Second renewal of the authorisation for import and processing of genetically modified maize Bt11

COGEM advice CGM/190211-01

- The present application (EFSA/GMO/RX/016) concerns the second renewal of the authorisation for import and processing of genetically modified (GM) maize Bt11;
- GM maize Bt11 was previously authorised for import and processing in 1998, and its authorisation was renewed in 2010;
- COGEM advised positively on the import and processing of maize Bt11 in 1997, and on the renewal of the authorisation in 2008;

- GM maize Bt11 expresses the *pat* and *cry1Ab* genes;
- GM maize Bt11 is resistant to certain lepidopteran insects and tolerant to herbicides containing the active ingredient glufosinate-ammonium;

- In the Netherlands, feral maize populations have never been observed and the appearance of volunteers is rare;
- In the Netherlands, the wild relative of maize (teosinte) is not present in maize fields and in nature;
- In conclusion, hybridisation of (GM) maize with other species is impossible;

- The molecular characterisation of maize Bt11 has been updated and meets the criteria of COGEM;
- The updated molecular characterisation, literature review and annual monitoring reports do not provide any indication of a potential environmental risk;

- COGEM is of the opinion that import and processing of maize Bt11 pose 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/016) filed by Syngenta, concerns the second renewal of the authorisation for import and processing of GM maize Bt11. The application contains amongst others monitoring reports, an updated molecular characterisation, and an updated literature search. GM maize Bt11 was authorised for import and processing for use in food and feed in 1998 (98/292/EC), and authorised as a novel food or novel food ingredient in 2004 (2004/657/EC).[1,2] The first renewal of these authorisations was granted in 2010 (2010/410/EU).[3]

2. Previous COGEM advice

In the past COGEM issued several advices on the authorisation for import, processing, and cultivation of GM maize Bt11. In 1997 COGEM advised positively on the authorisation for import and processing, and in 2005 positively on the authorisation for cultivation of GM maize Bt11.[4,5]

In 2008 COGEM advised positively on the first renewal of the authorisation for import and processing of GM maize Bt11.[6] COGEM noted that the sequence data in the renewed application differed from the information present in previous applications, but concluded that there were no reasons to assume that the observed differences changed the outcome of previous environmental risk assessments.

After COGEM's advice on the first renewal, additional information was provided by the applicant. In 2009, COGEM examined the additional information and concluded that its previous conclusion remained valid, i.e. that import and processing of maize Bt11 poses negligible risks to the environment.[7] In addition, COGEM considered the revised general surveillance plan sufficient for monitoring of import and processing of maize line Bt11.

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,[8,9] 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 probably highly limited but cannot be excluded.[10]

Recently, the wild relative of maize, teosinte was detected in Spain[11,12,13] and France.[14,15] In these countries, it is present as a weed in some arable fields. In the Netherlands, teosinte is absent in maize fields and in nature.[16] Hybridisation of maize with other species than teosinte cannot occur.

Maize requires warm conditions in order to grow.[10,17] In cultivation areas with warm 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.[10] Maize does not tolerate prolonged cold and frost. In the Netherlands, any volunteers emerging in or outside maize fields will be killed by frost at the onset of winter.[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.[9] 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.[10,20] 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, although maize plants occasionally have been observed outside agricultural fields.[22] COGEM is not aware of any reports of feral maize populations in the Netherlands.

Conclusion: In the Netherlands, feral maize populations do not occur and hybridisation of maize with other species is impossible.

3.2 Description of the introduced genes, traits and regulatory elements

A description of the inserted genetic elements in maize Bt11 is listed in the table below. The list is limited to information on the introduced genes, corresponding traits, and regulatory elements (promoters and terminators).

Introduced genes	Encoded proteins	Traits	Regulatory elements
cry1Ab	A variant of the Cry1Ab protein from *Bacillus thuringiensis* subsp. *kurstaki*[23]	Resistance to certain lepidopteran insects	35S promoter from *Cauliflower mosaic virus* (CaMV) and nopaline synthase (NOS) terminator from *Agrobacterium tumefaciens*
pat	Variant of phosphinothricin N-acetyltransferase (PAT) originating from *Streptomyces viridochromogenes* strain Tü 494[24,25]	Tolerance to glufosinate-ammonium containing herbicides	35S promoter from CaMV and NOS terminator from *A. tumefaciens*
For a detailed description of the introduced gene and trait, see references			

3.3 Updated bioinformatics analyses

The applicant states that, as part of a re-sequencing initiative in 2017 and 2018, the sequence of event Bt11 in several stacked lines was re-sequenced, and confirmed to be identical to that in the previously assessed single event.

Using recent databases, the applicant updated the bioinformatics analyses of the insert and the sequences spanning the 5' and 3' junctions of the insert and its flanking regions. The sequences were screened to identify all putative open reading frames (ORFs) between stop codons. According to the applicant, the ORFs did not generate any protein sequence similarities with known allergens or toxins. Bioinformatics analysis of the locus of integration shows that the insert does not disrupt an essential nuclear maize gene.

Conclusion: The molecular characterisation of maize Bt11 has been updated and is adequate.

3.4 Annual monitoring reports and literature review

The applicant supplied annual reports on the monitoring carried out from July 2009 to June 2017. Monitoring was performed by operators involved in the import, handling and processing of viable maize i.e. COCERAL, UNISTOCK and FEDIOL. As part of the monitoring reports, the applicant performed a yearly review of scientific publications to monitor the safety of maize Bt11. In addition,

the applicant performed a review of the scientific literature published between January 2007 and September 2018, using several electronic bibliographic databases and web pages of regulatory agencies, and a review of safety studies performed by the applicant in the last 10 years. The monitoring reports, the scientific publications and the safety studies contained no reports on adverse effects or incidents on the environment.

Conclusion: The information in the annual monitoring reports and the literature review do not contain any indication of potential environmental risks or incidents resulting from import and/or processing of maize Bt11.

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 these 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[26,27] but considers the current GS plan adequate for import and processing of maize Bt11.

6. Overall conclusion

There are no indications that expression of the introduced traits will alter the fitness of maize Bt11. COGEM is of the opinion that import and processing of maize Bt11 pose 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.

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