

Aan de minister van
Volkshuisvesting, Ruimtelijke
Ordening en Milieubeheer
Mevrouw J.C. Huizinga-Heringa
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DATUM 08 juni 2010
KENMERK CGM/100608-01
ONDERWERP Advies naar aanleiding van de EFSA opinie over import en verwerking van maïslijn
MIR604 x GA21

Geachte mevrouw Huizinga-Heringa,

De COGEM is gevraagd of het verschijnen van de EFSA opinie aangaande dossier EFSA/GMO/UK/2007/48 aanleiding geeft tot herziening van het eerder afgegeven advies betreffende import en verwerking van maïslijn MIR604 x GA21. De COGEM adviseert u als volgt.

Samenvatting

In mei 2008 heeft de COGEM geadviseerd over import en verwerking van de genetisch gemodificeerde hybride maïslijn MIR604 x GA21. Maïslijn MIR604 x GA21 brengt de genen *mcry3A*, *mepsps* en *pmi* tot expressie. Als gevolg hiervan is de plant resistent tegen bepaalde insecten behorende tot de orde der Coleoptera en tolerant voor glyfosaat bevattende herbiciden. De COGEM concludeerde dat de milieurisico's van import en verwerking van maïslijn MIR604 x GA21 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 een eerdere aanvraag voor ouderlijn MIR604 incorrecte sequentiedata aangeleverd waren. Overigens gaven de gereviseerde sequentiedata geen reden om te veronderstellen dat import en verwerking van MIR604 x GA21 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 MIR604 x GA21 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, stylized loop followed by a horizontal line that ends in a small hook.

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 MIR604 x GA21

COGEM advice CGM/100608-01

Introduction

Recently, EFSA published her opinion for placing on the market for feed and food uses, import and processing of maize MIR604 x GA21. EFSA concluded that the import and processing of MIR604 x GA21 is unlikely to have any adverse effect on human and animal health and the environment.

Maize line MIR604 x GA21 contains the *mcry3A*, *mepsps*, and *pmi* genes which are constitutively expressed. As a result MIR604 x GA21 is resistant to certain coleopteran insects and tolerant to glyphosate containing herbicides. The *pmi* gene is used as a selective marker and enables the plant to use mannose as a sole carbon source.

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.

Previous COGEM advice

COGEM advised on maize lines MIR604 and GA21 in 2005, 2006 and 2008.^{1,2,3,4} In 2008, COGEM advised positively on the import and processing of maize MIR604 x GA21.⁵ 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 MIR604 x GA21 the sequence-data of maize line 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.

In the general surveillance plan concerning import and processing of MIR604 x GA21 several organizations were mentioned representing trade organizations that import or use viable maize. 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 MIR604 x GA21 and considers the risks associated with import and processing of maize line MIR604 x GA21 negligibly small.

EFSA has published guidance and scientific opinion on the Post-Market Environmental Monitoring (PMEM).⁶ 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.⁷

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

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3. COGEM (2008). Toelichting advies GA21. Advies CGM/080117-02
4. COGEM (2008). Cultivation of genetically modified maize line GA21. Advies CGM/081219-02
5. COGEM (2008). Advice import and processing of maize MIR604 x GA21. Advies CGM/080521-02
6. 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
7. COGEM (2010). Reactie op EFSA conceptrichtsnoer milieurisicoanalyse van gg-planten. Advies CGM/100429-05