Renewal of the authorisation for import and processing of genetically modified maize MON87460

COGEM advice CGM/240919-03

- The present application (GMFF-2023-21251) concerns the renewal of the authorisation for import and processing for use in feed and food of genetically modified (GM) maize MON87460;
- MON87460 was previously authorised for import and processing in 2015;
- COGEM has advised positively on the import and processing of maize MON87460 in 2010
- MON87460 expresses the *cspB*, conferring drought stress tolerance, and *nptII* conferring resistance to the aminoglycoside containing antibiotics, used to facilitate the selection process of transformed plant cells;

- 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 MON87460 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 MON87460 poses a risk to the environment;

- COGEM is of the opinion that import and processing of maize MON87460 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-2023-21251) is filed by Bayer Agriculture BV, on behalf of Bayer CropScience LP, and concerns the renewal of the authorisation for food, feed, import and processing of genetically modified (GM) maize MON87460, which was granted in 2015.[1] Since market authorisations remain valid for a period of 10 years, the authorisation holder filed an application for a renewal of the authorisation. This application contains, amongst others, monitoring reports, updated bioinformatic analyses, and a systematic literature search.

The GM maize MON87460 was created through *Agrobacterium*-mediated transformation of conventional maize. It contains two genes, *cspB* and *nptII*, which code for the proteins CspB and Tn5 respectively. CspB provides drought stress tolerance, while Tn5 confers resistance to the

aminoglycoside containing antibiotics, neomycin and kanamycin, used to facilitate the selection process of transformed plant cells.

2. Previous COGEM advice

In 2010, COGEM advised on import and processing of MON87460 maize and concluded that it poses a negligible risk to the environment.[2]

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, originating from Central America, and nowadays cultivated globally. Maize is wind pollinated[3,4] 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.[5] Hybridisation of GM maize with other species than teosinte, the wild relative of maize, cannot occur.

Maize does not tolerate prolonged cold and frost,[6] and requires warm conditions in order to grow.[5,7] 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.[5]

Maize is very sensitive to weed competition.[8] During the long process of domestication, maize has lost the ability to persist in the wild.[4] A soil seed bank, small seeds, and an extended period of flowering and seed production are characteristics often observed in persistent weeds.[9] Maize lacks all these characteristics. After ripening, the seeds (the kernels) adhere to the cob and do not scatter naturally.[5,10] 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.[11,12] Any volunteers emerging will be killed by frost at the onset of winter.[6] 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,[6] 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 January 2023. The insertion site was assessed by analysing the 5' and 3' flanking regions. Results indicated that no endogenous gene features were directly disrupted at the MON 87460 insertion.

The insert in MON87460 and the sequences spanning the 5' and 3' junction of the insert and the genomic DNA were bioinformatically analysed from stop to stop codon in all six reading frames, using a general protein database and to a protein database filtered to contain only toxins. The best scoring match had an E-value of 2e-11 over 43 amino acids and a 58.1% identity. It, and all other hits, were deemed biologically irrelevantly by the applicant.

COGEM is of the opinion that the molecular characterisation of MON87460 has been performed correctly and meets the requirements of COGEM .[13]

Conclusion: The bioinformatic analyses of MON87460 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 covered the period from January 2014 to November 2023. The literature search was conducted for multiple GM maize products at once, as part of their applications for market authorisation renewals. 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 the relevant key organisations mentioned in the 2019 Explanatory note on literature searching for GMO applications.[14] Of the identified literature, 31 publications and 5 records from internet pages of key organisations were considered relevant for the review question, of which 8 publications and 0 records concerned the GM product MON87460 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 and/or processing of MON87460 maize poses an environmental risk.

3.5 Annual monitoring reports

The applicant supplied annual reports of the post-market environmental monitoring (PMEM) carried out between October 2015 and November 2023. These reports contain, amongst others, information on

the monitoring which is carried out by operators involved in import, handling and processing of viable GM maize. The annual reports concern multiple GM maize products of the applicant, among which MON87460. These operators are members of the European trade associations COCERAL, UNISTOCK or FEDIOL who have agreed to be part of the PMEM. They will report any occurrence of potential adverse effects arising from MON87460 maize, including adventitious populations resisting routine eradication procedures. No adverse effects associated with the import or use of MON87460 were reported.

The PMEM of import and processing of MON87460, carried out between 2015 and 2023 does not provide any indications that import and processing of MON87460 pose 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 MON87460 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 post-market environmental monitoring (PMEM) plan for MON87460 maize. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan,[15,16] which is part of a PMEM plan, but considers the current GS (and PMEM) plan adequate for import and processing of MON87460 maize.

6. Overall conclusion

COGEM is of the opinion that import and processing of MON87460 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

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