

Aan de minister van  
Volkshuisvesting, Ruimtelijke  
Ordening en Milieubeheer  
Mevrouw J.C. Huizinga-Heringa  
Postbus 30945  
2500 GX Den Haag

**DATUM** 08 juni 2010  
**KENMERK** CGM/100608-02  
**ONDERWERP** Advies naar aanleiding van de EFSA opinie over import en verwerking van maïslijn Bt11 x MIR604

Geachte mevrouw Huizinga-Heringa,

De COGEM is gevraagd of het verschijnen van de EFSA opinie aangaande dossier EFSA/GMO/UK/2007/50 aanleiding geeft tot herziening van het eerder afgegeven advies betreffende import en verwerking van maïslijn Bt11 x MIR604. De COGEM adviseert u als volgt.

### **Samenvatting**

In mei 2008 heeft de COGEM geadviseerd over import en verwerking van de genetisch gemodificeerde hybride maïslijn Bt11 x MIR604. Maïslijn Bt11 x MIR604 brengt de genen *cry1Ab*, *mcry3A*, *pat*, and *pmi* tot expressie. Als gevolg hiervan is de plant resistent tegen bepaalde insecten behorende tot de orde der Coleoptera en Lepidoptera en tolerant voor glufosinaat-ammonium bevattende herbiciden. De COGEM concludeerde dat de milieurisico's van import en verwerking van maïslijn Bt11 x MIR604 verwaarloosbaar klein zijn. Wel plaatste de COGEM enkele opmerkingen bij het 'general surveillance' plan. Daarnaast sprak zij haar zorg uit over het feit dat bij eerdere aanvragen voor de ouderlijnen incorrecte sequentiedata aangeleverd waren. Overigens gaven de gereviseerde sequentiedata geen reden om te veronderstellen dat import en verwerking van Bt11 x MIR604 tot milieurisico's leidt.

Naar aanleiding van het verschijnen van de EFSA opinie ziet de COGEM geen reden om haar eerder afgegeven advies te herzien. Hoewel de COGEM het door de aanvrager opgestelde 'general surveillance' plan onderschrijft, ziet zij enkele punten voor verbetering. Onlangs heeft de COGEM het door de EFSA uitgebrachte 'Conceptrichtsnoer milieurisicoanalyse van genetisch gemodificeerde planten' becommentarieerd. Daarmee heeft zij de EFSA rechtstreeks op de hoogte gebracht van haar visie op de criteria waaraan een 'general surveillance' plan dient te voldoen, inclusief de betreffende verbeterpunten. De COGEM hoopt dat in het vervolg de EFSA dezelfde eisen voor het 'general surveillance' plan zal hanteren als de COGEM.

Concluderend acht de COGEM de milieurisico's van import en verwerking van maïslijn Bt11 x MIR604 verwaarloosbaar klein en heeft zij geen bezwaar tegen import en verwerking van deze maïslijn. De COGEM wijst erop dat een beoordeling van de voedselveiligheid, inclusief incidentele consumptie, door een andere instantie wordt uitgevoerd en geen onderdeel is van de risicoanalyse in dit advies.

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

# **Additional advice on import and processing of genetically modified maize Bt11 x MIR604**

## **COGEM advice CGM/100608-02**

### **Introduction**

Recently, EFSA published her opinion for placing on the market for feed and food uses, import and processing of maize Bt11 x MIR604. EFSA concluded that the import and processing of Bt11 x MIR604 is unlikely to have any adverse effect on human and animal health and the environment.

The Netherlands' Ministry of Housing, Spatial Planning and the Environment (VROM) asked COGEM whether the opinion of the EFSA GMO panel gives reason to reconsider her previous advice.

Simultaneously, COGEM evaluated her advice on import and processing of hybrid maize MIR604 x GA21 in response to the published EFSA opinion concerning this line. Because both hybrid lines are interrelated, the reconsiderations are mostly identical.

