Renewal of the authorisation for import and processing of genetically modified maize T25

COGEM advice CGM/240919-04

- The present application (GMFF-2024-22651) concerns the renewal of the authorisation for import and processing for use in feed and food of genetically modified (GM) maize T25;
- T25 was previously authorised for import and processing in 2015;
- COGEM has advised positively on the import and processing of maize T25 in 1998;
- T25 expresses the *pat* gene, conferring tolerance to glufosinate ammonium containing herbicides;

- 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 T25 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 T25 poses a risk to the environment;

- COGEM is of the opinion that import and processing of maize T25 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-2024-22651) is filed by BASF Agricultural Solutions Seed US LLC, and concerns the renewal of the authorisation for food, feed, import and processing of genetically modified (GM) maize T25, 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.

GM maize T25 was generated by polyethylene-glycol mediated protoplasts transformation of maize tissues and expresses the *pat* gene. The resulting protein, phosphinothricin-N-acetyl transferase (PAT), confers resistance to glufosinate ammonium containing herbicides.

2. Previous COGEM Advice

In 1998, COGEM advised on import and processing of T25 maize and concluded that it poses a negligible risk to the environment, though the COGEM did identify some points in the general

surveillance plan that could use improvement.[2] In 2008 the COGEM positively advised on the renewal of T25 maize.[3] In 2013 the 'general surveillance plan' was updated and the COGEM published the opinion that that the 'general surveillance plan' is now adequate for import and processing of T25 maize.[4] Additionally, COGEM advised positively on the import and processing of several stacked events containing T25.[5]

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[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 a protein database assembled in October 2023 and a toxin database assembled in January 2023.The insertion site was assessed by analysing the 5' and 3' flanking regions. The applicant identified a sequence homology to putative retrotransposon genes, suggesting interruption upon transformation. However, these sequences are highly repetitive throughout the maize genome, leading the applicant to argue that the insertion is unlikely to cause any loss of function.

The insert and the junctions with the 5' and 3' flanking regions were bioinformatically analysed in all six reading frames. The ORFs sequences were compared from stop to stop codon to a general protein database and to a protein database filtered to contain only toxins combined with a venom database. The best scoring match had an E-value of 0.036 over 42 amino acids and a 38.1% identity. It, and all other hits, were deemed biologically irrelevantly by the applicant.

COGEM is of the opinion that the molecular characterisation of T25 has been performed correctly and meets the requirements of COGEM.[16]

Conclusion: The bioinformatic analyses of T25 maize have been updated and performed adequately. No indications for potential environmental risks were identified.

3.4 Systematic literature search

The applicant performed a literature search using several bibliographic databases and internet pages of relevant key organisations involved in the risk assessment of GM plants covering a publication period from January 2014 to November 2023. The literature search addressed the two questions: "Were any studies published during the reporting period that describe adverse effects on human or animal health or the environment of the T25 corn and its newly expressed proteinPAT/pat?" and "Were any studies published during the reporting period that focus on molecular characterization of the T25 corn and its newly expressed protein PAT/pat in corn?"

The literature search identified 3278 publications. Of the identified literature, 2 publications were considered relevant for the review question. According to the applicant, none of these studies were found to contain new data relevant to the risk assessment.

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 T25 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 April 2015 and June 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. 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 T25 maize, including adventitious populations resisting routine eradication procedures. No adverse effects associated with the import or use of T25 were reported.

The PMEM of import and processing of T25 carried out between 2015 and 2023 does not provide any indications that import and processing of T25 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 T25 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 T25 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 T25 maize.

6. Overall conclusion

COGEM is of the opinion that import and processing of T25 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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