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DATUM 12 augustus 2024
KENMERK CGM/240812-01
ONDERWERP Advies hernieuwing van de importvergunning voor gg-mais NK603

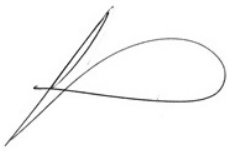
Geachte heer Jansen,

Naar aanleiding van een aanvraag voor een hernieuwing van de vergunning voor import en verwerking van genetisch gemodificeerde (gg-)maïs NK603 (GMFF-2023-21250), ingediend door Bayer Agriculture BV, namens Bayer CropScience LP, deelt de COGEM u het volgende mee.

Samenvatting:
De COGEM is gevraagd te adviseren over de hernieuwing van de in 2015 afgegeven vergunning voor import en verwerking van genetisch gemodificeerde (gg-)maïs NK603. Deze maïslijn brengt het *cp4 epsps* gen en het *cp4 epsps L214P* gen tot expressie waardoor het tolerant is voor glyfosaat bevattende herbiciden.
De aanvraag bevat o.a. geactualiseerde bio-informatica analyses, een recente literatuurstudie en de resultaten van de verplichte 'post-market environmental monitoring'. Hierin staan geen aanwijzingen dat import en verwerking van NK603 maïs een milieurisico zou kunnen veroorzaken. Het is onwaarschijnlijk dat gg-maïsplanten zich in Nederland kunnen vestigen, omdat verwildering van maïsplanten in Nederland nooit is waargenomen. Bovendien komt de wilde verwant van maïs, teosinte, niet in de natuurlijke omgeving in Nederland voor, waardoor de kans dat de ingebrachte genetische eigenschappen zich naar een andere soort kunnen verspreiden, te verwaarlozen is. De COGEM is van oordeel dat de risico's voor mens en milieu bij import en verwerking van gg-maïs NK603 verwaarloosbaar klein zijn. Omdat een voedselveiligheidsbeoordeling door andere instanties wordt uitgevoerd, heeft de COGEM 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. Y. de Keulenaar, Hoofd Bureau ggo
- Ministerie van IenW, Directie Omgevingsveiligheid en milieurisico's, DG Milieu en Internationaal
- Ing. M.A.C. Möllers, Food-Feed loket

Renewal of the authorisation for import and processing of genetically modified maize NK603

COGEM advice CGM/240812-01

- The present application (GMFF-2023-21250) concerns the renewal of the authorisation for import and processing for use in feed and food of genetically modified (GM) maize NK603;
- NK603 was previously authorised for import and processing in 2015;

- NK603 expresses the *cp4 epsps* and *cp4 epsps L214P* genes, conferring tolerance to glyphosate containing herbicides;

- In the Netherlands, feral maize populations have never been observed and the appearance of volunteers – maize not deliberately planted – is rare;
- In the Netherlands, the wild relative of maize (teosinte) is not present in nature, therefore hybridisation of GM maize with other species is not possible;

- The molecular characterisation of NK603 has been updated and meets the criteria of COGEM;
- The updated bioinformatic analyses, the literature review and post-market environmental monitoring reports do not provide indications that import of NK603 poses a risk to the environment;

- COGEM is of the opinion that import and processing of maize NK603 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.

1. Introduction

The present application (GMFF-2023-21250) is filed by Bayer Agriculture BV, on behalf of Bayer CropScience LP, and concerns the renewal of the authorisation for food, feed, import and processing of genetically modified (GM) maize NK603, which was granted in 2015.[1] Since market authorisations remain valid for a period of 10 years, the authorisation holder filed an application for a renewal of the authorisation. This application contains, amongst others, monitoring reports, updated bioinformatic analyses, and a systematic literature search.

GM maize NK603 was developed through microparticle bombardment-mediated transformation of maize tissues and expresses the *cp4 epsps* gene and the *cp4 epsps L214P* gene. The resulting proteins CP4 EPSPS and CP4 EPSPS L214P differ one amino acid on position 214 and are functionally equivalent. GM maize NK603 is tolerant to glyphosate containing herbicides.

2. Previous COGEM Advice

In 2003, COGEM advised on import and processing of NK603 maize and concluded that it poses a negligible risk to the environment.[2] In 2006, COGEM was requested to advise on the cultivation of NK603. COGEM considered the environmental risks of cultivation of this event negligible.[3] The application for the cultivation of NK603 was later withdrawn, and was therefore not authorised. Additionally, COGEM advised positively on the import and processing of several stacked events containing NK603.[e.g.4,5,6,7,8,9,10.]

3. Environmental risk assessment

The objective of an environmental risk assessment (ERA) is to identify and evaluate potential adverse effects of the genetically modified organism (GMO), direct or indirect, immediate or delayed, on human health and the environment. This ERA involves the import and processing of GM maize. Any concerns relating to cultivation, management or harvesting practices are beyond the scope of this advice. When assessing the environmental risk of incidental spillage of GM maize COGEM first considers the likelihood that the event could establish itself in the Netherlands or could hybridise with related species. Other so-called 'areas of concern' (e.g. effects on non-target organisms) are addressed only if there is a chance that the event could establish itself or if gene flow to other species might occur.

