Renewal of the authorisation for import and processing of genetically modified maize NK603xT25

COGEM advice CGM/241011-01

- The present application (GMFF-2023-21252; RX045) concerns the renewal of the authorisation for import and processing for use in feed and food of genetically modified (GM) maize NK603xT25;
- NK603xT25 was previously authorised for import and processing in 2015;
- COGEM advised positively on the import and processing of GM maize NK603xT25 in 2010;

- NK603xT25 was developed through traditional breeding methods of NK603 and T25 maize. NK603xT25 expresses the *cp4 epsps* and *cp4 epsps* L214P genes conferring tolerance to glyphosate-based herbicides (from NK603) and the *pat* gene conferring tolerance to glufosinate-ammonium-based herbicides (from T25);

- In the Netherlands, feral maize populations have never been observed and the occurrence 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 NK603xT25 has been updated and meets the criteria of COGEM;
- The updated bioinformatic analyses, the literature review and the post-market environmental monitoring reports provide no indication that the import of NK603xT25 poses a risk to the environment;

- COGEM is of the opinion that the import and processing of maize NK603xT25 poses a negligible risk to the environment in the Netherlands;
- COGEM abstains from giving advice on the potential risks of incidental consumption, as other organisations carry out a food/feed assessment.

1. Introduction

The present application (GMFF-2023-21252; RX045), filed by Bayer Agriculture BV, on behalf of Bayer CropScience LP, concerns the renewal of the authorisation for food, feed, import and processing of genetically modified (GM) maize NK603xT25, which was granted in 2015.[1] As market authorisations remain valid for a period of 10 years, the authorisation holder has filed an application for a renewal of the authorisation. This application includes monitoring reports, updated bioinformatic analyses, and a systematic literature search.

NK603xT25 was developed by crossing GM maize plants NK603 and T25 using traditional breeding methods. NK603xT25 is tolerant to glyphosate-based herbicides conferred by the expression of two CP4 EPSPS proteins (CP4 EPSPS and CP4 EPSPS L214P; from NK603) and is tolerant to glufosinate-ammonium-based herbicides conferred by PAT protein expression (from T25).

2. Previous COGEM advice

In 2010, COGEM advised on import and processing of NK603xT25 maize and concluded that it poses a negligible risk to the environment.[2] COGEM has also issued advises on the parental GM maize lines NK603 and T25.[3,4,5,6]

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 that originated from Central America, and is nowadays cultivated globally. Maize is wind-pollinated[7,8] 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.[9] Hybridisation of GM maize with species other than teosinte – the wild relative of maize – cannot occur.

Maize does not tolerate prolonged cold and frost,[10] and requires warm conditions in order to grow.[9,11] 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.[9]

Maize is very sensitive to weed competition.[12] During the long process of domestication, maize has lost the ability to persist in the wild.[8] A soil seed bank, small seeds, and an extended flowering period and seed production are characteristics often observed in persistent weeds.[13] Maize lacks all these characteristics. After ripening, the seeds (the kernels) adhere to the cob and do not scatter naturally.[9,14] Consequently, seed dispersal is severely hampered.

3.2 Receiving environment

In the Netherlands, the occurrence of maize volunteers is rare, although maize plants occasionally have been observed outside of agricultural fields.[15,16] Any volunteers emerging will be killed by frost at the onset of winter.[10] 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,[10] 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 analysis in a previous application of NK603xT25 was repeated with updated databases – assembled in 2023 – containing sequences from allergens, toxins and proteins. According to the applicant 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 NK603xT25 has been performed correctly and meets the requirements of COGEM.[17]

Conclusion: The bioinformatic analyses of NK603xT25 maize have been updated and performed adequately. No indications for potential environmental risks were identified.

