Renewal of the authorisation for import and processing of genetically modified maize MON89034x1507xNK603

COGEM advice CGM/230711-01

- The present application (GMFF-2022-3670 (RX-029)) concerns the renewal of the authorisation for import and processing for use in feed and food of genetically modified (GM) maize MON89034x1507xNK603;
- MON89034x1507xNK603 was previously authorised for import and processing in 2013;

- MON89034x1507xNK603 is resistant to certain lepidopteran pests due to the expression of the *cry1A.105*, *cry2Ab2* and *cry1F* genes, and tolerant to glyphosate and glufosinate-ammonium containing herbicides due to the expression of the *cp4 epsps*, *cp4 epsps l214p* and *pat* genes;

- 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 MON89034x1507xNK603 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 MON89034x1507xNK603 poses a risk to the environment;

- COGEM is of the opinion that import and processing of maize MON89034x1507xNK603 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-2022-3670 (RX-029)), filed by Bayer Agriculture BV and Corteva Agriscience Belgium BV, concerns the renewal of the authorisation for food, feed, import and processing of genetically modified (GM) maize MON89034x1507xNK603, which was granted in 2013[1]. Since market authorisations remain valid for a period of 10 years, the authorisation holders filed an application for a renewal of the authorisation. This application contains, amongst others, monitoring reports, updated bioinformatic analyses, and a systematic literature search.

MON89034x1507xNK603 was produced by conventional crossbreeding of the three parental lines. It expresses the *cry1A.105*, *cry2Ab2* and *cry1F* genes, thus conferring resistance to certain lepidopteran insects. It is also tolerant to glyphosate and glufosinate-ammonium containing herbicides, due to the expression of the *cp4 epsps, cp4 epsps l214p* and *pat* genes.

2. Previous COGEM advice

In 2009, COGEM advised on import and processing of MON89034x1507xNK603 maize and on import and processing of MON89034xNK603 and concluded that it poses a negligible risk to the environment.[2,3] In 2017, a positive opinion was issued on the renewal of the authorisation for import and processing of a stacked event containing two of the three parental lines, i.e. GM maize 1507xNK603.[4] In 2018, COGEM advised positively on import and processing of a stacked event with MON89034, NK603 and 1507 and two additional parental lines, i.e. MON89034x1507x MIR162xNK603xDAS-40278-9.[5]

3. Environmental risk assessment

3.1 Characteristics of maize

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[6,7] 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.[8] Hybridisation of GM maize with other species than teosinte, the wild relative of maize, cannot occur.

Maize does not tolerate prolonged cold and frost,[9] and requires warm conditions in order to grow.[8,10] 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.[8]

Maize is very sensitive to weed competition.[11] During the long process of domestication, maize has lost the ability to persist in the wild.[7] A soil seed bank, small seeds, and an extended period of flowering and seed production are characteristics often observed in persistent weeds.[12] Maize lacks all these characteristics. After ripening, the seeds (the kernels) adhere to the cob and do not scatter naturally.[8,13] 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.[14,15] Any volunteers emerging will be killed by frost at the onset of winter.[9] 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,[9] 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 2021 and 2022. Bioinformatic analyses were carried out to determine whether endogenous genes of maize were disrupted by the insertions in MON89034, 1507 and NK603. According to the applicants, there are no indications that endogenous genes were disrupted. The inserts in MON89034, 1507 and NK603 and the junctions with their 5' and 3' flanking regions were also bioinformatically analysed from stop to stop codon in all six potential reading frames using databases with sequences from allergens, toxins and proteins. As the sequence of the insert in 1507 has previously been corrected, the applicant used both the originally reported 1507 insert sequence and the corrected 1507 insert sequence which differs by four base pairs. The results of the bioinformatic analyses with the allergen databases were not assessed by COGEM, because the assessment of potential allergenicity is not part of the environmental risk assessment but is included in the food/feed safety assessment which is carried out by EFSA and WFSR (see paragraph 4). According to the applicants there were no biologically relevant amino acid sequence similarities to known allergens, toxins, or other proteins that would be harmful to humans or animals.

COGEM is of the opinion that the molecular characterisation of MON89034x1507xNK603 has been performed correctly and meets the requirements of COGEM.[16]

Conclusion: The bioinformatic analyses of MON89034x1507xNK603 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 2012 to July 2022 and addressed the question "Does MON89034x1507xNK603 maize, derived food/feed products and the inherited herbicide tolerance and insect protection traits have adverse effects on human and animal health and the environment?" Four out of 2437 identified publications were considered relevant. According to the applicant, these publications did not report any new hazards, modified exposure, or new scientific uncertainty for MON89034x1507xNK603 and therefore did not have any implication for its risk assessment.

Conclusion: The systematic literature search did not provide any indications that import of MON89034x1507xNK603 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 November 2013 and June 2021. These reports contain amongst others information on annual literature searches carried out by the applicant, and 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 are expected to report any occurrence of potential adverse effects arising from MON89034x1507x NK603 maize, including adventitious populations resisting routine eradication procedures. No adverse effects associated with the import or use of MON89034x1507xNK603 were reported. In the period between July 2017 and June 2018 operators did not monitor because MON89034x1507x NK603 was not commercially grown. The PMEM was therefore limited to a literature search. According to the PMEM reports, no relevant publications that would invalidate the initial conclusions on the risk assessment of MON89034x1507xNK603 were identified in the annual literature searches.

The PMEM of import and processing carried out between 2013 and 2021 did not provide any indications that import and processing of MON89034x1507xNK603 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 MON89034x1507xNK603 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 (PMEM)

The applicant did not propose any changes to the existing post-market environmental monitoring (PMEM) plan for MON89034x1507xNK603 maize. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan,[17,18] which is part of a PMEM plan, but considers the current GS (and PMEM) plan adequate for import and processing of MON89034x1507xNK603 maize.

6. Overall conclusion

COGEM is of the opinion that import and processing of MON89034x1507xNK603 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.

7. Additional remark

The applicant performed a systematic literature search as well as literature searches which are part of the annual PMEM reports. COGEM notes that in the systematic literature search only four publications were considered relevant, and two of them were written by employees of the companies which are the authorisation holders of this stacked event. In the annual literature searches several publications were considered irrelevant because the study did not use MON89034x1507xNK603 or its sub-combinations. Some of these studies contained information on one of the single events of MON89034x1507xNK603. COGEM is of the opinion that studies on the parental lines of a stacked event should not be automatically excluded from further analysis, as they may contain information that is relevant.

References

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