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KENMERK CGM/160824-01
ONDERWERP Advies import en verwerking van genetisch gemodificeerde maïs
MON87427xMON89034xMIR162xNK603

Geachte mevrouw Dijkma,

Naar aanleiding van een adviesvraag (EFSA/GMO/NL/2016/131) betreffende een vergunningaanvraag voor de import en verwerking van genetisch gemodificeerde maïs MON87427xMON89034xMIR162xNK603, ingediend door Monsanto Europe S.A., deelt de COGEM u het volgende mee.

Samenvatting:

De COGEM is gevraagd te adviseren over de mogelijke milieurisico's van import en verwerking van de genetisch gemodificeerde (gg-) maïslijn MON87427xMON89034xMIR162xNK603. In deze lijn komen de genen *cp4 epsps* en *cp4 epsps L214P* tot expressie, waardoor het gewas tolerant is voor herbiciden die glyfosaat bevatten. Ook komen de *cry1A.105*, *cry2Ab2* en *vip3Aa20* genen tot expressie in deze lijn, waardoor het gewas resistent is tegen plaaginsecten die behoren tot de vlinderachtigen.

De maïslijn MON87427xMON89034xMIR162xNK603 is tot stand gekomen door kruising van vier gg-ouderlijnen. De COGEM heeft eerder positief geadviseerd over alle vier de gg-ouderlijnen.

Verwildering van maïsplanten is in Nederland nooit waargenomen. Daarnaast worden planten uit gemorst zaad (opslag) hier nauwelijks aangetroffen. De moleculaire karakterisering van MON87427xMON89034xMIR162xNK603 is geactualiseerd. Er zijn geen redenen om aan te nemen dat expressie van de ingebrachte genen ervoor zorgt dat de gg-maïs zou kunnen verwilderen. Bovendien zijn er in Europa geen wilde verwanten van maïs aanwezig, waardoor de ingebrachte sequenties zich niet naar andere soorten kunnen verspreiden.

Gezien het bovenstaande acht de COGEM de milieurisico's van de import en verwerking van de gg-maïslijn MON87427xMON89034xMIR162xNK603 verwaarloosbaar klein. Omdat een voedselveiligheidsbeoordeling door andere instanties wordt uitgevoerd, heeft de COGEM bij deze vergunningaanvraag de risico's van incidentele consumptie niet beoordeeld.



De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,

Prof. dr. ing. Sybe Schaap
Voorzitter COGEM

c.c. Drs. H.P. de Wijs, Hoofd Bureau ggo
 Mr. J.K.B.H. Kwisthout, Ministerie van IenM

Import and processing of genetically modified maize MON87427xMON89034xMIR162xNK603

COGEM advice CGM/160824-01

- The present application (EFSA/GMO/NL/2016/131) concerns import and processing of genetically modified (GM) maize MON87427xMON89034xMIR162xNK603, for the use in feed and food;
- MON87427xMON89034xMIR162xNK603 was produced by conventional crossbreeding of the parental GM lines MON87427, MON89034, MIR162 and NK603;
- COGEM advised positively on the import and processing of all four parental lines;
- Maize MON87427xMON89034xMIR162xNK603 expresses the genes *cp4 epsps*, *cp4 epsps L214P*, *pmi*, *cry1A.105*, *cry2Ab2* and *vip3Aa20*;
- MON87427xMON89034xMIR162xNK603 is resistant to certain lepidopteran insects and is tolerant to glyphosate containing herbicides;
- The molecular characterization of MON87427xMON89034xMIR162xNK603 has been updated;
- In the Netherlands, feral maize populations do not occur;
- Hybridisation of maize with other species is not possible in the Netherlands;
- Import and processing of GM maize MON87427xMON89034xMIR162xNK603 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 carried out by other organisations.

1. Introduction

The present application (EFSA/GMO/NL/2016/131) filed by Monsanto Europe S.A. concerns import and processing of MON87427xMON89034xMIR162xNK603 maize. This maize line was produced by conventional crossbreeding of four genetically modified (GM) parental maize lines and contains four inserts. It is tolerant to glyphosate containing herbicides (due to the expression of the *cp4 epsps* and *cp4 epsps L214P* genes), and resistant to certain lepidopteran insects (due to the expression of the *cry1A.105*, *cry2Ab2* and *vip3Aa20* genes). In addition, it expresses the *pmi* gene enabling transformed plant cells to use mannose as a sole carbon source, which is used as a selection marker in the transformation process.

