

Additional advice on the import and processing of MON89034 x MON88017

COGEM advice CGM/100421-02

Introduction

Recently, the EFSA GMO Panel published her scientific opinion on the import and processing of maize MON89034 x MON88017, 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 x MON88017 is unlikely to have any adverse effect on human and animal health and the environment. The Ministry of Housing, Spatial Planning and the Environment (VROM) asked COGEM whether the additional information gives reason to reconsider her previous advice.

Previous COGEM advice

In 2007, COGEM advised negatively on the import and processing of maize line MON89034 x MON88017.¹ Although COGEM was of the opinion that import of MON89034 x MON88017 most likely poses negligible risks to man and the environment, the molecular analysis of parental line MON89034 did not meet the requirements at that time. The large T-DNA border sequences at the 5' and the 3' end of the insert were not fully analyzed. COGEM was of the opinion that sequences coding for putative polypeptides present in the entire border sequences should have been analysed for similarity to allergens or toxins. In addition, more detailed information should have been provided on the *Agrobacterium tumefaciens* strain that was used for the genetic modification. COGEM also judged the General Surveillance plan to be incomplete.

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. Furthermore, in 2008 COGEM re-evaluated her criteria concerning the molecular characterization of genetically modified crops.² In January 2009, COGEM issued a positive advice on the import and processing of maize MON89034.³ COGEM concluded that the molecular characterization of MON89034 fulfilled the revised requirements as set by COGEM for the environmental risk analysis. These criteria match the EFSA criteria.^{4, 5} In addition, COGEM performed a detailed search for publicly available information on the *A. tumefaciens* strain ABI. The obtained information removed previous questions on this subject. Based on this information, COGEM concluded that import and processing of MON89034 poses a negligible risk to the environment.

Advice

The applicant provided a revised General Surveillance plan concerning maize line MON89034 x MON88017. The General Surveillance plan states that unanticipated adverse effects will be monitored by existing monitoring systems which include the authorization holder and operators involved in the handling and use of viable MON89034 x MON88017 maize. In 2010, COGEM

formulated criteria for General Surveillance plans concerning applications for import and cultivation of GM crops⁶ Although the General Surveillance plan could be improved by a guarantee that operators will monitor for unanticipated effects, COGEM considers the current General Surveillance plan sufficient for import and processing of maize line MON89034 x MON88017.

In view of the above, COGEM withdraws its earlier objections and is of the opinion that import and processing of MON89034 x MON88017 poses a negligible risk to the environment.

References

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3. COGEM (2009). Advies moleculaire karakterisering van maïs MON89034. COGEM advies CGM/090126-01
4. EFSA (2009). Public Consultation on the Updated Guidance Document of the Scientific Panel on Genetically Modified Organisms (GMO) for the risk assessment of genetically modified plants and derived food and feed. Scientific Report of EFSA
5. EFSA (2006). Guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed
6. COGEM (2010). General Surveillance. COGEM signalering CGM/100226-01