COMMISSIE
COGEM
GENETISCHE
MODIFICATIE

BEZOEKADRES:
A. VAN LEEUWENHOEKLAAN 9
3721 MA BILTHOVEN

POSTADRES:
POSTBUS 578
3720 AN BILTHOVEN

TEL.: 030 274 2777
FAX: 030 274 4476
INFO@COGEM.NET
WWW.COGEM.NET

Aan de staatssecretaris van
Infrastructuur en Milieu
Mevrouw S.A.M. Dijksma
Postbus 20901
2500 EX Den Haag

DATUM 14 augustus 2017

KENMERK CGM/170814-01

ONDERWERP Advies import en verwerking gg-maïs MON89034x1507xMON88017x59122xDAS-40278-9

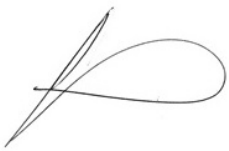
Geachte mevrouw Dijksma,

Naar aanleiding van een adviesvraag betreffende de vergunningaanvraag voor de import en verwerking van de genetisch gemodificeerde maïs MON89034x1507xMON88017x59122x DAS-40278-9 (EFSA/GMO/NL/2013/113), ingediend door Dow AgroSciences LLC, deelt de COGEM u het volgende mee.

Samenvatting:
De COGEM is gevraagd te adviseren over de mogelijke milieurisico's van import en verwerking van de genetisch gemodificeerde (gg-) maïslijn MON89034x1507x MON88017x59122xDAS-40278-9. In deze lijn komen de genen *pat, cp4-epsps* en *aad-1* tot expressie, waardoor de plant tolerant is voor bepaalde herbiciden. Ook komen de genen *cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1* en *cry35Ab1* tot expressie in deze lijn, waardoor de plant resistent is tegen bepaalde vlinder- en keverachtigen. De COGEM heeft eerder positief geadviseerd over import en verwerking van elk van de vijf gg-ouderlijnen die met elkaar zijn gekruist om deze gg-maïslijn te verkrijgen. Verwildering van maïsplanten is in Nederland nooit waargenomen. Maïsplanten uit gemorst zaad (opslagplanten) worden hier nauwelijks aangetroffen. Bovendien zijn er in Nederland geen wilde verwanten van maïs aanwezig, waardoor de ingebrachte sequenties zich niet naar andere soorten kunnen verspreiden.
De moleculaire karakterisering van MON89034x1507xMON88017x59122xDAS-40278-9 voldoet aan de eisen van de COGEM. Er zijn geen redenen om aan te nemen dat expressie van de ingebrachte genen ervoor zorgt dat deze gg-maïslijn zou kunnen verwilderen.
Gezien het bovenstaande acht de COGEM de milieurisico's van de import en verwerking van de gg-maïslijn MON89034x1507xMON88017x59122xDAS-40278-9, en sub-combinaties hiervan, verwaarloosbaar klein.
Omdat een voedselveiligheidsbeoordeling door andere instanties wordt uitgevoerd, heeft de COGEM bij deze vergunningaanvraag de risico's van incidentele consumptie niet beoordeeld.

De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,



Prof. dr. ing. Sybe Schaap
Voorzitter COGEM

c.c. Drs. H.P. de Wijs, Hoofd Bureau ggo
Mr. J.K.B.H. Kwisthout, Ministerie van IenM
Ing. M.A.C. Möllers, Food-Feed loket

Import and processing of genetically modified maize MON89034x1507xMON88017x59122xDAS-40278-9

COGEM advice CGM/170814-01

- The present application (EFSA/GMO/NL/2013/113) concerns the authorisation for import and processing for use in feed and food of genetically modified (GM) maize MON89034x1507xMON88017x59122xDAS-40278-9 and GM maize consisting of sub-combinations of the parental GM maize lines;
- Maize MON89034x1507xMON88017x59122xDAS-40278-9 was produced by conventional crossbreeding of the five GM parental maize lines;
- COGEM advised positively on the import and processing of all five parental lines;

- The molecular characterisation of MON89034x1507xMON88017x59122xDAS-40278-9 has been updated and meets the criteria of COGEM;
- The updated molecular characterisation does not provide indications for potential environmental risks;

