Import and processing of insect resistant and herbicide tolerant maize MON87427xMON89034x1507xMON88017x59122

COGEM advice CGM/150825-02

Summary

The present application (EFSA/GMO/BE/2013/118) concerns import and processing for use in feed and food of genetically modified maize MON87427xMON89034x1507xMON88017x59122. Cultivation is not part of this application.

Maize MON87427xMON89034x1507xMON88017x59122 expresses the cry1A.105, cry1F, cry2Ab2, cry3Bb1, cry34Ab1, cry35Ab1, cp4 epsps *and* pat *genes. As a result it is resistant to certain lepidopteran and coleopteran insects. In addition, the maize line is tolerant to glyphosate and glufosinate-ammonium containing herbicides.*

MON87427xMON89034x1507xMON88017x59122 was produced by conventional crossbreeding. Previously, COGEM issued positive opinions on import and processing of MON89427, MON89034, 1507, MON88017 and 59122. COGEM also advised positively on cultivation of 1507 and 1507x59122. The molecular characterization of MON87427xMON89034x 1507xMON88017x59122 is updated and 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 will allow maize MON87427xMON89034x1507xMON88017x59122 to establish feral populations. The introduced sequences cannot spread to other species since wild relatives of maize are not present in Europe.

COGEM abstains from giving advice on the potential risks of incidental consumption because a food/feed assessment is already carried out by other organisations. COGEM is of the opinion that incidental spillage of MON87427xMON89034x1507xMON88017x59122 poses a negligible risk to the environment.

In view of the above, COGEM considers the environmental risks associated with import and processing of maize MON87427xMON89034x1507xMON88017x59122 to be negligible.

Introduction

The scope of the present application (EFSA/GMO/BE/2013/118) filed by Monsanto Company concerns import and processing of maize MON87427xMON89034x1507xMON88017x59122. It expresses the *cry1A.105, cry1F, cry2Ab2, cry3Bb1, cry34Ab1 and cry35Ab1* genes conferring resistance to certain lepidopteran and coleopteran insects. In addition, the *cp4 epsps* and *pat* genes are expressed conferring tolerance to glyphosate and glufosinate-ammonium containing herbicides.

Maize MON87427xMON89034x1507xMON88017x59122 was produced by conventional crossbreeding of the genetically modified maize lines MON87427 and MON89034x1507x MON88017x59122. In an overall opinion on import and processing of this maize line EFSA has recently concluded that MON87427 is as safe as its conventional counterpart.[1] Since 2012

MON87427 is authorized for import, processing and cultivation in Canada and the United States.[2] The parental line MON89034x1507xMON88017x59122 has an EU approval for import and processing since 2013.[3] In Japan, Canada and the United States this parental line is authorized for cultivation in 2009.[3]

Previous COGEM advices

COGEM advised positively on import and processing of maize lines MON89427, MON89034, 1507, MON88017 and 59122,[4,5,6,7,8,9] and on import and processing of 59122x1507, MON89034x MON88017 and MON89034x1507xMON88017x59122.[10,11,12] COGEM also advised positively on cultivation of 1507, 59122 and 1507x59122.[13,14,15] COGEM issued advices on cultivation of MON89034 and MON89034xMON88017 but did not finalize its opinions because not all data necessary to assess potential effects on non-target organisms was submitted by the applicant.[16,17]

Aspects of the crop

Maize (*Zea mays* L.) is a member of the grass family *Poaceae*. Maize is a highly domesticated crop, originating from Central America, but nowadays maize is cultivated globally. Maize is predominantly wind pollinated.[18,19] Insect pollination is limited since the female flowers do not produce nectar and are therefore not attractive to insect pollinators.[20] In Europe, no wild relatives of maize are present and thus hybridisation with other species cannot occur.

In the Netherlands, the appearance of volunteers is very rare to absent.[21] Domesticated maize requires warm conditions in order to grow and does not tolerate prolonged cold and frost.[20,22] The seeds (kernels) remain on the cob after ripening and do not shatter naturally.[20,23] In cultivation areas with warmer climatic conditions, the appearance of volunteers can occur the year following maize cultivation due to spilled cobs or kernels. However, these volunteers are usually killed by common mechanical pre-planting soil preparation practices.[20]

Maize is very sensitive to weed competition.[24] During the long process of domestication, maize has lost the ability to survive in the wild.[19] Establishment of maize plants in the wild has never been observed in the Netherlands and COGEM is not aware of any reports of wild maize plants elsewhere in Europe.

