COMMISSIE
COGEM
GENETISCHE
MODIFICATIE

Aan de minister van
Volkshuisvesting, Ruimtelijke
Ordening en Milieubeheer
Mevrouw dr. J.M. Cramer
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DATUM	30 september 2009
KENMERK	CGM/090930-01
ONDERWERP	Advies 'Import and processing of gm-MON89034x1507xNK603 maize'

Geachte mevrouw Cramer,

Naar aanleiding van een adviesvraag (EFSA/GMO/NL/2009/65) betreffende import en verwerking van de genetisch gemodificeerde maïslijn MON89034x1507xNK603 van Monsanto S.A. en Dow Agrosciences Europe deelt de COGEM u het volgende mee.

Samenvatting

De COGEM is gevraagd om te adviseren over de mogelijke milieurisico's van import en verwerking van MON89034x1507xNK603 maïs. Deze maïslijn is tot stand gekomen door drie genetisch gemodificeerde lijnen met elkaar te kruisen. MON89034x1507xNK603 brengt de genen *cry1A.105, cry2Ab2, cry1F, pat* en *cp4 epsps* tot expressie. Als gevolg hiervan is de maïslijn resistent tegen bepaalde insecten die behoren tot de orde van de Lepidoptera en tolerant voor glyfosaat en glufosinaat-ammonium bevattende herbiciden.

De moleculaire karakterisering van MON89034x1507xNK603 en van de individuele ouderlijnen voldoet aan de criteria van de COGEM.

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 of interacties tussen transgene eiwitten het verwilderingspotentieel van maïs vergroten. Bovendien zijn er in Europa geen wilde verwanten van maïs aanwezig, waardoor uitkruising niet mogelijk is. Daarom acht de COGEM de kans dat incidenteel morsen tot verspreiding van deze maïslijn leidt verwaarloosbaar klein.

Omdat andere instanties een voedselveiligheidsbeoordeling uitvoeren heeft de COGEM bij deze vergunningaanvraag de risico's van incidentele consumptie niet beoordeeld.

Concluderend heeft de COGEM in het licht van de door haar uitgevoerde risicobeoordeling geen bezwaar tegen import en verwerking van MON89034x1507xNK603 maïs en acht zij de risico's voor mens en milieu verwaarloosbaar klein.

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. Drs. H.P. de Wijs
Dr. I. van der Leij

Import and processing of genetically modified MON89034x1507xNK603 maize

COGEM advice CGM/090930-01

The present application by Monsanto S.A. and Dow Agrosciences Europe (file EFSA/GMO/NL/2009/65) concerns import and processing for use in feed and food of genetically modified MON89034x1507xNK603 maize. Cultivation is not part of this application.

MON89034x1507xNK603 maize expresses the cry1A.105*,* cry2Ab2*,* cry1F*,* pat *and* cp4 epsps *genes. As a result MON89034x1507xNK603 is resistant to certain lepidopteran insects. In addition, it is tolerant to glyphosate and glufosinate-ammonium containing herbicides.*

MON89034x1507xNK603 was produced by conventional cross-breeding of three genetically modified parental lines. Previously, COGEM advised positively on import and processing of parental line MON89034. In addition, COGEM issued positive advices on import, processing and cultivation of 1507, NK603 and hybrid 1507xNK603.

The molecular characterization of MON89034x1507xNK603 and its individual parental lines meets the criteria of COGEM.

During its 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 introduced traits or interactions between the transgenic proteins will increase the potential of maize to establish feral populations. The introduced genes 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 the risks for humans and the environment associated with import and processing of MON89034x1507xNK603 maize are negligible. A food/feed safety assessment is carried out by other organizations. With regard to the present application, COGEM accordingly abstains from advice on the potential risks of incidental consumption.

