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KENMERK CGM/170731-02
ONDERWERP Advies hernieuwing vergunning voor import en verwerking van de gg-maïslijn
1507xNK603

Geachte mevrouw Dijkma,

Naar aanleiding van een adviesvraag betreffende een hernieuwing van de vergunning voor import en verwerking van genetisch gemodificeerde maïs 1507xNK603 (EFSA/GMO/RX/008), ingediend door Pioneer Hi-Bred Int. en Dow AgroScience LLC, deelt de COGEM u het volgende mee.

Samenvatting:

De COGEM is gevraagd om te adviseren over de hernieuwing van de vergunning voor import en verwerking van de genetisch gemodificeerde (gg-) maïslijn 1507xNK603. De eerdere vergunning is in 2007 voor een periode van 10 jaar afgegeven. De COGEM heeft eerder positief geadviseerd over de import en verwerking (2005), en teelt (2006) van deze kruisingslijn. Maïslijn 1507xNK603 produceert de eiwitten CP4 EPSPS en PAT waardoor de plant tolerant is voor herbiciden met als werkzame stof glyfosaat of glufosinaat-ammonium. Daarnaast produceert de maïslijn het Cry1F eiwit, waardoor de plant resistent is voor bepaalde vlinderachtigen.

De hernieuwingsaanvraag bevat onder meer geactualiseerde bioinformatische analyses, een recente literatuurreview en de resultaten van de verplichte 'post-market environmental monitoring' die sinds 2008 is uitgevoerd.

Verwildering van maïsplanten is in Nederland nooit waargenomen. Maïsplanten uit gemorst zaad (opslagplanten) worden hier nauwelijks aangetroffen. Bovendien zijn er in Nederland geen wilde verwanten van maïs aanwezig, waardoor de ingebrachte sequenties zich niet naar andere soorten kunnen verspreiden.

De geactualiseerde bioinformatische analyses van maïslijn 1507xNK603 voldoen aan de criteria van de COGEM. Uit de geactualiseerde bioinformatische analyses, literatuurstudie en de monitoringsrapporten zijn geen nieuwe inzichten over mogelijke risico's voor mens en milieu naar voren gekomen.

Concluderend acht de COGEM de risico's van import en verwerking van gg-maïs 1507xNK603 voor mens en milieu 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
 Ing. M.A.C. Möllers, Food-Feed loket

Renewal of the authorisation for import and processing of genetically modified 1507xNK603 maize

COGEM advice CGM/170731-02

- The present application (EFSA/GMO/RX/008) concerns the renewal of the authorisation for import and processing for use in feed and food of genetically modified 1507xNK603 maize;
- Maize 1507xNK603 has previously been authorised for import and processing in 2007;
- COGEM has advised positively on the import and processing (2005), and on the cultivation (2006) of 1507xNK603;

- Maize 1507xNK603 produces the CP4 EPSPS and PAT proteins conferring tolerance to glyphosate and glufosinate-ammonium containing herbicides, and the Cry1F protein conferring resistance to certain lepidopteran insects;
- In the Netherlands, feral maize populations have never been observed and the appearance of volunteers is rare;
- In the Netherlands, wild relatives of maize have never been observed and hybridisation of maize with other species is therefore not possible;

- The updated bioinformatic analyses of 1507xNK603 maize meet the criteria of COGEM;
- There are no indications that the introduced traits alter the fitness of 1507xNK603 maize;
- The updated bioinformatic analyses, literature review and monitoring reports do not give any indication of a potential environmental risk;

- COGEM is of the opinion that import and processing of 1507xNK603 maize 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/RX/008), filed by Pioneer Hi-Bred Int. and Dow AgroScience LLC, concerns the renewal of the authorisation for import and processing of the genetically modified (GM) 1507xNK603 maize for use in feed and food. Maize 1507xNK603 contains the *cry1F*, *cp4 epsps* and *pat* genes, conferring insect resistance and herbicide tolerance to the crop. Maize 1507xNK603 has been authorised for import, food, feed and processing in Europe on October 24th in 2007 (2007/703/EC).¹ In 2006, EFSA issued a positive opinion on the import and processing of maize line 1507xNK603.² Since import and processing authorisations remain valid for a period of 10 years, the applicant filed an application for the renewal of the authorisation

for import and processing. The application contains amongst others monitoring reports, updated molecular characterisation and an updated literature search.

