

**Renewal of authorization for import and processing of maize Bt11:
additional information**

COGEM advice CGM/090310-01

Summary

In May 2008, COGEM advised on the renewal of the authorization for import and processing of the genetically modified maize line Bt11. COGEM was of the opinion that incidental spillage of Bt11 poses negligible risks to the environment. Therefore, COGEM considered the risks associated with import and processing of maize line Bt11 negligible.

In the application concerning the renewal of the authorization new sequence data were provided. The sequence of the insert and its flanking regions was updated. In her previous advice on this application, COGEM had some remarks on the fact that the sequence data in this application differ from the information present in previous applications. However, COGEM concluded that the differences in the sequence data did not affect the outcome of the environmental risk analysis negatively.

In addition, COGEM questioned some aspects of the general surveillance plan provided. The applicant has now provided more and detailed information on monitoring. COGEM considers the revised general surveillance plan sufficient for import and processing of Bt11 maize.

In view of the above COGEM remains of the opinion that import and processing of maize Bt11 poses a negligible risk to the environment.

Introduction

The present application by Syngenta S.A.S., file EFSA/GMO/RX/Bt11, concerns the renewal of the authorization for import and processing of maize line Bt11. Maize line Bt11 has been cultivated in the USA and Canada since 1997. In 1998 maize line Bt11 was authorized for food and feed use in the European Union. Maize line Bt11 contains the *cryIAb* and *pat* genes, which are constitutively expressed. As a result Bt11 is resistant to certain lepidopteran insects and tolerant to glufosinate ammonium containing herbicides.

Previous COGEM advices and examination of additional information

In 1997, COGEM issued a positive advice on import and processing of maize line Bt11 (1). In addition, a positive advice on cultivation of this maize line has been issued in 2005 (2).

In 2008, COGEM advised positively on the renewal of the application for import and processing of maize line Bt11 (3). However, COGEM did question some aspects of the general surveillance plan provided and had some remarks on the fact that the sequence data in the current application differed from the information that was presented in previous applications.

Molecular characterization

The application for the renewal of the authorization for import and processing of maize line Bt11 contained updated sequence information for the insert and the maize genomic regions that flank the insert. Eight nucleotides differed from the sequence in previous applications. Two of the observed differences were located in the two terminators that are present in the insert. Therefore, COGEM concluded that the observed differences resulted from flawed analyses.

In response to questions of the EFSA the applicant provided additional data. The applicant showed that the updated sequence of the insert in Bt11 maize was identical to the sequence of the plasmid that was used for transformation. This indicates that the original sequence data contained flaws.

In 2008, COGEM examined the differences in the sequence data and concluded that the differences in sequence information did not change the outcome of previous environmental risk assessments (3).

General surveillance

The General surveillance plan that was part of the application for renewal of the authorization for import and processing of maize Bt11 did not clarify whether the organizations mentioned agreed to cooperate in the general surveillance. Therefore, COGEM stated that the applicant should ascertain that information on potential adverse effects is obtained.

The applicant provided more and detailed information on monitoring. The applicant, represented by the European association for Bioindustries (EuropaBio), will contact networks of operators (European trade associations COCERAL, UNISTOCK and FEDIOL) annually and will remind them of their agreement to report any unanticipated effects. Each year these networks will inform and remind their member organizations and companies to monitor for potential unanticipated adverse effects and will remind them to report any adverse effect.

COGEM considers the revised general surveillance plan sufficient for import and processing of Bt11 maize.

Conclusion

In her previous advice on the renewal of the authorization for import and processing of Bt11 COGEM was of the opinion that the risks associated with import and processing of maize line Bt11 were negligible. Since this advice additional information has been provided by the applicant. COGEM examined the additional information and concludes that her previous conclusion remains valid, i.e. that import and processing of maize Bt11 poses negligible risks to the environment. In addition, COGEM considers the revised general surveillance plan sufficient for monitoring of import and processing of maize line Bt11.

References

1. COGEM (1997). Advies C/GB/96/M4-01 betreffende het in het handelsverkeer brengen van genetisch gemodificeerde maïs waarin het *cry-IA(b)* gen (Bt-toxine) en het *pat* gen tot expressie komen (CGM/970204-06)
2. COGEM (2005). Assessment of an EFSA opinion on the cultivation of Bt11 maize (CGM/050816-01)
3. COGEM (2008). Renewal of authorization for import and processing of maize Bt11 (CGM/080523-02)