Introduction

The scope of the present application (EFSA/GMO/NL/2009/65) filed by Monsanto Europa S.A. and Dow Agrosciences Europe concerns import and processing of MON89034x1507xNK603 maize. MON89034x1507xNK603 expresses the *cry1A.105, cry2Ab2* and *cry1F* genes, thus conferring resistance to certain lepidopteran insects. In addition, the *cp4 epsps* and *pat* genes are expressed resulting in tolerance to glyphosate and glufosinate-ammonium containing herbicides.

MON89034x1507xNK603 maize was produced by conventional crossbreeding of three genetically modified parental lines. In the United States the individual genetically modified parental lines were authorized for use as food and/or feed in 2000 (NK603), 2001 (1507), and 2007 (MON89034).[1] They were authorized for cultivation in 2000 (NK603), 2001 (1507), and

2008 (MON89034).[1] 1507 and NK603 are in commercial use in e.g. Canada, the United States and Argentina and have a history of safe use.[2] In the EU, the cross between NK603 and 1507 was authorized for import and processing in 2007.[3] The authorization for MON89034 is currently under consideration in the European Union. The EFSA GMO panel considered it unlikely that import and processing of MON89034 would have adverse effects on human or animal health or on the environment.[4]

Previous COGEM advice

COGEM advised positively on import and processing of the three parental maize lines[5,6,7] and on import and processing of the hybrid 1507xNK603.[8] In addition, COGEM advised positively on cultivation of 1507, NK603 and 1507xNK603.[9,10,11]

Aspects of the crop

Maize (*Zea mays* L.) is a member of the grass family Poaceae. Maize is cultivated as an agricultural crop, originating from Central America. Although insect pollination cannot be completely excluded, maize is predominantly wind pollinated.[12,13] According to literature, pollen viability varies between 30 minutes and 9 days.[13,14,15] In Europe, no wild relatives of maize are present and therefore, hybridization with other species cannot occur.

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 the harvest of fodder maize.[12] Establishment of maize plants in the wild has never been observed in the Netherlands.

Molecular characterization

MON89034x1507xNK603 maize was produced by conventional cross-breeding of three genetically modified parental lines. COGEM evaluated the molecular characterization in previous applications concerning import and processing and/or cultivation of these genetically modified parental lines.[5,9,10] In addition, an update of the molecular characterization of 1507 maize was made available by the EFSA GMO panel in the context of the renewal of an application for feed purposes. This includes the analysis of putative open reading frames spanning the insert-genomic DNA junction from stop codon to stop codon. The analysis of these open reading frames from stop codon to stop codon is one of the criteria COGEM has laid down in 2008 for the molecular characterization of genetically modified crops for commercial releases.[16] COGEM is of the opinion that the molecular characterization of all parental lines meet the criteria as laid out by the COGEM.

In addition, the cross between 1507 and NK603 has been authorized for import and processing in the European Union.[3] Furthermore, the molecular characterization of MON89034 was positively assessed by the EFSA GMO Panel.[4]

Properties of the introduced genes conferring herbicide tolerance

MON89034x1507xNK603 maize contains the *pat* gene, encoding the enzyme phosphinothricin acetyltransferase protein (PAT). Expression of PAT confers tolerance to glufosinate-ammonium containing herbicides. The active ingredient in glufosinate-ammonium

is L-phosphinothricin (L-PPT), which binds to glutamine synthetase in plants. The detoxification of excess ammonia is thereby prevented, leading to plant death.[17]

The PAT enzyme, that is produced in MON89034x1507xNK603, catalyses the conversion of L-PPT to an inactive form, which does not bind glutamine synthetase.[18] Therefore, the application of glufosinate-ammonium containing herbicides to MON89034x1507xNK603 will be ineffective.

In addition, MON89034x1507xNK603 expresses the *cp4 epsps* gene, which encodes the CP4 EPSPS protein. EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) is an enzyme involved in the biosynthesis of aromatic amino acids and occurs in plants, fungi and bacteria. Glyphosate inhibits maize EPSPS, resulting in a lack of amino acids essential for growth and development of plants.[19] MON89034x1507xNK603 maize expresses the bacterial CP4 EPSPS protein, which is not inhibited by glyphosate and is therefore tolerant to glyphosate containing herbicides.