- The GM line expresses the genes *cry1A.105*, *cry2Ab2*, *cry1F*, *cry3Bb1*, *cry34Ab1* and *cry35Ab1* conferring tolerance to certain lepidopteran and coleopteran insects, and the genes *pat*, *cp4-epsps* and *aad-1* genes conferring tolerance to glyphosate, glufosinate-ammonium, aryloxyphenoxypropionate (AOPP) and auxin acting herbicides;

- In the Netherlands, feral maize populations have never been observed and the appearance of volunteers is rare;
- Wild relatives of maize in the Netherlands have never been observed and hybridisation of maize with other species is therefore not possible;

- There are no indications that the introduced traits allow MON89034x1507xMON88017x 59122xDAS-40278-9 to survive in the Netherlands;
- There are no indications that MON87427xMON87460xMON89034 xMIR162xNK603 could establish feral populations in the Netherlands;

- COGEM is of the opinion that import and processing of maize MON89034x1507x MON88017x59122xDAS-40278-9 and GM maize consisting of sub-combinations of its parental GM maize line poses a negligible risk to the environment in the Netherlands;
- COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is carried out by other organisations.

1. Introduction

The present application (EFSA/GMO/NL/2013/113), filed by Dow AgroSciences LLC, concerns import and processing of genetically modified (GM) maize MON89034x1507xMON88017x 59122xDAS-40278-9, for use in feed and food. Maize MON89034x1507xMON88017x59122x DAS-40278-9 was produced by conventional crossbreeding of the five GM parental maize lines. The stacked line contains the *pat*, *cp4-epsps* and *aad-1* genes conferring tolerance to glyphosate, glufosinate-ammonium and aryloxyalkanoate containing herbicides. This maize line expresses the genes *cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1* and *cry35Ab1* conferring tolerance to certain lepidopteran and coleopteran insects, and the genes *pat, cp4-epsps* and *aad-1* genes conferring tolerance to glyphosate, glufosinate-ammonium, aryloxyphenoxypropionate (AOPP) and auxin acting herbicides.

Parental lines MON89034[1], 1507[2,3], MON88017[4], and 59122[5] have been authorised for import and processing for use in food and feed in the European Union since 2009, 2006, 2009 and 2007 respectively. In 2016, EFSA issued a positive opinion on the import and processing of maize line DAS-40278-9.[6] Several stacked lines have also been authorized for import and processing for use in food and feed in the European Union.[(e.g. 7)]

2. Previous COGEM advices

COGEM has previously advised positively on import and processing all five parental lines; MON89034[8,9], 1507[10,11,12], MON88017[13,], 59122[14,15] and DAS-40278-9[16*]. COGEM also advised positively on the import and processing of several stacked lines including MON89034x1507xNK603[17] and MON89034x1507xNK603xDAS-40278-9[18].

3. Environmental risk assessment

3.1 Aspects of the wild-type crop

Maize (*Zea mays*) is a member of the grass family *Poaceae*. It is a highly domesticated crop originating from Central America, but nowadays cultivated globally. Maize is wind pollinated,[19,20] and has both male and female flowers that are spatially separated. Female flowers are not attractive to insect pollinators, because they do not produce nectar. Insect pollination of maize is probably highly limited but cannot be excluded.[21]

In the Netherlands, no wild relatives of maize are present and hybridisation with other species cannot occur. Maize requires warm conditions in order to grow and does not tolerate prolonged cold and frost.[21,22] In cultivation areas with warmer climatic conditions, the appearance of volunteers can occur the year following maize cultivation due to spilled cobs or kernels. However, these volunteers are usually killed by common mechanical pre-planting soil preparation practices.[21]

Maize is very sensitive to weed competition.[23] During the long process of domestication, maize has lost the ability to persist in the wild.[20] A soil seed bank, small seeds, and an extended period of

[*] In the 2011 COGEM advice, the maize line DAS-40278-9 was incorrectly named DAS-40728-9.

flowering and seed production are characteristics often observed in persistent weeds.[24] Maize lacks all these characteristics. After ripening, the seeds (the kernels) adhere to the cob and do not shatter naturally.[21,25] Consequently, seed dispersal is severely hampered.

