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KENMERK CGM/170628-01

ONDERWERP Advies hernieuwing vergunning voor import en verwerking van de gg-maïslijn NK603xMON810

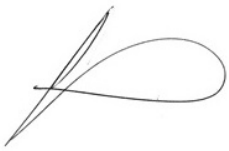
Geachte mevrouw Dijksma,

Naar aanleiding van een adviesvraag betreffende een hernieuwing van de vergunning voor import en verwerking van genetisch gemodificeerde maïs NK603xMON810 (EFSA/GMO/RX/007), ingediend door Monsanto Europe S.A., 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 NK603xMON810. De eerdere vergunning is in 2007 voor een periode van 10 jaar afgegeven. De COGEM heeft eerder positief geadviseerd over de import en verwerking (2004), en teelt (2007) van deze gg-maïslijn.
De maïslijn produceert de eiwitten CP4 EPSPS en CP4 EPSPS L214P waardoor de plant tolerant is voor herbiciden met als werkzame stof glyfosaat. Daarnaast bevat de maïslijn het gen *cry1Ab*, waardoor de plant resistent is voor bepaalde insecten.
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 moleculaire karakterisering van NK603xMON810 en geactualiseerde bioinformatische analyses 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 NK603xMON810 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,



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Voorzitter COGEM

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Renewal of the authorisation for import and processing of genetically modified NK603xMON810 maize

COGEM advice CGM/170628-01

- The present application (EFSA/GMO/RX/007) concerns the renewal of the authorisation for import and processing for use in feed and food of genetically modified NK603xMON810 maize;
- Maize NK603xMON810 has been authorised for import and processing in 2007;
- COGEM has previously advised positively on the import and processing (2004), and on the cultivation (2007) of NK603xMON810;

- Maize NK603xMON810 produces the CP4 EPSPS and CP4 EPSPS L214P proteins conferring tolerance to glyphosate containing herbicides, and the *cry1Ab* gene 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 molecular characterisation and updated bioinformatic analyses of NK603xMON810 maize meet the criteria of COGEM;
- There are no indications that the introduced traits alter the fitness of NK603xMON810 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 NK603xMON810 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/007), filed by Monsanto Europe S.A., concerns the renewal of the consent for import and processing of the genetically modified (GM) NK603xMON810 maize for use in feed and food. Maize NK603xMON810 contains the *cry1Ab, cp4 epsps* and *cp4 epsps L214P* genes, conferring insect resistance and herbicide tolerance to the crop. Maize NK603xMON810 has been authorised for import, food, feed and processing in Europe on October 24th in 2007 (2007/701/EC).[1] 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, an updated bioinformatic analyses and an updated literature search.

2. Previous COGEM advices

COGEM advised positively on import, processing and cultivation of both parental lines NK603 and MON810.[2,3,4,5,6] COGEM has also advised positively on the import and processing (2004), and on the cultivation (2007) of NK603xMON810.[7,8] COGEM furthermore advised positively on the import and processing of several stacked lines including 1507xNK603, MON89034x1507xNK603, 1507x59122xMON810xNK603 and 1507xMON810xMIR162xNK603.[9,10,11,12]

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,[13,14] 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.[15]

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.[15,16] 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.[15]

Maize is very sensitive to weed competition.[17] During the long process of domestication, maize has lost the ability to persist in the wild.[14] A soil seed bank, small seeds, and an extended period of flowering and seed production are characteristics often observed in persistent weeds.[18] Maize lacks all these characteristics. After ripening, the seeds (the kernels) adhere to the cob and do not shatter naturally.[15,19] Consequently, seed dispersal is severely hampered.

During field observations in Austria some volunteers and maize plants were observed in non-agricultural habitats.[20] In the Netherlands, the appearance of volunteers is very rare, however, maize plants occasionally have been observed outside agricultural fields.[21] COGEM is not aware of any reports of feral maize populations in the Netherlands or elsewhere in Europe.