### *Maize line Bt11 x MIR604*

Maize line Bt11 x MIR604 contains the *cry1Ab*, *mcry3A*, *pat*, and *pmi* genes which are constitutively expressed. As a result Bt11 x MIR604 is resistant to certain lepidopteran and coleopteran insects, and tolerant to glufosinate-ammonium containing herbicides. The *pmi* gene is used as a selective marker and enables the plant to use mannose as a sole carbon source.

### **Previous COGEM advice**

COGEM advised on maize lines Bt11 and MIR604 in 2005, 2008 and 2009.<sup>1,2,3</sup> In 2008, COGEM advised positively on the import and processing of maize Bt11 x MIR604.<sup>4</sup> However, COGEM commented on the information regarding the molecular characterization and questioned some aspects of the general surveillance plan provided.

Strikingly, in the application concerning import and processing of Bt11 x MIR604 the sequence-data of parent lines Bt11 and MIR604 were revised. COGEM was of the opinion that both the original and the revised sequence data gave no reason to expect any adverse effects on the environment. However, COGEM pointed out that it is of the utmost importance that data provided by the applicant are correct in order to perform a proper risk assessment.

Several organizations representing trade organizations that import or use viable maize were mentioned in the general surveillance plan concerning import and processing of Bt11 x MIR604. According to the applicant these organizations were 'well-placed' to detect unanticipated effects on human health or the environment. However, information on their expertise in the field of environmental issues was not given and it was unclear whether these organizations agreed to cooperate in the general surveillance. In her advice COGEM stated to prefer independent organizations to be involved in general surveillance. Furthermore, COGEM was of the opinion

that the applicant should ascertain that information on potential adverse effects was obtained. 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. In COGEM's opinion all effects observed, including indirect and delayed effects, should be reported annually.

### **Advice**

In response to the recently published EFSA opinion, COGEM iterates her previously issued positive advice on import and processing of maize Bt11 x MIR604 and considers the risks associated with import and processing of maize line Bt11 x MIR604 negligibly small.

EFSA has published guidance and scientific opinion on the Post-Market Environmental Monitoring (PMEM).<sup>5</sup> The EFSA GMO panel is of the opinion that the information supplied by the applicant is in line with the guidance on PMEM. COGEM questions some aspects on the general surveillance plan supplied by the applicant. In the framework of the public consultation of the European member states and stakeholders on the EFSA draft guidance for environmental risk assessment of genetically modified plants, COGEM recently informed EFSA on her remarks concerning criteria for general surveillance and hopes that these will be acknowledged.<sup>6</sup>

As stated before, the revised sequence data gives no reason to expect any adverse effects on the environment. However, COGEM is of the opinion that data on molecular analyses have to be correct. If the information provided by the applicant turns out to be incorrect later, this can seriously harm the confidence of the competent authorities assessing this information. Moreover, this also applies to the confidence of European citizens in (future) consumer products containing GMOs and indirectly in the confidence in the European and national governments and the industry involved.

COGEM points out that a food/feed safety assessment is carried out by other organizations. Therefore, COGEM abstains from advice on the potential risks of incidental consumption.

### **References**

1. COGEM (2005). Advice import and processing of maize variety MIR604 (EFSA/GMO/UK/2005/11). Advies CGM/051122-02
2. COGEM (2008). Advies hernieuwing vergunning import en verwerking maislijn Bt11 (EFSA/GMO/RX/Bt11). Advies CGM/080523-02
3. COGEM (2009). Renewal of authorization for import and processing of maize Bt11: additional information. Advies CGM/090310-01
4. COGEM (2008). Advice import and processing of maize Bt11 x MIR604. Advies CGM/080521-03
5. EFSA (2006). Guidance document for the risk assessment of genetically modified plants and derived food and feed, prepared by the Scientific Panel on Genetically Modified organisms of the European Food safety Authority
6. COGEM (2010). Reactie op EFSA conceptrichtsnoer milieurisicoanalyse van gg-planten. Advies CGM/100429-05