Import and processing of insect resistant and herbicide tolerant genetically modified maize 1507xMON810xMIR162xNK603

COGEM advice CGM/160412-01

- The present application (EFSA/GMO/NL/2015/127) concerns import and processing for use in feed and food of genetically modified maize 1507xMON810xMIR162xNK603;
- 1507xMON810xMIR162xNK603 was produced by conventional crossbreeding of the parental GM lines 1507, MON810, MIR162 and NK603;
- COGEM advised positively on import and processing of all four parental lines;
- The GM line expresses the *cry1F*, *cry1Ab*, *vip3Aa20*, *pmi*, *cp4 epsps* and *pat* genes;
- 1507xMON810xMIR162xNK603 is resistant to certain lepidopteran insects, tolerant to glyphosate and glufosinate-ammonium containing herbicides and has the ability to utilize mannose as the primary carbon source;
- The molecular characterization of 1507xMON810xMIR162xNK603 is updated and meets the criteria of COGEM;
- In the Netherlands feral maize populations cannot occur;
- Hybridisation of maize with other species is not possible in the Netherlands;
- The molecular characterization of 1507xMON810xMIR162xNK603 maize is adequate;
- There are no indications that expression of the introduced traits or any combination thereof will alter the fitness of 1507xMON810xMIR162xNK603 maize;
- Import and processing of maize 1507xMON810xMIR162xNK603 poses a negligible risk to the environment in the Netherlands;
- COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is already carried out by other organisations.

1. Introduction

The scope of the present application (EFSA/GMO/NL/2015/127) filed by Pioneer Hi-Bred International, Inc. is import and processing of genetically modified (GM) maize 1507xMON810xMIR162xNK603. It expresses the *cry1F*, *cry1Ab* and *vip3Aa20* genes conferring resistance to certain lepidopteran insects. In addition, the *pat* and *cp4 epsps* proteins are expressed conferring tolerance to glyphosate and glufosinate-ammonium containing herbicides. 1507xMON810xMIR162xNK603 also expresses the *pmi* gene which allows the plant to utilize mannose as the primary carbon source. The *pmi* gene is used as a selection marker.

1507xMON810xMIR162xNK603 maize was produced by conventional crossbreeding of GM maize lines 1507, MON810, MIR162 and NK603. EFSA issued positive opinions on all four parental lines for food and feed uses, import and processing.[1,2,3,4]

The traits of the stacked GM maize will segregate in its progeny, leading to different combinations of traits being present in the kernels (seeds). Therefore, COGEM will assess the risk of 1507xMON810xMIR162xNK603 and all possible subcombinations.

Previous COGEM advices

COGEM advised positively on import and processing of parental lines 1507, MON810, MIR162 and NK603[5,6,7,8] and on import and processing of several crosses including 1507xNK603, NK603xMON810, MON89034x1507xNK603, 1507x59122xMON810xNK603 and Bt11x MIR162x1507xGA21.[9,10,11,12,13] COGEM also advised positively on cultivation of 1507, MON810 and NK603.[14,15,16]

2. Environmental risk assessment

2.1 Aspects of the wild-type crop

Maize (*Zea mays*) 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.[17,18] Insect pollination is limited since the female flowers do not produce nectar and therefore are not attractive to insect pollinators.[19] 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.[20] Domesticated maize requires warm conditions in order to grow and does not tolerate prolonged cold and frost.[19,21] The kernels remain on the cob after ripening and do not shatter naturally.[19,22] 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.[19]

Maize is very sensitive to weed competition.[23] During the long process of domestication, maize has lost the ability to survive in the wild.[18] Establishment of maize plants in the wild has never been observed in the Netherlands and COGEM is not aware of any reports of feral maize populations elsewhere in Europe.

Conclusion: In the Netherlands feral maize populations cannot occur. Hybridisation of maize with other species is not possible in the Netherlands.

2.2 Description of the introduced genes and traits

1507xMON810xMIR162xNK603 maize was produced by conventional crossbreeding of GM maize lines 1507, MON810, MIR162 and NK603. COGEM previously evaluated the molecular characterization of all parental lines and considered them to be adequate.[5,7,8,15] The bioinformatic

analyses were updated using recent databases. COGEM is of the opinion that the molecular characterization of 1507xMON810xMIR162xNK603 is adequate.

Introduced genes	Encoded protein	Trait
cry1F	Cry1F δ-endotoxin originating from *Bacillus thuringiensis* subsp. *aizawai*[12]	Lepidopteran insect resistance
cry1Ab	Cry1Ab δ-endotoxin originating from *B. thuringiensis* subsp. *kurstaki*[12]	Lepidopteran insect resistance
vip3Aa20	Vegetative insecticidal protein (vip3Aa variant) originating from *B. thuringiensis* strain AB88[7]	Lepidopteran insect resistance
cp4 epsps	Herbicide tolerant form of 5-enolpyruvulshikimate-3-phosphate synthase (EPSPS) enzyme originating from *Agrobacterium tumefaciens* strain CP4[12]	Tolerance to glyphosate containing herbicides
pat	Phosphinothricin N-acetyltransferase (PAT) enzyme originating from *Streptomyces viridochromogenes* strain Tü 494[12]	Tolerance to glufosinate-ammonium herbicides
pmi	Phosphomannose Isomerase (PMI) enzyme originating from *Escherichia coli* strain K-12[7]	Metabolizes mannose and allows for easy recovery of transformed plants
For a detailed description of the introduced genes and traits, see references.		

Conclusion: The molecular characterization of 1507xMON810xMIR162xNK603 maize is adequate. There are no indications that expression of the introduced traits or any combination thereof will alter the fitness of 1507xMON810xMIR162xNK603 maize.

2.3 Food/feed assessment

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 and/or feed assessment for Regulation (EC) 1829/2003 applications is carried out by RIKILT. The outcome of the assessment by other organisations (EFSA, RIKILT) was not known when this advice was completed.

3. General Surveillance

COGEM has published several recommendations for further improvement of the general surveillance (GS) plan[24,25] but considers the current GS plan adequate for import and processing of 1507xMON810xMIR162xNK603.

4. Overall conclusion

Import and processing of maize 1507xMON810xMIR162xNK603 including subcombinations that might be present in the kernels poses a negligible risk to the environment in the Netherlands. COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is already carried out by other organisations.

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