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KENMERK CGM/261001-01
ONDERWERP Advies hernieuwing importvergunning van gg-mais Bt11x59122xMIR604x1507xGA21

Geachte mevrouw Bertram,

Naar aanleiding van een adviesvraag (MA 260010_001) over de milieurisico's van een hernieuwing van de vergunning voor import en verwerking van gg-mais Bt11 x 59122 x MIR604 x 1507 x GA21 en subcombinaties (GMFF-2026-37615/RX052), ingediend door Syngenta Crop Protection, deelt de COGEM u het volgende mee. Op verzoek van het Food-Feed loket voor ggo-markttoelatingen is het advies in het Engels opgesteld.

Samenvatting:

De COGEM is gevraagd om te adviseren over de hernieuwing van de vergunning voor import van de genetisch gemodificeerde (gg-)maïslijn Bt11 x 59122 x MIR604 x 1507 x GA21 en subcombinaties hiervan. De eerdere vergunning is in 2017 voor een periode van 10 jaar afgegeven. Deze maïslijn brengt de genen *Cry1Ab*, *Cry34Ab1*, *Cry35Ab1*, *mCry3A*, *Cry1F*, *mepsps* en *pat* tot expressie en is hierdoor beter bestand tegen vraat door insecten en tolerant voor bepaalde herbiciden. Daarnaast bevat de gg-mais het *pmi*-gen dat dient als selectiemarker. De hernieuwingsaanvraag bevat onder meer geactualiseerde bioinformatica analyses, een literatuurreview en de resultaten van de verplichte 'post-market environmental monitoring' die sinds 2017 wordt uitgevoerd.

In Nederland zijn geen verwilderde maïspopulaties aanwezig. De wilde verwant van maïs, teosinte, komt in Nederland niet voor in de natuur of op agrarische percelen. In de aangeleverde informatie zijn geen aanwijzingen voor mogelijke risico's voor mens en milieu naar voren gekomen. Gezien het bovenstaande is de COGEM van oordeel dat de risico's van import en verwerking van gg-maïslijn Bt11 x 59122 x MIR604 x 1507 x GA21 voor mens en milieu 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.

- Bureau ggo, Afdeling Gentechnologie en Biologische Veiligheid, RIVM
- Directie Omgevingsveiligheid en milieurisico's, DG Milieu en Internationaal, Ministerie van IenW
- Food-Feed loket, RIVM

Advice on the renewal of import and processing of GM maize Bt11 × 59122 × MIR604 × 1507 × GA21 and its subcombinations

COGEM advice CGM/261001-01

COGEM has been requested to evaluate the environmental risks associated with the renewal of the authorisation for import, processing and food and feed use of genetically modified (GM) maize Bt11 × 59122 × MIR604 × 1507 × GA21 and its subcombinations^a (GMFF-2026-37615/RX052), as submitted by Syngenta Crop Protection NV/SA, acting on behalf of Syngenta Crop Protection AG (MA 260010_001).

GM maize Bt11 × 59122 × MIR604 × 1507 × GA21 was produced by crossing the five GM parental maize lines using conventional breeding methods. The resulting line expresses multiple introduced genes. The GM maize expresses the *mepsps* gene, derived from GA21, which confers tolerance to glyphosate containing herbicides, and three copies of the *pat* gene, derived from Bt11, 59122 and 1507, which confer tolerance to glufosinate-ammonium-containing herbicides. Additionally, this GM maize expresses the *mcry3A* gene from MIR604 and the *cry34Ab1* and *cry35Ab1* genes from 59122, which confer resistance against certain coleopteran species. Furthermore, the GM maize expresses the transgenes *cry1Ab*, derived from Bt11, and *cry1F*, derived from 1507, which both confer resistance against certain lepidopteran pests. Lastly, GM maize Bt11 × 59122 × MIR604 × 1507 × GA21 contains the *pmi* gene, which was used as a selectable marker during the development of MIR604.

COGEM has previously issued a positive advice on the import and processing of this stacked GM maize in 2012,¹ as well as on the import and processing of several stacked events containing Bt11, 59122, MIR604, 1507 or GA21 as one of the parental lines. This GM maize was authorised for placement on the market in the European Union in 2017.²

Maize (*Zea mays*) is a highly domesticated crop that is cultivated globally. Maize is wind-pollinated.^{3,4} Insect pollination of maize is highly limited but cannot be excluded.⁵ Maize is very sensitive to weed competition.⁶ During the long process of domestication, maize has lost the ability to persist in the wild.⁴ After ripening, the seeds (the kernels) adhere to the cob and do not scatter naturally.^{5,7} Consequently, seed dispersal is severely hampered.

Maize does not tolerate prolonged cold and frost, and requires warm conditions to grow.^{5,8,9} In cultivation areas with warm climatic conditions, volunteers can 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.⁵ In the Netherlands, the appearance of volunteers is rare, although maize plants occasionally have been observed outside agricultural fields.^{8,10} Any volunteers emerging will be killed by frost at the onset of winter.⁸ COGEM is not aware of any reports

a. The subcombinations are: Bt11 × MIR604 × 1507 × GA21, Bt11 × 59122 × 1507 × GA21, Bt11 × 59122 × MIR604 × GA21, Bt11 × 59122 × MIR604 × 1507, 59122 × MIR604 × 1507 × GA21, Bt11 × 59122 × MIR604, Bt11 × 59122 × 1507, Bt11 × 59122 × GA21, Bt11 × MIR604 × 1507, Bt11 × 1507 × GA21, 59122 × MIR604 × 1507, 59122 × MIR604 × GA21, 59122 × 1507 × GA21, MIR604 × 1507 × GA21, Bt11 × 59122, Bt11 × 1507, 59122 × MIR604, 59122 × GA21, MIR604 × 1507, and 1507 × GA21.

of feral maize populations in the Netherlands.⁸ Hybridisation of GM maize with species other than teosinte – the wild relative of maize – cannot occur. Teosinte seeds can be purchased in the Netherlands;¹¹ however, as it is absent from maize fields and nature in the Netherlands⁸, the risks of hybridisation of GM maize with teosinte is negligible in the Netherlands.

In the application for renewal, the bioinformatic analyses of the inserted elements and their 3' and 5' junctions in the genome of GM maize Bt11 × 59122 × MIR604 × 1507 × GA21 were updated using up-to-date databases of known protein allergens and toxins to assess protein sequence similarities. No indications for potential environmental risks were identified. The introduced traits in GM maize Bt11 × 59122 × MIR604 × 1507 × GA21 will not allow the GM maize to survive in the Dutch environment.

In addition, the applicant performed a systematic literature search using a broad collection of bibliographic databases, covering the period from Januari 2015 to February 2026. No publications were identified that would invalidate the conclusions of the previous risk assessment.

The applicant also supplied annual reports on the monitoring carried out between July 2017 and June 2025. The information in the annual monitoring reports gives no indication of adverse effects or incidents resulting from import and processing of GM maize Bt11 × 59122 × MIR604 × 1507 × GA21. The application includes a post-market environmental monitoring (PMEM) plan for maize Bt11 × 59122 × MIR604 × 1507 × GA21. COGEM has published several recommendations for further improvement of the PMEM plan,^{12,13} but considers the current plan adequate for import and processing of GM maize Bt11 × 59122 × MIR604 × 1507 × GA21.

COGEM is of the opinion that renewal of the market authorisation for import and processing of GM maize Bt11 × 59122 × MIR604 × 1507 × GA21 poses a negligible risk to the Dutch environment. COGEM abstains from giving advice on the potential risks of incidental consumption, as a food/feed assessment is carried out by other organisations.

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