

Advice Renewal of import & processing of GM maize Bt11 × MIR162 × MIR604 × GA21

COGEM advice CGM/260127-01

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 × MIR162 × MIR604 × GA21 and its subcombinations (GMFF-2025-35594), as submitted by Syngenta Crop Protection NV/SA on behalf of Syngenta Crop Protection AG.

GM maize Bt11 × MIR162 × MIR604 × GA21 was produced by conventional crossbreeding of the four GM parental maize lines and expresses multiple introduced genes. The GM maize expresses the *pat* gene conferring tolerance to glufosinate-ammonium containing herbicides and the *mepsps* gene conferring tolerance to glyphosate containing herbicides derived from Bt11 and GA21, respectively. Furthermore, the GM maize expresses the transgenes *Cry1Ab* derived from Bt11, and *mCry3A*, derived from MIR162, which both confer resistance against certain lepidopteran pests. Additionally, *vip3Aa20* (from MIR604) is expressed which confers resistance against certain coleopteran species. Lastly, GM maize Bt11 × MIR162 × MIR604 × GA21 contains two copies of *pmi*, which were used as selectable markers during the development of MIR162 and MIR604.

COGEM has previously advised positively on the import and processing of Bt11 × MIR162 × MIR604 × GA21¹, and the GM maize has been authorised for placement on the market in the European Union in 2016.²

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.

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1. COGEM (2009). Advies “Import and processing of gm-maize Bt11xMIR162xMIR604xGA21”. COGEM advice CGM/090917-05
 2. Commission Implementing Decision (EU) 2016/1685 of 16 september 2016 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maizes combining two or three of the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU of the European Parliament and of the Council OJEU
 3. Hin CJA (2001). Landbouwkundige risico's van uitkruising van GGO-gewassen. [In Dutch] Centrum voor Landbouw en Milieu (CLM)
 4. Treu R & Emberlin J (2000). Pollen dispersal in the crops Maize (*Zea mays*), Oil Seed Rape (*Brassica napus* ssp. *oleifera*), Potatoes (*Solanum tuberosum*), Sugar Beet (*Beta vulgaris* ssp. *vulgaris*) and Wheat (*Triticum aestivum*). Evidence from Publications. Soil Association
 5. Andersson M & Carmen de Vicente M (2010). Gene flow between crops and their wild relatives. The John Hopkins University Press, Baltimore, Maryland, The United States of America
 6. CAB International (2007). Crop Protection Compendium. *Zea mays* (maize). CD-ROM edition, Wallingford
 7. Organisation for Economic Cooperation and Development (OECD) (2003). Consensus document on the biology of *Zea mays* ssp. *mays* (Maize)

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 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 in maize fields and nature in the Netherlands,⁸ the risks of hybridisation of GM maize with teosinte is negligible in the Netherlands.

In the application for renewal, the bioinformatic analysis of the inserted elements and their 3' and 5' junctions in the genome of GM maize Bt11 × MIR162 × MIR604 × GA21 was updated to assess protein sequence similarities using up-to-date databases of allergens, toxins, and general proteins. No indications for potential environmental risks were identified.

The applicant performed a systematic literature search using a collection of bibliographic databases, covering the period from 2015 to 2025. No publications were identified that would invalidate the conclusions of the previous risk assessment. There is no indication that the introduced traits in GM maize Bt11 × MIR162 × MIR604 × GA21 will allow the GM maize to survive or establish in the Dutch environment.

A post-market environmental monitoring (PMEM) plan is provided in the application. The applicant also supplied annual reports on the monitoring carried out between 2017 and 2024. The information in the annual monitoring reports gives no indication of adverse effects or incidents resulting from import and processing of maize Bt11 × MIR162 × MIR604 × GA21. The applicant did not propose any changes to the existing (PMEM) plan for maize Bt11 × MIR162 × MIR604 × GA21. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan^{12,13} – which is part of a PMEM plan – but considers the current GS plan adequate for import and processing of GM maize Bt11 × MIR162 × MIR604 × GA21.

COGEM is of the opinion that renewal of the market authorisation for import and processing of GM maize Bt11 × MIR162 × MIR604 × 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.

8. Huiting HF et al. (2018). Are teosinte and feral maize present in the Netherlands? COGEM report CGM 2018-06

9. Miedema P (1982). The effect of low temperature on *Zea mays*. Adv. Agron. 35: 93-128

10. Van de Wiel CCM et al. (2011). Crop volunteers and climate change. Effects of future climate change on the occurrence of Maize, Sugar Beet and Potato volunteers in the Netherlands. COGEM report 2011-11

11. Vreeken zaden. <https://www.vreeken.nl/190840-oermais-teosinte> (bezocht: 27-1-2026)

12. COGEM (2010). General Surveillance. COGEM report CGM/100226-01

13. COGEM (2015). Advice on improving the general surveillance of GM crops. COGEM advice CGM/150601-02