

Aan de minister van
Volkshuisvesting, Ruimtelijke
Ordening en Milieubeheer
Mevrouw dr. J.M. Cramer
POSTBUS 30945
2500 GX Den Haag

DATUM 19 oktober 2009
KENMERK CGM/091019-02
ONDERWERP Advies 'Import and processing of maize Bt11xGA21'

Geachte mevrouw Cramer,

De COGEM is advies gevraagd naar aanleiding van het verschijnen van de EFSA opinie over dossier EFSA/GMO/UK/2007/49, getiteld "Import and processing of maize Bt11xGA21". De COGEM adviseert als volgt.

Samenvatting

In april 2008 heeft de COGEM geadviseerd over import en verwerking van de genetisch gemodificeerde hybride maïslijn Bt11xGA21. Deze maïslijn brengt het *cryIAB* gen tot expressie en is daardoor resistent voor bepaalde insecten die behoren tot de orde van de Lepidoptera. Daarnaast bevat Bt11xGA21 de *pat* en *mepsps* genen, waardoor deze maïslijn tolerant is voor glyfosfaat en glufosinaat-ammonium bevattende herbiciden.

De COGEM heeft in 2008 geconcludeerd dat de milieurisico's van import en verwerking van maïslijn Bt11xGA21 verwaarloosbaar klein zijn. Verwildering van maïsplanten is in Nederland nooit waargenomen. Daarnaast is opslag van maïsplanten in Nederland nagenoeg uitgesloten. Er zijn geen redenen om aan te nemen dat expressie van de geïnserteerde genen het verwilderingspotentieel van maïs vergroot. Bovendien zijn in Europa geen wilde varianten van maïs aanwezig waardoor uitkruising naar wilde varianten niet mogelijk is.

De COGEM plaatste echter wel enkele kanttekeningen bij het aanwezige general surveillance plan. De EFSA opinie heeft de in deze kanttekeningen verwoorde bezwaren niet weggenomen. Echter, het general surveillance plan voldoet wel aan de minimale eisen voor de import en verwerking van maïslijn Bt11xGA21.

Concluderend acht de COGEM de milieurisico's van import en verwerking van maïslijn Bt11xGA21 verwaarloosbaar klein en heeft zij geen bezwaar tegen import en verwerking van deze maïslijn.

De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,

A handwritten signature in black ink, consisting of a large loop on the left and a long horizontal stroke extending to the right.

Prof. dr. ir. Bastiaan C.J. Zoeteman
Voorzitter COGEM

c.c. Drs. H.P. de Wijs
Dr. I. van der Leij

Import and processing of Bt11xGA21 maize

COGEM advice CGM/091019-02

In April 2008, COGEM advised on the import and processing for use in feed and food of the genetically modified maize line Bt11xGA21. This maize line was obtained by conventional cross-breeding of the two parental lines Bt11 and GA21. In response to the EFSA opinion, COGEM was asked whether the comments in her previous advice were sufficiently answered by the currently available information.

The hybrid maize line Bt11xGA21 contains the cry1Ab gene conferring resistance to certain lepidopteran insects. In addition, this maize line contains the pat and mepsps genes, resulting in tolerance to glyphosate and glufosinate ammonium containing herbicides.

COGEM considered the environmental risks associated with import and processing of maize line Bt11xGA21 negligible. During its long domestication process, maize has lost its ability to survive in the wild. In the Netherlands, the appearance of maize volunteers is rare and establishment of volunteers in the wild has never been reported. There are no reasons to assume that the introduced traits will increase the potential of maize to establish feral populations. The genes introduced in Bt11xGA21 cannot spread to closely related species since wild relatives of maize are not present in Europe.

In her previous advice on maize line Bt11xGA21 COGEM questioned some aspects of the provided general surveillance plan. COGEM upholds her remarks which are meant to improve the general surveillance plan. However, the provided general surveillance plan meets the minimal requirements for import and processing of maize Bt11xGA21.