2. Previous COGEM advices

COGEM advised positively on import, processing and cultivation of both parental lines 1507 and NK603.^{3,4,5,6,7} COGEM also advised positively on the import and processing (2005), and on the cultivation (2006) of 1507xNK603.^{8,9} In addition, COGEM advised positively on the import and processing of several stacked lines containing 1507 and NK603, including 59122x1507xNK603, MON89034x1507xNK603, 1507x59122xMON810xNK603 and 1507xMON810xMIR162xNK603.^{10,11,12,13}

3. Environmental risk assessment

3.1 Aspects of the wild-type crop

Maize (*Zea mays*) is a member of the grass family *Poaceae*. It is a highly domesticated crop originating from Central America, but nowadays cultivated globally. Maize is wind pollinated,^{14,15} and has both male and female flowers that are spatially separated. Female flowers are not attractive to insect pollinators, because they do not produce nectar. Insect pollination of maize is probably highly limited but cannot be excluded.¹⁶

In the Netherlands, no wild relatives of maize are present and hybridisation with other species cannot occur. Maize requires warm conditions in order to grow and does not tolerate prolonged cold and frost.^{16,17} 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.¹⁶

Maize is very sensitive to weed competition.¹⁸ During the long process of domestication, maize has lost the ability to persist in the wild.¹⁵ A soil seed bank, small seeds, and an extended period of flowering and seed production are characteristics often observed in persistent weeds.¹⁹ Maize lacks all these characteristics. After ripening, the seeds (the kernels) adhere to the cob and do not shatter naturally.^{16,20} Consequently, seed dispersal is severely hampered.

During field observations in Austria some volunteers and maize plants were observed in non-agricultural habitats.²¹ In the Netherlands, the appearance of volunteers is very rare, however, maize plants occasionally have been observed outside agricultural fields.²² COGEM is not aware of any reports of feral maize populations in the Netherlands or elsewhere in Europe.

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

3.2 Description of the introduced genes and traits

Maize 1507xNK603 was produced by conventional crossbreeding of the GM maize lines 1507 and NK603.

Introduced genes	Encoded proteins (enzymes)	Traits
<i>cry1F</i>	The Cry1F protein originating from <i>Bacillus thuringiensis</i> subsp. <i>Aizawa</i> ^{3,5,23}	Resistance to certain lepidopteran insects
<i>cp4 epsps</i>	The 5-enolpyruvulshikimate-3-phosphate synthase (EPSPS) enzyme originating from <i>Agrobacterium tumefaciens</i> strain CP4 ^{6,24}	Tolerance to glyphosate containing herbicides
<i>pat</i>	The phosphinothricin N-acetyltransferase (PAT) enzyme originating from <i>Streptomyces viridochromogenes</i> strain Tü 494 ^{3,5,25,26}	Tolerance to glufosinate-ammonium containing herbicides
For a detailed description of the introduced genes and traits, see references		

3.3 Updated bioinformatics analyses

The updated molecular characterisation confirmed that no endogenous maize genes were disrupted by the T-DNA insertion. The bioinformatics analyses were updated using recent databases. COGEM is of the opinion that the molecular characterisation of 1507xNK603 has been performed correctly and meets the requirements of COGEM.²⁷

Conclusion: The molecular characterisation of 1507xNK603 maize is adequate and no indications for potential environmental risks are identified.

3.4 Systematic literature search

The applicant performed a systematic review of literature relevant to the scope of the authorisation. None of the retrieved articles indicated any potential adverse effects on human and animal health.

Conclusion: The systematic literature search does not give any indication of potential environmental risks of 1507xNK603 associated with import and processing.

3.5 Annual monitoring reports

The applicant supplied annual monitoring reports carried out between December 2008 and October 2016. Monitoring was performed by operators involved in the import, handling and processing of 1507xNK603 maize; i.e., COCERAL, UNISTOCK and FEDIOL. Also, as part of the monitoring, the applicant performed a yearly review of scientific publications to monitor the safety of 1507xNK603 maize. The publications that are retrieved during the yearly review are identical to the results of the systematic literature review and have already been covered in section 3.4.

Conclusion: Annual monitoring reports give no indication of adverse effects or incidents resulting from import and/or processing of 1507xNK603 maize.

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

5. Post-market environmental monitoring (PMEM)

The applicant supplied a new post-market environmental monitoring (PMEM) plan. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan^{28,29} but considers the current GS plan adequate for import and processing of 1507xNK603 maize.

6. Overall conclusion

There are no indications that expression of the introduced traits or any combination thereof will alter the fitness of 1507xNK603 maize. COGEM is of the opinion that import and processing of maize 1507xNK603 poses a negligible risk to the environment in the Netherlands. COGEM abstains from giving advice on the potential risks of incidental consumption since other organisations carry out a food/feed assessment.

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