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

3.2 Description of the introduced genes and traits

NK603xMON810 maize was produced by conventional crossbreeding of the GM maize lines NK603 and MON810.

Introduced genes	Encoded proteins (enzymes)	Traits
cry1Ab	Cry1Ab δ-endotoxin originating from *B. thuringiensis* subsp. *kurstaki*[22,23]	Insect resistance against lepidopteran pest species.
cp4 epsps	The 5-enolpyruvulshikimate-3-phosphate synthase (EPSPS) enzyme originating from *Agrobacterium tumefaciens* strain CP4[24]	Tolerance to glyphosate containing herbicides
cp4 epsps L214P	A variant of the EPSPS enzyme from *A. tumefaciens* strain CP4[24]	Tolerance to glyphosate containing herbicides
See references for a detailed description of the traits		

3.3 Updated bioinformatics analyses

For each parental line, the applicant updated the bioinformatic analyses of the inserted elements spanning the insertion sites and junctions of the 5' and 3' flanking regions using recent databases. According to the applicant, no essential endogenous genes were disrupted at the insertion site, and the putative reading frames did not generate any protein sequence similarity with known allergens, toxins or other biologically active proteins. COGEM is of the opinion that the molecular characterisation of NK603xMON810 has been performed correctly and meets the requirements of COGEM.[7,25] The results from the updated bioinformatic analyses do not provide indications that NK603xMON810 could pose a risk to the environment.

Conclusion: The molecular characterisation of NK603xMON810 maize is adequate and no indications for potential environmental risks were identified.

3.4 Systemic literature search

The applicant performed a literature search using two different bibliographic databases, covering publications published from 2007 to 2016. The search identified 21 references from the Web of Science™ Core Collection database, and 25 from the CABI CAB Abstracts® database. None of the retrieved articles indicated any potential adverse effects on human and animal health.

According to Article 23 under the Regulation (EC) No 1829/2003 the applicant is obliged to provide all new information that has become available with regard to the evaluation of the safety in the use of feed and risks of feed to animals, humans and the environment. The systemic literature search performed by the applicant focussed on food and feed aspects and does not provide information on potential environmental risks associated with import of NK603xMON810 maize. This information is included in the annual monitoring reports. COGEM is of the opinion that the systemic literature search can be improved by inclusion of literature on environmental risks associated with NK603xMON810 import and processing.

Conclusion: The systemic literature search did not include literature on potential environmental risks of NK603xMON810. It can be improved by including literature on potential environmental risks associated with NK603xMON810 maize import and processing.

3.5 Annual monitoring reports

The applicant supplied annual monitoring reports carried out between December 2008 and October 2015. Monitoring was performed by operators involved in the import, handling and processing of NK603xMON810 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 NK603xMON810 maize. The monitoring reports and the scientific publications contained no reports on adverse effects or incidents.

Conclusion: Annual monitoring reports give no indication of adverse effects or incidents resulting from import and/or processing of NK603xMON810 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 proposes to discontinue the PMEM efforts for NK603xMON810 maize. According to Directive 2001/18, PMEM is required also in case of a renewal application, but the original monitoring plan can be adjusted. COGEM notes that NK603xMON810 has been imported in the EU since 2007 and that no adverse effects on the environment have been reported. Therefore, it appears proportional and justified to reduce the monitoring requirements. However, the minimal requirements have not been defined. COGEM recommends to initiate a discussion by all parties involved, including the risk assessors of the member states, on the question whether and how the monitoring requirements can be adjusted in the case of renewal applications if 10 years of post-market monitoring has not revealed any harmful effects to the environment. Such a discussion should aim for a broad consensus on the minimal requirements for PMEM in the case of substantial evidence collected over many years on the absence of unexpected environmental effects.

6. Overall conclusion

There are no indications that expression of the introduced traits will alter the fitness of maize NK603xMON810. COGEM is of the opinion that import and processing of maize NK603xMON810 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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