EFSA adopted positive opinions on import and processing of MON89034xNK603 and each of the parental maize lines.^{1,2,3,4,5} These maize lines have been authorised for import and processing in the European Union.^{6,7,8,9,10}

Previous COGEM advices

COGEM has advised previously on import and processing of the parental lines MON87427, MON89034, MIR162 and NK603 and combinations thereof.^{11,12,13,14,15,16,17,18} The environmental

risks of import and processing were considered negligible.^{11,12,14,15,16,18} In addition, COGEM has previously concluded that the environmental risks of cultivation of NK603 maize are negligible.¹⁹

2. Environmental risk assessment

MON87427xMON89034xMIR162xNK603 maize contains four inserts. These inserts may segregate in the progeny of the GM maize line. As a result, the imported kernels (seeds) of this GM maize line may possess all traits that are present in MON87427xMON89034xMIR162xNK603 or a combination thereof. Potential risks of MON87427xMON89034xMIR162xNK603 maize kernels will be assessed as part of the environmental risk assessment of MON87427xMON89034xMIR162xNK603.

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 it is cultivated globally. Maize is predominantly wind pollinated.^{20,21} Insect pollination is limited since the female flowers do not produce nectar and are therefore not attractive to insect pollinators.²² 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.²³ Domesticated maize requires warm conditions in order to grow and does not tolerate prolonged cold and frost.^{22,24} The kernels remain on the cob after ripening and do not shatter naturally.^{22,25} In cultivation areas with warm 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.²²

Maize is very sensitive to weed competition.²⁶ During the long process of domestication, maize has lost the ability to survive in the wild.²¹ Establishment of maize plants in the wild has never been observed in the Netherlands and COGEM is not aware of any reports on feral maize populations elsewhere in Europe.

Conclusion: In the Netherlands, feral maize populations do not occur and hybridisation of maize with other species is not possible.

2.2 Description of the introduced genes and traits

Introduced gene	Encoded protein	Trait
<i>cp4 epsps</i> (two copies)	The 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme originating from <i>Agrobacterium tumefaciens</i> strain CP4 ¹⁹	Tolerance to glyphosate containing herbicides, because of a decreased binding affinity for glyphosate
<i>cp4 epsps L214P</i>	A variant of the EPSPS enzyme from <i>A. tumefaciens</i> strain CP4 ¹⁹	Tolerance to glyphosate containing herbicides, because of a decreased binding affinity for

		glyphosate
<i>cry1A.105</i>	The Cry1A.105 protein is a chimeric protein with domains from different Cry1 proteins from <i>Bacillus thuringiensis</i> . It consists of domains I and II from Cry1Ab/Cry1Ac, a variant of domain III from Cry1F and substantially the entire C terminal domain from Cry1Ac ¹³	Tolerance to certain lepidopteran insects ¹⁶
<i>cry2Ab2</i>	Variant of the Cry2Aa protein from <i>B. thuringiensis</i> var. <i>kurstaki</i> ³	Tolerance to certain lepidopteran insects ¹⁶
<i>vip3Aa20</i>	A modified version of the <i>vip3Aa1</i> gene from <i>B. thuringiensis</i> strain AB88 ¹²	Tolerance to certain lepidopteran insects ¹²
<i>pmi</i>	The phosphomannose isomerase (PMI) enzyme derived from <i>Escherichia coli</i> ¹²	Enables transformed plant cells to use mannose as a sole carbon source ¹²
For a detailed description of the traits see references.		

2.3 Molecular characterisation

Previously, COGEM evaluated the molecular characterisation of each parental line and considered these to be adequate.^{11,12,14,15} The applicant updated the bio-informatic analyses of the junctions of the inserts with maize genomic DNA and included bio-informatic analyses of *in silico* translations of the different T-DNAs in all six reading frames. According to the applicant, no biologically relevant similarities with allergens, toxins or biologically active proteins were observed in these analyses.

In addition, the applicant performed bio-informatic analyses to assess whether coding sequences or regulatory elements were disrupted by the insertion of the inserts in the parental lines. According to the applicant, it is unlikely that open reading frames at or in the flanking genomic DNA of the insertion sites were disrupted.

The molecular characterisation was conducted according to the criteria previously laid down by COGEM.²⁷

2.4 Food/feed assessment

COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is carried out by EFSA and other national organizations.²⁸ The present application is submitted in the Netherlands under Regulation (EC) 1829/2003, therefore the food and/or feed assessment is carried out by RIKILT. The outcome of the assessment by other organizations (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,^{29,30} but considers the current GS plan adequate for the import and processing of MON87427xMON89034xMIR162xNK603.

4. Overall conclusion

Import and processing of MON87427xMON89034xMIR162xNK603 maize kernels that may possess all or a subcombination of its traits, 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 and/or feed assessment is carried out by other organisations.

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