Molecular characterization

MON87427xMON89034x1507xMON88017x59122 maize was produced by crossing the two genetically modified parental maize lines MON87427 and MON89034x1507xMON88017x59122. COGEM previously evaluated the molecular characterization of all parental lines and concluded them to be adequate.[4,5,6,7,8,9] The bioinformatic analysis of maize MON87427xMON89034x1507x MON88017x59122 was updated using recent databases. The molecular characterization of MON87427xMON89034x1507xMON88017x59122 meets COGEMs criteria for the molecular characterization of genetically modified crops.[25] The elements that are inserted in MON87427xMON89034x1507xMON88017x59122 are described in the previous opinions on the parental lines.[4,5,6,8,9]

Herbicide tolerance traits

MON87427xMON89034x1507xMON88017x59122 contains two copies of the *cp4 epsps* gene and two copies of the *pat* gene, which encode the CP4 EPSPS and PAT proteins respectively.

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. In contrast to EPSPS, the CP4 EPSPS protein is not inhibited by glyphosate and therefore maize MON87427xMON89034x1507xMON88017x59122 is tolerant to glyphosate containing herbicides.[26]

Expression of PAT confers tolerance to glufosinate-ammonium herbicides.[27] 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 MON87427xMON89034x1507xMON88017x59122 produces PAT which catalyzes the conversion of L-PPT to an inactive form, which does not bind glutamine synthetase, therefore this maize line retains the ability to detoxify ammonia even if glufosinate-ammonium is used.[28]

Insect resistance traits

MON87427xMON89034x1507xMON88017x59122 expresses the *cry1A.105, cry1F, cry2Ab2, cry3Bb1, cry34Ab1 and cry35Ab1* genes. These proteins encode Cry1A.105, Cry1F, Cry2Ab2, Cry3Bb1, and the binary protein pair Cry34Ab1 and Cry35Ab1. When these proteins are ingested by susceptible insects (e.g. the European corn borer and several corn rootworms) they are proteolytically cleaved in the midgut of the insect. The resulting delta-endotoxins bind to specific receptors on the epithelial surface of the midgut, which causes the formation of pores. This leads to disruption of the movement of solutes across the gut epithelium and ultimately in death of the insect.[29,30] As a result maize line MON87427xMON89034x1507xMON88017x59122 is resistant to certain lepidopteran insects, such as the European corn borer (*Ostrinia nubilalis*) and resistant to certain coleopteran insects, such as corn rootworms (*Diabrotica* spp.).

Food/ feed assessment

COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is already carried out by other organisations.[31] This application is submitted under Regulation (EC) 1829/2003, therefore a food/feed assessment is carried out by EFSA and national organisations involved in the assessment of food safety. In the Netherlands, a food/feed assessment for Regulation (EC) 1829/2003 applications is carried out by RIKILT. The outcome of the assessment by these organisations (EFSA, RIKILT) was not known upon the completion of this advice.

Conclusion

COGEM has been asked to advice on the import and processing of genetically modified maize line MON87427xMON89034x1507xMON88017x59122. It expresses the *cry1A.105, cry1F, cry2Ab2, cry3Bb1, cry34Ab1, cry35Ab1, cp4 epsps* and *pat genes*, thus conferring resistance to certain

lepidopteran and coleopteran insects and tolerance to glyphosate and glufosinate-ammonium containing herbicides.

MON87427xMON89034x1507xMON88017x59122 maize was produced by conventional crossbreeding of the genetically modified parental maize lines MON87427 and MON89034x 1507xMON88017x59122. In the past, COGEM advised positively on import and processing of these two parental maize lines and the cultivation of 1507x59122. The molecular characterization of maize MON87427xMON89034x1507xMON88017x59122 was updated and meets the criteria of COGEM.

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. COGEM is of the opinion that the risk of spread of MON87427xMON89034x1507xMON88017x59122 maize within the Netherlands due to spillage of the maize line is negligible. There is no reason to assume that the introduced traits increase the potential of maize MON87427xMON89034x1507x MON88017x59122 to establish feral populations. In addition, introgression of the introduced sequences into closely related species cannot occur, as wild relatives of maize are not present in Europe.

COGEM has published several recommendations for further improvement of the general surveillance (GS) plan[32,33], but considers the current GS plan adequate for import and processing of MON87427xMON89034x1507xMON88017x59122 maize.

In view of the above, COGEM is of the opinion that import and processing of maize line MON87427xMON89034x1507xMON88017x59122 poses a negligible risk to the environment.

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