment of maize plants in the wild has never been observed in the Netherlands. Besides, observations outside the Netherlands indicate that no feral maize populations are present in Europe.

Molecular characterization

Maize line MON89034xMON88017 was produced by traditional crossing of the two genetically modified parental maize lines MON89034 and MON88017. The molecular characterization of these parental lines will be briefly discussed. A more detailed description of the inserted genes can be found in the COGEM advices concerning the individual parental maize lines (1,2).

Properties of the introduced genes conferring insect resistance

Maize line MON89034 was genetically modified by the insertion of the *cry1A.105* and the *cry2Ab2* genes. MON88017 was modified by insertion of the *cry3Bb1* gene. The *cry1A.105*, *cry2Ab2* and *cry3Bb1* genes encode δ-endotoxins specific for insects of the order Lepidoptera and Coleoptera. The δ-endotoxins are solubilized in the midgut of susceptible insects and are activated by midgut proteases to release a toxin fragment. The toxin fragment binds to specific receptors on the epithelial surface of the midgut. Subsequently, pores are formed in the membranes of the gut cells of the insect, enabling midgut bacteria to enter the body cavity, which leads to septicemia and death (6).

Properties of the introduced genes conferring herbicide tolerance

Besides the *cry3Bb1* gene, maize line MON88017 was genetically modified by the insertion of the *cp4 epsps* gene, which encodes the CP4 EPSPS protein. EPSPS is an enzyme involved in the biosynthesis of aromatic amino acids. Glyphosate inhibits EPSPS, resulting in a lack of amino acids essential for growth and development of plants.

Maize line MON88017 expresses the CP4 EPSPS protein, which is not inhibited by glyphosate and is therefore tolerant to glyphosate containing herbicides (7).

Molecular analysis

Previously, the molecular aspects of parental maize line MON88017 have been positively assessed (1). However, COGEM is of the opinion that the molecular data provided for parental maize line MON89034 are incomplete (2,3).

Environmental risk assessment

During the long process of domestication, maize has lost the ability to survive in the wild. In addition, maize needs human intervention to disseminate its seed. Maize kernels exhibit no dormancy and only survive under a narrow range of climatic conditions. Furthermore, maize is very sensitive to weed competition and cannot persist as a weed (4, 5). In the Netherlands, volunteers are rarely found and establishment of maize plants in the wild has never been observed. There are no reasons to assume that there will be an increase in the potential of MON89034xMON88017 to establish feral populations in case of incidental spillage.

General surveillance plan

A general surveillance plan is supplied by the applicant. As stated in previous advices (1,2), COGEM is of the opinion that the applicant should describe in more detail how the general surveillance will be organized and should indicate which organizations are involved. In addition, the applicant should ascertain that information on eventual adverse effects is indeed obtained. Furthermore, direct and indirect effects should be reported annually.

Advice

COGEM has been asked to advice on import and processing for use in feed and food of hybrid maize line MON89034xMON88017.

Maize has lost the ability to survive in the wild. In the Netherlands, volunteers are rarely found and establishment of maize plants in the wild has never been observed. In addition, maize needs human intervention to disseminate its seed. There is no reason to assume that the expression of the *cry1A.105*, *cry2Ab2*, *cry3Bb1* and *cp4 epsps* genes in MON89034xMON88017 increases the potential of maize to establish feral populations. Introgression of the genes introduced into closely related species cannot occur, since wild relatives of maize are not present in Europe. In view of the above, COGEM is of the opinion that incidental spillage of maize will not pose a risk to man and the environment.

A general surveillance plan has been provided by the applicant. In COGEM's opinion the applicant should describe in more detail how the general surveillance will be organized and should indicate which particular organizations are involved. In addition, the applicant should ascertain that information on possible adverse effects is indeed obtained. Furthermore, direct and indirect effects should be reported annually. Previously, COGEM has outlined the standards that have to be met by a post-market monitoring system and has identified organizations which could be involved in post-market monitoring in the Netherlands (8).

In COGEM's view, the molecular analysis of parental maize line MON88017 was adequate (1). However, COGEM is of the opinion that the molecular data provided for parental maize line MON89034 is incomplete (2).

In view of the above, COGEM is of the opinion that import of MON89034xMON88017 most likely poses negligible risks to man and the environment. However, because of the incomplete molecular analysis of MON89034 COGEM cannot advice positively on import and processing of maize line MON89034xMON88017.

References

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