Renewal of the authorisation for import and processing of genetically modified 1507xNK603 maize

COGEM advice CGM/170731-02

- The present application (EFSA/GMO/RX/008) concerns the renewal of the authorisation for import and processing for use in feed and food of genetically modified 1507xNK603 maize;
- Maize 1507xNK603 has previously been authorised for import and processing in 2007;
- COGEM has advised positively on the import and processing (2005), and on the cultivation (2006) of 1507xNK603;

- Maize 1507xNK603 produces the CP4 EPSPS and PAT proteins conferring tolerance to glyphosate and glufosinate-ammonium containing herbicides, and the Cry1F protein 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 updated bioinformatic analyses of 1507xNK603 maize meet the criteria of COGEM;
- There are no indications that the introduced traits alter the fitness of 1507xNK603 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 1507xNK603 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/008), filed by Pioneer Hi-Bred Int. and Dow AgroScience LLC, concerns the renewal of the authorisation for import and processing of the genetically modified (GM) 1507xNK603 maize for use in feed and food. Maize 1507xNK603 contains the *cry1F*, *cp4 epsps* and *pat* genes, conferring insect resistance and herbicide tolerance to the crop. Maize 1507xNK603 has been authorised for import, food, feed and processing in Europe on October 24th in 2007 (2007/703/EC).[1] In 2006, EFSA issued a positive opinion on the import and processing of maize line 1507xNK603.[2] 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, updated molecular characterisation and an updated literature search.

2. Previous COGEM advices

COGEM advised positively on import, processing and cultivation of both parental lines 1507 and NK603.[3,4,5,6,7] COGEM also advised positively on the import and processing (2005), and on the cultivation (2006) of 1507xNK603.[8,9] In addition, COGEM advised positively on the import and processing of several stacked lines containing 1507 and NK603, including 59122x1507xNK603, MON89034x1507xNK603, 1507x59122xMON810xNK603 and 1507xMON810xMIR162 xNK603.[10,11,12,13]

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,[14,15] 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.[16]

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.[16,17] 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.[16]

Maize is very sensitive to weed competition.[18] During the long process of domestication, maize has lost the ability to persist in the wild.[15] A soil seed bank, small seeds, and an extended period of flowering and seed production are characteristics often observed in persistent weeds.[19] Maize lacks all these characteristics. After ripening, the seeds (the kernels) adhere to the cob and do not shatter naturally.[16,20] Consequently, seed dispersal is severely hampered.

During field observations in Austria some volunteers and maize plants were observed in non-agricultural habitats.[21] In the Netherlands, the appearance of volunteers is very rare, however, maize plants occasionally have been observed outside agricultural fields.[22] 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

Maize 1507xNK603 was produced by conventional crossbreeding of the GM maize lines 1507 and NK603.

Introduced genes	Encoded proteins (enzymes)	Traits
cry1F	The Cry1F protein originating from *Bacillus thuringiensis* subsp. *Aizawa* [3,5,23]	Resistance to certain lepidopteran insects
cp4 epsps	The 5-enolpyruvulshikimate-3-phosphate synthase (EPSPS) enzyme originating from *Agrobacterium tumefaciens* strain CP4 [6,24]	Tolerance to glyphosate containing herbicides
pat	The phosphinothricin N-acetyltransferase (PAT) enzyme originating from *Streptomyces viridochromogenes* strain Tü 494 [3,5,25,26]	Tolerance to glufosinate-ammonium containing herbicides
For a detailed description of the introduced genes and traits, see references		

3.3 Updated bioinformatics analyses

The updated molecular characterisation confirmed that no endogenous maize genes were disrupted by the T-DNA insertion. The bioinformatics analyses were updated using recent databases. COGEM is of the opinion that the molecular characterisation of 1507xNK603 has been performed correctly and meets the requirements of COGEM.[27]

Conclusion: The molecular characterisation of 1507xNK603 maize is adequate and no indications for potential environmental risks are identified.

3.4 Systematic literature search

The applicant performed a systematic review of literature relevant to the scope of the authorisation. None of the retrieved articles indicated any potential adverse effects on human and animal health.

Conclusion: The systematic literature search does not give any indication of potential environmental risks of 1507xNK603 associated with import and processing.

