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Ruimtelijke Ordening en Milieubeheer
Mevrouw dr. J.M. Cramer
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DATUM 26 januari 2009
KENMERK CGM/090126-01
ONDERWERP Advies moleculaire karakterisering van maïs MON89034 (EFSA/GMO/NL/2007/37)

Geachte mevrouw Cramer,

Naar aanleiding van aanvullende informatie omtrent dossier EFSA/GMO/NL/2007/37, getiteld "Import and processing of maize MON89034", adviseert de COGEM als volgt.

Samenvatting:

In oktober 2007 heeft de COGEM een negatief advies uitgebracht over import en verwerking van genetisch gemodificeerde maïs MON89034. Alhoewel zij de kans zeer klein achtte dat import en verwerking van maïslijn MON89034 tot risico's voor mens en milieu zou leiden, stelde zij dat de moleculaire karakterisering van de maïslijn onvolledig was. Ook wees de COGEM erop dat het monitoringsplan onvoldoende was uitgewerkt.

In 2008 heeft de European Food Safety Authority (EFSA) de aanvrager om aanvullende informatie gevraagd. De aanvrager heeft vervolgens een nieuw monitoringsplan aangeleverd. De COGEM acht dit monitoringsplan voldoende bij import en verwerking van deze maïslijn. De aanvullende informatie bevatte geen gegevens met betrekking tot de andere opmerkingen die de COGEM in haar advies had over de moleculaire karakterisering van MON89034. Echter, sinds 2008 onthoudt de COGEM zich van de beoordeling van de risico's van incidentele consumptie en vraat wanneer er een voedselveiligheidsbeoordeling wordt uitgevoerd door andere instanties. Bovendien heeft de COGEM recent heroverwogen welke aspecten van de moleculaire karakterisering noodzakelijk zijn voor het beoordelen van milieurisico's. De moleculaire karakterisering van MON89034 voldoet aan de criteria die de COGEM onlangs heeft opgesteld. Daarnaast neemt publiek verkregen informatie de eerdere vragen over *Agrobacterium tumefaciens* stam ABI weg.

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 er in Europa geen wilde verwanten van maïs aanwezig waardoor uitkruising niet mogelijk is.

Gezien het bovenstaande acht de COGEM de milieurisico's van import en verwerking van maïslijn MON89034 verwaarloosbaar klein.

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. B.C.J. Zoeteman
Voorzitter COGEM

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

Molecular characterization of maize MON89034

COGEM advice CGM/090126-01

Summary

*In October 2007, COGEM advised negatively on the import and processing for use in feed and food of genetically modified maize MON89034. COGEM was of the opinion that incidental spillage of maize line MON89034 would probably not pose a risk to the environment. However, COGEM pointed out that putative polypeptides in the entire border regions should have been analyzed for similarity to allergens and toxins. In addition, more detailed information should have been provided on the *Agrobacterium tumefaciens* strain that was used for the genetic modification. COGEM also had comments on the General Surveillance plan that was provided.*

In 2008, the European Food Safety Authority (EFSA) requested the applicant for additional information. A revised general surveillance plan was presented by the applicant. COGEM considers this general surveillance plan sufficient for import and processing of MON89034 maize.

*No additional information was provided on the analysis of putative polypeptides in the border regions. Since 2008, COGEM abstains from advice on the potential risks of incidental consumption in case a food/feed assessment is already carried out by other organizations. This is the case for MON89034. At the publication of this advice, the outcome of the food/feed assessment was not known to COGEM. In addition, COGEM recently reconsidered the elements of the molecular characterization which are needed for the environmental risk analysis and formulated criteria for the molecular characterization of commercial releases of genetically modified crops. The molecular characterization of MON89034 maize fulfils 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.*

In the Netherlands, no wild relatives of maize are present and establishment of maize plants in the wild has never been observed. There are no reasons to assume that the inserted traits will increase the potential of the maize line to establish feral populations. In addition, the appearance of volunteers is very rare under Dutch conditions.

In view of the above COGEM is of the opinion that import and processing of maize MON89034 poses a negligible risk to the environment.

Previous COGEM advice

The application concerns the commercial import for food and feed purposes of maize event MON89034. This maize line has been genetically modified by introduction and expression of

the *cryIA.105* and *cry2Ab2* genes, which confer resistance to certain lepidopteran insects, such as the fall armyworm, the black cutworm and the corn earworm.

Molecular characterization

In October 2007, COGEM advised on this application and concluded that the molecular characterization was incomplete (1). COGEM stated that the entire T-DNA border regions should have been examined by bioinformatic analyses.

The PV-ZMIR245 plasmid contained, according to the applicant, left and right border regions of about 350 base pairs (bp). The applicant stated that these regions contain a 25 bp left or a 24 bp right border sequence used for transfer of the T-DNA. The remaining sequence of these large border regions had not been specified by the applicant. Furthermore, a molecular rearrangement took place, so that two left border regions are present in MON89034. These left border regions are truncated to about 235 base pairs.

