COMMISSIE
COGEM
GENETISCHE
MODIFICATIE

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

DATUM	20 oktober 2009
KENMERK	CGM/091020-01
ONDERWERP	Advies naar aanleiding van de EFSA opinie over import en verwerking van hybride maïslijn MON89034xNK603.

Geachte mevrouw Cramer,

De COGEM is advies gevraagd naar aanleiding van het verschijnen van de EFSA opinie betreffende het dossier EFSA/GMO/NL/2007/38, getiteld "Import and processing of MON89034xNK603". De COGEM adviseert als volgt.

Samenvatting

In oktober 2007 heeft de COGEM negatief geadviseerd over import en verwerking van de genetisch gemodificeerde hybride maïslijn MON89034xNK603. Alhoewel zij de kans zeer klein achtte dat import en verwerking van maïslijn MON89034xNK603 tot risico's voor mens en milieu zou leiden, voldeed de moleculaire karakterisering van ouderlijn MON89034 niet. Om die reden kon zij ook niet positief adviseren over MON89034xNK603. Ook wees de COGEM erop dat het general surveillance plan van MON89034xNK603 onvolledig was uitgewerkt.

Sinds 2008 onthoudt de COGEM zich van een risicobeoordeling voor incidentele consumptie als het ggo al door andere instanties op voedselveiligheid wordt beoordeeld. Daarnaast heeft de COGEM de afgelopen drie jaar veel ervaring opgedaan met de risicobeoordeling bij markttoelatingen. Dit heeft ertoe geleid dat de COGEM onlangs haar criteria met betrekking tot de moleculaire karakterisering van gg-gewassen heeft heroverwogen. De COGEM heeft in januari 2009 geconcludeerd dat de moleculaire karakterisering van MON89034 voldoet aan deze herziene criteria. Het eerdere bezwaar voor MON89034xNK603 komt daarmee te vervallen. Daarnaast heeft de aanvrager een nieuw general surveillance plan aangeleverd voor MON89034xNK603. De COGEM acht dit general surveillance plan voldoende voor de import en verwerking van maïslijn MON89034xNK603.

Concluderend acht de COGEM de milieurisico's van import en verwerking van maïslijn MON89034xNK603 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,

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

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

Additional advice on the import and processing of MON89034xNK603

COGEM advice CGM/091020-01

Summary

In October 2007, COGEM advised negatively on the import and processing for use in feed and food of genetically modified maize line MON89034xNK603. The hybrid maize line MON89034xNK603 contains the genes cry1A.105 and cry2Ab2, conferring resistance to certain lepidopteran insects. In addition, this maize line contains the genes cp4 epsps and cp4 epsps L214P, resulting in tolerance to glyphosate containing herbicides.

In her previous advice, COGEM concluded that incidental spillage of MON89034xNK603 most likely poses negligible risks to man and the environment. However, the molecular characterization of parental maize line MON89034 was incomplete. Therefore, she could not issue a positive advice on the import and processing of MON89034xNK603. COGEM also had comments on the general surveillance plan that was provided. In response to the recently published EFSA opinion, the ministry of VROM asked COGEM whether the comments in her previous advice were sufficiently answered by the currently available information.

Since 2008, COGEM abstains from advice on the risks of incidental consumption when food safety is already assessed by a different authority. Moreover, COGEM has gathered extensive experience with the risk assessment for commercial releases of genetically modified crops. In view of this, COGEM recently reconsidered the elements of the molecular characterization which are needed for the environmental risk analysis.

In January 2009, COGEM concluded that the molecular characterization of MON89034 fulfilled the requirements as set by COGEM for the environmental risk analysis. In addition, obtained information on the A. tumefaciens strain ABI removed previous questions on this subject by COGEM. The applicant also presented a revised general surveillance plan for import and processing of maize MON89034xNK603 which meets the requirements for import and processing of this maize line.

In view of the above, COGEM withdraws her previous objections concerning the import and processing of maize line MON89034xNK603.

Introduction

The present application by Monsanto S.A., file EFSA/GMO/NL/2007/38, concerns the import and processing of hybrid maize line MON89034xNK603 for use in feed and food. This line contains the *cry1A.105, cry2Ab2, cp4 epsps* and *cp4 epsps L214P* genes, which are constitutively expressed. As a result MON89034xNK603 is resistant to certain lepidopteran insects and tolerant to glyphosate containing herbicides.

Previous COGEM advices

In October 2007, COGEM issued a negative advice on the import and processing for use in feed and food of genetically modified maize line MON89034xNK603[1]. COGEM concluded that the

molecular characterization of maize MON89034 did not meet its standards and therefore could not advise positively on import and processing of MON89034xNK603. In addition, information was lacking on the *Agrobacterium tumefaciens* strain that was used for the genetic modification. COGEM was, however, of the opinion that incidental spillage of MON89034xNK603 most likely poses negligible risks to man and the environment because of the following reasons.

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 MON89034xNK603 to establish feral populations in case of incidental spillage.

COGEM also had some comments on the general surveillance plan. The applicant stated that general surveillance would be performed either by selected networks and/or specific company stewardship programs. However, the applicant did not indicate which networks or organizations would be involved in general surveillance and did not describe how the general surveillance would be organized. In addition, the applicant stated that key stakeholders and networks are requested to participate in the general surveillance plan and ask them to inform the consent holder if any unanticipated adverse effects occur. However, it was unclear how these adverse effects are monitored if key stakeholders and networks do not assist. In addition, the applicant made a distinction between reporting direct and indirect effects in the monitoring plan. According to the applicant direct effects would be reported annually, whereas indirect effects would only be reported at the stage of re-evaluation or at the end of a given permit.

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Advice

In response to the recently published EFSA opinion, COGEM was asked whether the comments in her previous advice were sufficiently answered by the currently available information.

In 2008 COGEM re-evaluated her criteria concerning the molecular characterization of these crops. In January 2009 COGEM issued a positive advice on the import and processing of maize MON89034.[4] COGEM concluded that the molecular characterization of MON89034 fulfilled the revised requirements as set by COGEM for the environmental risk analysis.[5]

After a detailed search for publicly available information on strain ABI, COGEM found information about the ABI strain used by the applicant. COGEM was of the opinion that this information gave enough reason to consider the presence of additional T-DNA regions in strain ABI very unlikely. COGEM's previous objections concerning the import and processing of maize line MON89034xNK603 were therefore withdrawn.

The applicant provided a revised general surveillance plan. Following the initial placing on the market, general surveillance reports on direct and indirect effects are submitted on an annual basis. COGEM considers the revised general surveillance plan sufficient for monitoring of import and processing of MON89034xNK603 maize.

In view of the above, COGEM withdraws its earlier objections and is of the opinion that import and processing of MON89034xNK603 poses a negligible risk to the environment.

References

1. COGEM 2007. Advies import en verwerking van hybride maïslijn MON89034xNK603 CGM/090126-01.
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. COGEM 2009. Advies moleculaire karakterisering van maïs MON89034 CGM/090126-01.
5. COGEM 2008. Signalering moleculaire karakterisering CGM/081219-01