3.4 Systematic literature search

The systematic literature search that was carried out, covers the period from January 2014 to November 2023. The literature search was conducted simultaneously for several GM maize products, 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 only one record concerned the GM product NK603xT25 specifically. This record is a technical report of the National Technical Commission of Biosecurity of Brazil on the market authorisation of NK603xT25, published in 2015.[18] No publications were identified concerning NK603xT25 specifically. 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 NK603xT25 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 2016 and November 2023. These reports include information on the monitoring

that is conducted by operators involved in the import, handling and processing of viable GM maize. The annual reports concern several of the applicant's GM maize products, including NK603xT25. These operators are members of the European trade associations COCERAL, UNISTOCK or FEDIOL. They will report any occurrence of potential adverse effects arising from NK603xT25 maize, including adventitious populations resisting routine eradication procedures. No adverse effects associated with the import or use of NK603xT25 have reported.

The PMEM of the import and processing of NK603xT25 carried out between 2016 and 2023 did not provide any indication that the import and processing of NK603xT25 poses 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 NK603xT25 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 PMEM plan for NK603xT25 maize. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan,[19,20] which is part of a PMEM plan, but considers the current GS (and PMEM) plan adequate for import and processing of NK603xT25 maize.

6. Overall conclusion

COGEM is of the opinion that import and processing of NK603xT25 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.

References

1. Commission Implementing Decision (EU) 2015/2279 of 4 December 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603 × T25 (MON-ØØ6Ø3-6 × ACS-ZMØØ3-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. OJEU 8.12.2015
2. COGEM (2010). Import and processing of genetically modified maize NK603xT25. COGEM advice CGM/101213-02
3. COGEM (2013). Additional advice on import of T25 maize. COGEM advice CGM/131028-01
4. COGEM (2008). Renewal application cultivation of maize T25. COGEM advice CGM/080806-02

5. COGEM (2003). Markttoelating 'NK603 maize tolerant to glyphosate'. [In Dutch] COGEM advice CGM/030319-08
6. COGEM (2006). Cultivation of herbicide tolerant maize line NK603. COGEM advice CGM/060704-01
7. Hin CJA (2001). Landbouwkundige risico's van uitkruising van GGO-gewassen. [In Dutch] Centrum voor Landbouw en Milieu (CLM) 511-2001
8. 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
9. Andersson M *et al.* (2010). Gene flow between crops and their wild relatives. The John Hopkins University Press, Baltimore, Maryland, The United States of America
10. Huiting HF *et al.* (2018). Are teosinte and feral maize present in the Netherlands? COGEM report CGM 2018-06
11. Miedema P (1982). The effect of low temperature on *Zea mays*. Adv. Agron. 35: 93-128
12. CAB International (2007). Crop Protection Compendium. *Zea mays* (maize). CD-ROM edition, Wallingford
13. Kos SP *et al*. (2012). Can transgenic crops go wild? A literature study on using plant traits for weediness pre-screening. COGEM research report CGM 2012-01
14. Organisation for Economic Cooperation and Development (OECD) (2003). Consensus document on the biology of *Zea mays* ssp. *mays* (Maize)
15. Trtikova M *et al.* (2017). Teosinte in Europe – Searching for the origin of a novel weed. Sci. Rep. 7: 1560
16. 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 research report 2011-11
17. COGEM (2014). Reconsideration of the molecular characterisation criteria for marketing authorisation of GM crops. COGEM report CGM/140929-02
18. Comissão Técnica Nacional de Biossegurança – CTNBio – National Technical Commission of Biosecurity, Brazil (2015) Parecer Tecnico nº 4407: Liberacao Comercial: NK603xT25 [In Portuguese] http://ctnbio.mctic.gov.br/documents/566529/1686245/Parecer+Técnico+nº 4407+-+2015/7d8fecb3-4e85-4c51-bb63-d39d1aca947a?version=1.0 (accessed on 19th August 2024)
19. COGEM (2010). General Surveillance. COGEM report CGM/100226-01
20. COGEM (2015). Advice on improving the general surveillance of GM crops. COGEM advice CGM/150601-02