The applicant analyzed the putative polypeptides present at the junctions between the genomic maize DNA and the T-DNA for homology to known proteins, such as allergens or toxins. However, the applicant does not clarify which elements are present in the large border regions that have been inserted in MON89034. The putative polypeptides in these entire border regions were not analyzed for similarity to allergens and toxins.

Moreover, a reference to *A. tumefaciens* strain ABI, which was used for genetic modification of MON89034, was not provided. The applicant stated that in addition to plasmid PV-XMIR245, a helper plasmid is present in strain ABI. According to the applicant this helper plasmid did not contain any T-DNA, but allowed for the transfer of T-DNA I and II present in PV-ZMIR245. However, the applicant did not indicate whether other plasmids, that may contain additional T-DNA regions, are present or absent in the ABI strain. If additional T-DNA regions are present in the ABI strain these unknown T-DNA regions could be transferred into the maize genome. To ascertain that additional T-DNA regions are not present in *A. tumefaciens* strain ABI COGEM asked for more information on this strain.

General surveillance

COGEM also made comments on the general surveillance plan. The applicant stated that general surveillance will be performed either by selected networks and/or specific company stewardship programs. The permit holder would request key stakeholders and networks to participate and ask them to be informed if any unanticipated adverse effects occur. However, it was unclear to COGEM how these adverse effects are monitored if key stakeholders and networks fail to cooperate. In COGEM's opinion the permit holder should ascertain that information on adverse effects is also obtained when key stakeholders and networks do not participate.

In addition, the applicant made a distinction between reporting direct and indirect effects in the monitoring plan. According to the applicant direct effects will be reported annually,

whereas indirect effects will only be reported at the stage of re-evaluation or at the end of a given permit. COGEM stated that both direct and indirect effects should be reported annually.

Environmental risk assessment

During its long domestication process, maize has lost its ability to survive in the wild. In the Netherlands, the appearance of maize volunteers is very 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. In addition, the introduced genes cannot spread to closely related species, since wild relatives of maize are not present in Europe. Therefore, COGEM was of the opinion that incidental spillage of maize line MON89034 would probably not pose a risk to human health and the environment.

Conclusion

In her previous advice on MON89034 COGEM considered the chance negligible, that import and processing of this maize line would pose a risk to the environment. Moreover, COGEM was of the opinion that the risk for food safety was minimal. However, this opinion could not be substantiated because the molecular characterization was incomplete.

Evaluation of the additional information

Recently, the EFSA GMO Panel published her scientific opinion on the import and processing of maize MON89034, considering the comments of member states and additional information provided by the applicant. Based on this information, EFSA concluded that the import and processing of MON89034 poses no risk to human health or the environment. The ministry of VROM asked COGEM whether the additional information gives reason to reconsider her former advice.

Molecular characterization

In her previous advice COGEM indicated that putative polypeptides encoded by the T-DNA border regions should have been analyzed for similarity to allergens and toxins. However, no additional information was provided. Since last year COGEM abstains from advice on the potential risks of incidental consumption in case a food/feed assessment is already carried out by other organizations, which is the case for this application. At the issue of this advice, the outcome of the food/feed assessment was not known to COGEM.

In addition, COGEM recently reconsidered the elements of the molecular characterization that are needed for the environmental risk analysis and formulated revised criteria for the molecular characterization of commercial releases of GM crops (2). The molecular characterization of MON89034 maize fulfils the requirements as set by COGEM for the environmental risk analysis.

In addition, COGEM was of the opinion that the applicant should provide information about the presence or absence of other plasmids and additional T-DNA regions in *A. tumefaciens* strain ABI. No additional information was provided on *A. tumefaciens* strain ABI.

However, COGEM performed a search for publicly available information on strain ABI. This search revealed a description of strain ABI in a patent application (3) and in a file for an application on maize MON88017 (4). These sources specify details of the helper plasmid and also indicate more frequent use. COGEM is of the opinion that this information gives enough reason to consider the presence of additional T-DNA regions in strain ABI very unlikely.

The general surveillance plan

The applicant provided more and detailed information on monitoring. 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 import and processing of MON89034 maize.

Conclusion

The molecular characterization of MON89034 meets the criteria that were recently formulated by COGEM. Considering the obtained information on strain *A. tumefaciens* ABI, the presence of additional T-DNA regions in this strain is very unlikely. In addition, COGEM considers the revised general surveillance plan sufficient for monitoring of import and processing of MON89034 maize.

In view of the above, COGEM is of the opinion that import and processing of maize MON89034 poses a negligible risk to the environment.

References

1. COGEM (2007). Import and processing of maize MON89034 (CGM/071022-02)
2. COGEM (2008). Heroverweging criteria voor de moleculaire karakterisering bij markttoelatingen van gg-gewassen (CGM/081219-01)
3. Internet: <http://www.freepatentsonline.com/7067719.html> (26-01-2009)
4. COGEM (2008). Cultivation of genetically modified maize line MON88017 (CGM/081112-02)