3.5 Annual monitoring reports

The applicant supplied annual monitoring reports carried out between December 2008 and October 2016. Monitoring was performed by operators involved in the import, handling and processing of 1507xNK603 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 1507xNK603 maize. The publications that are retrieved during the yearly review are identical to the results of the systematic literature review and have already been covered in section 3.4.

Conclusion: Annual monitoring reports give no indication of adverse effects or incidents resulting from import and/or processing of 1507xNK603 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 supplied a new post-market environmental monitoring (PMEM) plan. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan[28,29] but considers the current GS plan adequate for import and processing of 1507xNK603 maize.

6. Overall conclusion

There are no indications that expression of the introduced traits or any combination thereof will alter the fitness of 1507xNK603 maize. COGEM is of the opinion that import and processing of maize 1507xNK603 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. European Commission (2007). authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2007/703/EC). Official Journal of the European Union 31.10.2007 L 285/47
2. European Food Safety Authority (EFSA) (2016). Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2004-05) for the placing on the market of insect-protected and glufosinate and glyphosate-tolerant genetically modified maize 1507xNK603, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred and Mycogen Seeds. The EFSA Journal 355: 1-23
3. COGEM (2003). Insect resistant and glufosinate ammonium tolerant transformation event 1507 maize. COGEM advice CGM/030115-01
4. COGEM (2003). Insect resistent and glufosinate ammonium tolerant transformation event 1507 maize. COGEM advice CGM/030919-04
5. COGEM (2015). Renewal of the authorisation for import and processing of genetically modified maize line 1507. COGEM advice CGM/150928-01
6. COGEM (2003). NK603 maize tolerant to glyphosate. COGEM advice CGM/030319-08
7. COGEM (2006). Cultivation of herbicide tolerant maize line NK603. COGEM advice CGM/060704-01
8. COGEM (2005). Import and processing of insect resistant and herbicide tolerant maize 1507 x NK603. COGEM advice CGM/050526-01

9. COGEM (2006). Cultivation of insect resistant and herbicide tolerant maize 1507 x NK603. COGEM advice CGM/060510-01
10. COGEM (2007). Import of genetically modified maize 59122 x 1507 x NK603. COGEM advice CGM/070817-01
11. COGEM (2009). Import and processing of genetically modified MON89034x1507xNK603 maize. COGEM advice CGM/090930-01
12. COGEM (2012) Import and processing of maize 1507xMON810xMIR162xNK603. COGEM advice CGM/120402-01
13 COGEM (2016). Import and processing of insect resistant and herbicide tolerant genetically modified maize 1507xMON810xMIR162xNK603. COGEM advice CGM/160412-01
14. Hin CJA (2001). Landbouwkundige risico's van uitkruising van GGO-gewassen. Centrum voor Landbouw en Milieu (CLM)
15. 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
16. 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
17. Miedema P (1982). The effect of low temperature on *Zea mays*. Advances in Agronomy 35: 93-128
18. CAB International (2007). Crop Protection Compendium. *Zea mays* (maize). CD-ROM edition, Wallingford
19. 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
20. Organisation for Economic Cooperation and Development (OECD) (2003). Consensus Document on the Biology of *Zea mays* ssp. *mays* (Maize)
21. Pascher K (2016). Spread of volunteer and feral maize plants in Central Europe: recent data from Austria. Environ. Sci. Eur. 28: 30
22. 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
23. US-EPA (U.S. Environmental Protection Agency). Biopesticide registration action document, Cry1Ab and Cry1F Bacillus thuringiensis (Bt) corn plant-incorporated protectants (2010). https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/decision_PC-006481_1-Sep-10.pdf (visited: June 19th 2017).
24. Funke T *et al*. (2006). Molecular basis for the herbicide resistance of Roundup Ready crops. PNAS 103: 13010-13015
25. Organisation for Economic Cooperation and Development (OECD) (1999). Consensus document on general information concerning the genes and their enzymes that confer tolerance to phosphinothricin herbicide
26. Wohlleben W *et al*. (1988). Nucleotide sequence of the phosphinothricin N-acetyltransferase gene form *Streptomyces viridochromogenes* Tü494 and its expression in *Nicotoana tabacum*. Gene 70: 25-37

27. COGEM (2014). Reconsideration of the molecular characterisation criteria for marketing authorisation of GM crops. COGEM topic report CGM/140929-02
28. COGEM (2010). General Surveillance. COGEM report CGM/100226-01
29. COGEM (2015). Advice on improving the general surveillance of GM crops. COGEM advice CGM/150601-02