3.1 Characteristics of the crop

Maize (*Zea mays*) is a member of the grass family *Poaceae*. It is a highly domesticated crop, originating from Central America, and nowadays cultivated globally. Maize is wind pollinated[11,12] and has both male and female flowers that are spatially separated. The female flowers are not attractive to insect pollinators, because they do not produce nectar. Insect pollination of maize is highly limited but cannot be excluded.[13] Hybridisation of GM maize with other species than teosinte, the wild relative of maize, cannot occur.

Maize does not tolerate prolonged cold and frost,[14] and requires warm conditions in order to grow.[13,15] In cultivation areas with warm climatic conditions, volunteers – i.e. maize not deliberately planted – may be present 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.[13]

Maize is very sensitive to weed competition.[16] During the long process of domestication, maize has lost the ability to persist in the wild.[12] A soil seed bank, small seeds, and an extended period of flowering and seed production are characteristics often observed in persistent weeds.[17] Maize lacks all these characteristics. After ripening, the seeds (the kernels) adhere to the cob and do not scatter naturally.[13,18] Consequently, seed dispersal is severely hampered.

3.2 Receiving environment

In the Netherlands, the appearance of maize volunteers is rare, although maize plants occasionally have been observed outside agricultural fields.[19,20] Any volunteers emerging will be killed by frost at the onset of winter.[14] COGEM is not aware of any reports of feral maize populations in the Netherlands. Maize can hybridise with teosinte, the wild relative of maize. However, as teosinte is absent in maize

fields and in nature in the Netherlands,[14] hybridisation of GM maize with teosinte will not occur in the Netherlands.

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

3.3 Updated bioinformatic analyses

The bioinformatic analyses were updated using databases assembled in January 2023. The insert in NK603 and the junctions with the 5' and 3' flanking regions were bioinformatically analysed from stop-to-stop codon in all six reading frames, using databases with sequences from allergens, toxins and proteins. According to the applicants there were no biologically relevant amino acid sequence similarities to known allergens, toxins, or other biologically active proteins with adverse effects for human or animal health. COGEM is of the opinion that the molecular characterisation of NK603 has been performed correctly and meets the requirements of COGEM.[21]

Conclusion: The bioinformatic analyses of NK603 maize have been updated and performed adequately. No indications for potential environmental risks were identified.

3.4 Systematic literature search

The systematic literature search which was carried out, covered the period from January 2014 to November 2023. The literature search was conducted for multiple GM maize products at once, among which drought tolerant and glufosinate-ammonium tolerant GM maize products, as part of their applications for market authorisation renewals. Therefore, the literature search addressed the broad review question "Does the Bayer GM maize products, derived food/feed products and the introduced glyphosate tolerance, glufosinate-ammonium tolerance and drought tolerance traits have adverse effects on human and animal health and the environment?"

The literature search identified 1571 publications in electronic databases and 520 records of internet pages of relevant key organisations. Of the identified literature, 31 publications and 5 records of key organisations were considered relevant for the review question, of which 21 publications and 0 records concerned the GM product NK603 specifically. According to the applicant, these publications and records do not contain new data relevant to the risk assessment. Overall, no adverse effects on human and animal health, or the environment were identified in the literature searches of the applicant.

Conclusion: The systematic literature search did not provide any indications that import of NK603 maize poses an environmental risk.

3.5 Annual monitoring reports

The applicant supplied annual reports on the post-market environmental monitoring (PMEM) carried out between October 2015 and November 2023. These reports contain amongst others information on

the monitoring which is carried out by operators involved in import, handling and processing of viable GM maize. These operators are members of the European trade associations COCERAL, UNISTOCK or FEDIOL. They will report any occurrence of potential adverse effects arising from NK603 maize, including adventitious populations resisting routine eradication procedures. No adverse effects associated with the import or use of NK603 were reported.

The PMEM of import and processing of NK603 carried out between 2015 and 2023 does not provide any indications that import and processing of NK603 pose a risk to the environment.

Conclusion: The information in the annual monitoring reports gives no indication of adverse effects or incidents resulting from import and/or processing of NK603 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, a food and/or feed assessment for Regulation (EC) 1829/2003 applications is carried out by Wageningen Food Safety Research (WFSR). The outcome of the assessment by other organisations (EFSA, WFSR) was not known when this advice was completed.

5. Post-market environmental monitoring

The applicant did not propose any changes to the existing post-market environmental monitoring (PMEM) plan for NK603 maize. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan,[22,23] which is part of a PMEM plan, but considers the current GS (and PMEM) plan adequate for import and processing of NK603 maize.

6. Overall conclusion

COGEM is of the opinion that import and processing of NK603 maize 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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