Import and processing of insect resistant and herbicide tolerant maize MON87427xMON89034xNK603

COGEM advice CGM/150817-01

Summary

The present application (EFSA/GMO/BE/2013/117) concerns import and processing for use in feed and food of genetically modified maize MON87427xMON89034xNK603. Cultivation is not part of this application.

Maize MON87427xMON89034xNK603 expresses the cry1A.105, cry2Ab2, cp4 epsps and cp4 epsps L214P genes. As a result it is resistant to certain lepidopteran insects and tolerant to glyphosate containing herbicides.

MON87427xMON89034xNK603 was produced by conventional crossbreeding. Previously, COGEM issued positive opinions on import and processing of MON87427, MON89034, NK603 and MON89034xNK603. COGEM also advised positively on cultivation of parental line NK603. The molecular characterization of MON87427xMON89034xNK603 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 MON87427xMON89034xNK603 to establish feral populations. The introduced sequences 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 MON87427x MON89034xNK603 poses a negligible risk to the environment. COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is already carried out by other organizations.

In conclusion, COGEM considers the environmental risks associated with import and processing of maize MON87427xMON89034xNK603 to be negligible.

Introduction

The scope of the present application (EFSA/GMO/BE/2013/117) filed by Monsanto Company concerns import, processing and the use for food and feed of maize line MON87427xMON89034x NK603. It expresses the *cry1A.105* and *cry2Ab2* genes conferring resistance to the European corn borer (*Ostrinia nubilalis*) and several other insects of the lepidopteran order. In addition, the *cp4 epsps* and *cp4 epsps L214P* genes are expressed conferring tolerance to glyphosate containing herbicides.

Maize MON87427xMON89034xNK603 was produced by conventional crossbreeding of the genetically modified maize lines MON87427 and MON89034×NK603. EFSA has recently concluded that MON87427 is as safe as its conventional counterpart and finalised its overall opinion on import and processing of this maize line.[1] In 2012 MON87427 is authorized for import, processing and cultivation in Canada and the United States.[2] The parental line MON89034xNK603

has an EU approval for import and processing since 2010.[3] In Argentina, Brazil and South Africa the parental maize line MON89034xNK603 was authorized for cultivation in 2012, 2010 and 2012, respectively.[3]

Previous COGEM advices

COGEM advised positively on import and processing of maize lines MON87427, MON89034 and NK603,[4,5,6] and on import and processing of MON89034xNK603.[7] COGEM also advised positively on cultivation of parental line NK603.[8]

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.[9,10] Insect pollination is limited since the female flowers do not produce nectar and are therefore not attractive to insect pollinators.[11] In Europe, no wild relatives of maize are present and therefore hybridisation with other species cannot occur.

In the Netherlands, the appearance of volunteers is very rare to absent.[12] Domesticated maize requires warm conditions in order to grow and does not tolerate prolonged cold and frost.[11,13] The seeds (kernels) remain on the cob after ripening and do not shatter naturally.[11,14] 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.[11]

Maize is very sensitive to weed competition.[15] During the long process of domestication, maize has lost the ability to survive in the wild.[10] 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

MON87427xMON89034xNK603 maize was produced by conventional crossbreeding of genetically modified maize MON87427 and MON89034×NK603. COGEM previously evaluated the molecular characterization of the parental lines MON87427, MON89034 and NK603 in previous applications and concluded that the molecular characterization of all parental lines is adequate.[4,5,6] The bioinformatic analysis of maize MON87427xMON89034xNK603 was updated using recent databases. The molecular characterization of MON87427xMON89034xNK603 meets the criteria for the molecular characterization of genetically modified crops.[16] The elements that are inserted in MON87427xMON89034xNK603 are described in the previous opinions on the parental lines.[4,5,6]

Herbicide tolerance trait

MON87427xMON89034xNK603 expresses the *cp4 epsps L214P* gene and two copies of the *cp4 epsps* gene, which encode 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. In contrast to EPSPS, the CP4 EPSPS protein is not inhibited by glyphosate and therefore maize MON87427xMON89034xNK603 is tolerant to glyphosate containing herbicides.[17]

Insect resistance traits

MON87427xMON89034xNK603 expresses the *cry1.105* and *cry2Ab2* genes encoding the Cry1.105 and Cry2Ab2 proteins. When these proteins are ingested by susceptible insects (e.g. European corn borer) 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.[18,19]

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.[20] 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 completion of this advice.

Conclusion

COGEM has been asked to advice on the import and processing of genetically modified maize MON87427xMON89034xNK603. It expresses the *cry1A.105*, *cry2Ab2*, *cp4 epsps* and *cp4 epsps L214P* genes, thus conferring resistance to certain lepidopteran insects and tolerance to glyphosate containing herbicides.

MON87427xMON89034xNK603 maize was produced by conventional crossbreeding of the genetically modified parental maize lines MON87427 and MON89034xNK603. In the past, COGEM advised positively on import and processing of these two parental maize lines and cultivation of NK603. The molecular characterization of maize MON87427xMON89034xNK603 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 MON87427xMON89034xNK603 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 MON87427xMON89034xNK603 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[21,22], but considers the current GS plan adequate for import and processing of MON87427x MON89034xNK603 maize.

In view of the above, COGEM is of the opinion that import and processing of maize line MON87427xMON89034xNK603 poses a negligible risk to the environment.

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