Properties of the introduced genes conferring insect resistance

MON89034x1507xNK603 maize contains the *cry1A.105, cry2Ab2,* and *cry1F* genes. Each of these genes encodes a different δ-endotoxin, which is specific for certain lepidopteran insects.

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.[20] As a result MON89034x1507xNK603 is resistant to certain lepidopteran insects, such as the European corn borer *(Ostrinia nubilalis*), the southwestern corn borer (*Diatraea grandiosella*), the corn earworm (*Helicoverpa zea*), fall armyworm (*Spodoptera frugiperda*), the sugarcane borer *(Diatraea saccharalis*) and the black cutworm (*Agrostis ipsilon*).

Environmental risk assessment

The current application of MON89034x1507xNK603 concerns import and processing. In case of spillage maize kernels may be released into the environment. Maize kernels exhibit no dormancy and can only survive within a narrow range of climatic conditions. 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. Furthermore, maize is very sensitive to weed competition and cannot persist as a weed.[21,22] In the Netherlands, volunteers are rarely found and establishment of maize plants in the wild has never been observed.

The introduced traits do not increase the ability of maize kernels to survive in the climatic conditions in the Netherlands. Neither is it expected that interactions between the expressed transgenic proteins will increase this ability. In addition, according to the agronomic assessment of MON89034x1507xNK603 the ecological characteristics of this maize line have not been influenced by the introduced traits.

In view of the above, there are no reasons to assume that the expression of the *cry1A.105, cry2Ab2, cry1F, pat* and *cp4 epsps* genes increases the potential of MON89034x1507xNK603 to establish feral populations in case of incidental spillage.

Recently, COGEM abstains from advices on the potential risks of incidental consumption in case a food/feed safety assessment is already carried out by other organizations. This application is submitted under Regulation (EC) 1829/2003, therefore a food/feed safety assessment is carried out by EFSA. Other organizations who advice the competent authorities can perform an additional assessment on food safety although this is not obligatory. In the Netherlands a food and/or feed safety assessment for Regulation (EC) 1829/2003 applications is carried out by RIKILT. Regarding the risks for food and feed safety, the outcome of the assessment by other organizations (EFSA, RIKILT) was not known at the moment of the completion of this advice.

General surveillance

General surveillance has been introduced to be able to observe unexpected adverse effects of genetically modified crops on the environment. The setting or population in which these effects might occur is either not, or hardly predictable.

The general surveillance plan describes that unanticipated adverse effects will be monitored by existing systems which include the authorization holder and operators involved in the handling and use of viable MON89034x1507xNK603 maize. Although the general surveillance plan could be improved by a guarantee that operators will monitor for unanticipated effects, COGEM considers the general surveillance plan sufficient for import and processing of MON89034x1507xNK603.

Advice

COGEM has been asked to advise on import and processing of MON89034x1507xNK603 maize. MON89034x1507xNK603 was created by conventional crossbreeding of three genetically modified parental lines. In the past, COGEM advised positively on import and processing of all three parental lines.

The molecular characterization of MON89034x1507xNK603 and its individual parental lines meets the criteria of COGEM.

Maize has lost the ability to survive in the wild. In addition, maize needs human intervention to disseminate its seed. In the Netherlands, volunteers are rare and establishment of maize plants in the wild has never been observed. There is no reason to assume that the expression of the *cry1A.105, cry2Ab2, cry1F, pat* and *cp4 epsps* genes or interactions between the transgenic proteins increase the potential of MON89034x1507xNK603 to establish feral populations in case of incidental spillage. In addition, introgression of the introduced genes into closely related species cannot occur, as wild relatives of maize are not present in Europe.

In view of the above, COGEM is of the opinion the risks for humans and the environment associated with import and processing of MON89034x1507xNK603 maize are negligible. A food/feed safety assessment was carried out by other organizations. With regard to the present

application, COGEM accordingly abstains from advice on the potential risks of incidental consumption.

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