In conclusion, COGEM remains of the opinion that import and processing of maize Bt11xGA21 poses a negligible risk to the environment and has no objections against an authorization for import and processing of Bt11xGA21.

Introduction

The present application by Syngenta S.A.S., file EFSA/GMO/UK/2007/49, concerns the import and processing of maize line Bt11xGA21 for use in feed and food. Maize line Bt11xGA21 was obtained by conventional cross-breeding of the two parental lines Bt11 and GA21. The hybrid maize line Bt11xGA21 contains the *cry1Ab*, *pat* and *mepsps* genes, which are constitutively expressed. As a result, Bt11xGA21 is resistant to certain lepidopteran insects and tolerant to glyphosate and glufosinate ammonium containing herbicides.

Previous COGEM advice

In April 2008, COGEM advised on import and processing for use in feed and food of the genetically modified maize line Bt11xGA21¹. COGEM concluded that the molecular analysis of Bt11xGA21 does not indicate that import and processing of this line would pose a risk to the environment.

Furthermore, maize has lost the ability to survive in the wild and needs human intervention to disseminate its seed. Maize kernels exhibit no dormancy and can only survive within a narrow range of climatic conditions. Maize is very sensitive to weed competition and cannot persist as a weed^{2,3}. In the Netherlands, volunteers are rarely found and establishment of maize plants in the wild has never been observed. In addition, there are no reasons to assume that the introduced traits will increase the potential of Bt11xGA21 to establish feral populations in case of incidental spillage.

In view of the above COGEM considered the environmental risks associated with import and processing of maize line Bt11xGA21 negligible.

General surveillance

COGEM did question some aspects of the general surveillance plan. The applicant mentioned several organizations (COCERAL, UNISTOCK and FEDIOL) that represent organizations that import or use viable maize. It was unclear whether these organizations agreed to cooperate in the general surveillance of Bt11xGA21 and information concerning their expertise in dealing with environmental matters was not given. COGEM is of the opinion that the applicant should ascertain that information on potential adverse effects is obtained. In addition, COGEM would prefer independent organizations which have environmental expertise to be involved in general surveillance.

Furthermore, according to the applicant indirect or delayed effects would be reported at the stage of re-evaluation or at the end of a given consent. As stated before, in COGEM's opinion all observed effects, including indirect and delayed effects, should be reported annually.

Re-evaluation of the information

In her previous advice on the import and processing for use in feed and food of the genetically modified maize line Bt11xGA21 COGEM concluded that import and processing of maize Bt11xGA21 poses a negligible risk to the environment. COGEM did however question some aspects of the provided general surveillance plan.

Recently, the EFSA GMO panel published her scientific opinion on the import and processing of maize line Bt11xGA21. EFSA concluded that it was unlikely that maize Bt11xGA21 would have an adverse effect on human and animal health or on the environment in the context of its intended use⁴. The ministry of VROM asked COGEM whether the comments in her previous advice on maize Bt11xGA21 were sufficiently answered by the currently available information.

The applicant did not revise the general surveillance plan. Therefore, COGEM upholds her remarks which were meant to improve the general surveillance plan. However, the general surveillance plan provided meets the minimal requirements for import and processing of maize Bt11xGA21.

Conclusion

In conclusion, COGEM remains of the opinion that import and processing of maize Bt11xGA21 poses a negligible risk to the environment.

References

1. COGEM (2008) Advies import en verwerking maïslijn Bt11xGA21. Advies CGM/080417-01.
2. OECD (2003). Consensus document on the biology of *Zea mays* subsp. *mays* (Maize)
3. Crop Protection Compendium (2004). *Zea mays* (maize). CD-ROM edition, © Cab International 2004, Wallingford, UK.
4. EFSA GMO panel 2009. Scientific Opinion on application (EFSA-GMO-UK-2007-49) for the placing on the market of the insect resistant and herbicide tolerant genetically modified maize Bt11xGA21 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Seeds. EFSA Journal 2009; 7(9):1319