Import and processing of genetically modified maize line MON89034x1507xMON88017x 59122

COGEM advice CGM/090428-12

The present application (file EFSA/GMO/CZ/2008/62) concerns import and processing for use in feed and food of the genetically modified maize line MON89034x1507xMON88017x59122. Cultivation is not part of this application.

Maize line MON89034x1507xMON88017x59122 expresses the cry1A.105, cry2Ab2, cry3Bb1, cry34Ab1, cry35Ab1, cry1F, cp4 epsps and pat genes. As a result the maize line is resistant to certain lepidopteran and coleopteran insects. In addition, the maize line is tolerant to glyphosate and glufosinate-ammonium containing herbicides.

Maize line MON89034x1507xMON88017x59122 was produced by crossing the four genetically modified parental maize lines. Previously, COGEM issued positive advices on import and processing of MON89034 and MON88017. In addition, COGEM issued positive advices on import and processing and on cultivation of 1507, 59122 and 1507x59122.

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 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 incidental spillage of MON89034x1507xMON88017x59122 poses negligible risks to the environment. Therefore, COGEM considers the risks associated with import and processing of maize line MON89034x1507xMON88017x 59122 negligible.

Introduction

The scope of the present application (EFSA/GMO/CZ/2008/62) filed by Monsanto Europa S.A. and Dow Agrosciences Europe concerns import and processing of maize line MON89034x1507xMON88017x59122. Maize line MON89034x1507xMON88017x59122 expresses the *cry1A.105, cry2Ab2, cry3Bb1, cry34Ab1, cry35Ab1, cry1F* genes, thus conferring resistance to certain lepidopteran and coleopteran insects. In addition, the *cp4 epsps* and *pat* genes are expressed resulting in tolerance to glyphosate and glufosinate-ammonium containing herbicides.

Maize line MON89034x1507xMON88017x59122 was produced by conventional crossbreeding of the four genetically modified parental maize lines. In the United States of America the individual genetically modified parental maize lines were authorized for use as food and/or feed in 2001 (maize line 1507), 2004 (maize line 59122), 2005 (maize line MON88017) and 2007 (maize line MON89034).[1] They were also authorized for cultivation in 2001 (maize line 1507), 2004 (maize line 59122), 2005 (maize line MON88017) and 2008 (maize line MON89034).[1] In Europe, parental maize lines 1507 and 59122 were authorized for import and processing in respectively 2006 and 2007.[2,3] 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]

The use of genetically modified crops for cultivation is a matter of debate in the European Union. An argument that is often used is that cultivation of genetically modified crops might affect non-target organisms adversely. Recently, Germany banned the cultivation of the only genetically modified maize variety which is currently authorized for cultivation in the European Union (MON810). The discussion on putative effects of the cultivation of genetically modified crops on non-target organisms is not relevant to this application since the current application only concerns import and processing.

Previous COGEM advices

COGEM advised positively on import and processing of the four parental maize lines[5,6,7,8] and on import and processing of the hybrid maize line 1507x59122.[9] COGEM also issued an advice on import and processing of hybrid maize line MON89034xMON88017.[10] COGEM was of the opinion that import and processing of this maize line most likely posed negligible risks to the environment, but could not advice positively because the molecular characterization of MON89034 was incomplete.[11] Recently, COGEM reconsidered the elements of the molecular characterization which are needed for environmental risk analysis and formulated criteria for the molecular characterization of commercial releases of genetically modified crops.[12] In a more recent advice on MON89034 COGEM concluded that the molecular characterization of this maize line fulfils the requirements of COGEM for environmental risk analysis.[5]

COGEM advised positively on cultivation of maize lines 1507, 59122 and 1507x59122.[13,14,15] COGEM also issued an advice on cultivation of MON88017. COGEM was of the opinion that the studies assessing the effect of MON88017 on non-target organisms were insufficient.[16] Therefore, COGEM could not advice positively on cultivation of MON88017.

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.[17,18] According to literature, pollen viability varies between 30 minutes and 9 days.[18,19,20] 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.[17] Establishment of maize plants in the wild has never been observed in the Netherlands.

Molecular characterization

Maize line MON89034x1507xMON88017x59122 was produced by crossing four genetically modified parental maize lines. COGEM evaluated the molecular characterization in previous applications concerning import and processing of the genetically modified parental lines and concluded that the molecular characterization of the individual parental lines was adequate.[5,6,7,8]

In addition, the individual parental lines 1507 and 59122 have already been authorized for import and processing in the European Union.[2,3] The molecular characterization of MON89034 was positively assessed by the EFSA GMO Panel.[4]

Properties of the introduced genes conferring herbicide tolerance

Maize line MON89034x1507xMON88017x59122 contains the *pat* gene, encoding the enzyme phosphinothricin acetyltransferase protein (PAT). Expression of PAT confers tolerance to glufosinate-ammonium containing herbicides.[21]

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.

The PAT enzyme, that is produced in maize line MON89034x1507xMON88017x59122, catalyses the conversion of L-PPT to an inactive form, which does not bind glutamine synthetase. Therefore, the application of glufosinate-ammonium containing herbicides to maize line MON89034x1507xMON88017x59122 will be ineffective.[22]

In addition, maize line MON89034x1507xMON88017x59122 expresses 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 MON89034x1507xMON88017x59122 expresses the CP4 EPSPS protein, which is not inhibited by glyphosate and is therefore tolerant to glyphosate containing herbicides.[23]

Properties of the introduced genes conferring insect resistance

Maize line MON89034x1507xMON88017x59122 contains the *cry1A.105, cry2Ab2, cry3Bb1, cry34Ab1, cry35Ab1, cry1F* genes. Each of these genes encodes a different δ-endotoxin, which is either specific for certain lepidopteran or for certain coleopteran 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.[24] As a result maize line MON89034x1507xMON88017x59122 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*), the black cutworm (*Agrostis ipsilon*) and the western bean cutworm (*Richia albicosta*); and resistant to certain coleopteran insects, such as corn rootworms (*Diabrotica* spp.).

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 can only survive within a narrow range of climatic conditions. Furthermore, maize is very sensitive to weed competition and cannot persist as a weed.[25] 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 the expression of the *cry1A.105, cry2Ab2, cry3Bb1, cry34Ab1, cry35Ab1, cry1F, pat* and *cp4 epsps* genes increased the potential of MON89034x1507xMON88017x59122 to establish feral populations.

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 MON89034x1507xMON88017x59122 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 MON89034x1507xMON88017x59122 maize.

Advice

COGEM has been asked to advice on import and processing of maize line MON89034x1507xMON88017x59122. This maize line expresses the *cry1A.105, cry2Ab2, cry3Bb1, cry34Ab1, cry35Ab1, cry1F* genes, thus conferring resistance to certain lepidopteran and coleopteran insects. In addition, the *cp4 epsps* and *pat* genes are expressed resulting in tolerance to glyphosate and glufosinate-ammonium containing herbicides.

Maize line MON89034x1507xMON88017x59122 was created by conventional crossbreeding of four genetically modified parental maize lines. In the past, COGEM advised positively on import and processing of these four parental maize lines.

Maize has lost the ability to survive in the wild. 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 introduced traits increased the potential of maize MON89034x1507xMON88017x59122 to establish feral populations. 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 that import and processing of maize line MON89034x1507xMON88017x59122 poses a negligible risk to the environment.

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