During field observations in Austria some volunteers and maize plants were observed in non-agricultural habitats.[26] In the Netherlands, the appearance of volunteers is very rare, however, maize plants occasionally have been observed outside agricultural fields.[27] COGEM is not aware of any reports of feral maize populations in the Netherlands or elsewhere in Europe.

Conclusion: In the Netherlands, feral maize populations do not occur and hybridisation of maize with other species is not possible.

3.2 Description of the introduced genes and traits

MON89034x1507xMON88017x59122xDAS-40278-9 maize was produced by conventional crossbreeding of the five parental GM maize lines.

Introduced genes	**Encoded proteins (enzymes)**	**Traits**
cry1A.105	The Cry1A.105 protein is a chimeric protein with domains from different Cry1 proteins from *Bacillus thuringiensis*[8,9,28]	Resistance to certain lepidopteran insects
cry2Ab2	Variant of the Cry2Ab2 protein from *B. thuringiensis* subsp. *kurstaki*[8,9,28]	Resistance to certain lepidopteran insects
cry1F	The Cry1F protein originating from *B. thuringiensis* subsp. *aizawa*[10,11,29]	Resistance to certain lepidopteran insects
cry3Bb1	Variant of the Cry3Bb1 protein originating *from B. thuringiensis* subsp. *kumamotoensis*[13,30]	Resistance to certain coleopteran insects
cry34Ab1	The Cry34Ab1 protein originating from *B. thuringiensis* strain PS149B1[14,15,31]	Resistance to certain coleopteran insects
cry35Ab1	Cry35Ab1 protein originating from *B. thuringiensis* strain PS149B1[14,15,31]	Resistance to certain coleopteran insects
cp4-epsps	The 5-enolpyruvulshikimate-3-phosphate synthase (EPSPS) enzyme originating from *Agrobacterium tumefaciens* strain CP4[13,32]	Tolerance to glyphosate containing herbicides
aad-1	Aryloxyalkanoate dioxygenase (AAD-1) enzyme originating from *Sphingobium herbicidovorans*[16,33]	This enzyme can cleave several synthetic auxins, and certain 'aryloxyphenoxy-propionate' (AOPP) herbicides, resulting in a tolerance to several synthetic auxin acting herbicides like 2,4 dichlorophenoxoxyacetic acid' (2,4-D) and to AOPP containing herbicides
pat (two copies)	Variant of phosphinothricin N-acetyltransferase (PAT) originating from *Streptomyces viridochromogenes* strain Tü 494[10,11,15,34,35]	Tolerance to glufosinate-ammonium containing herbicides
See references for a detailed description of the traits		

3.3 Molecular characterisation

Previously, COGEM evaluated the molecular characterisation of each parental line and considered these to be adequate.[9,11,13,15,16]

The applicant confirmed by Southern blot and sequencing that the hybrid line contained the parental transgenic inserts of MON89034, 1507, MON88017, 59122 and DAS-40278-9, and that no rearrangements of these inserts occurred.

The applicant also updated the bioinformatic analyses of the inherited inserted elements, and the sequenes spanning the insertion sites at the 5' and 3' flanking regions using recent databases.

According to the applicant, no essential endogenous genes were disrupted at the insertion sites, and the putative products of the open reading frames spanning the 5' and 3' junctions of the inserts, did not generate any protein sequence similarity with known allergens, toxins or other biologically active proteins.

The molecular characterisation was conducted according to the criteria previously laid down by COGEM.[36] The results from the updated molecular characterisation do not provide indications that MON89034x1507xMON88017x59122xDAS-40278-9 could pose a risk to the environment.

Conclusion: The molecular characterisation of maize MON89034x1507xMON88017x59122x DAS-40278-9 is adequate and no indications for potential environmental risks were identified.

3.4 Phenotypic and agronomic characteristics

Previously, COGEM evaluated the phenotypic and agronomic characteristics of each parental line of MON89034x1507xNK603xDAS-40278-9, and found no deviations influencing the outcome of the environmental risk assessment.[8,10,13,14,16]

The applicant analysed the phenotypic and agronomic characteristics of MON89034x1507xMON88017x59122xDAS-40278-9 and noted that most agronomic characteristics did not differ from those in the non-GM near-isogenic line. When differences were observed, they were within ranges considered to be normal for conventional maize. The results of the phenotypic evaluation do not give reason to assume that the GM maize line could pose an environmental risk. According to the applicant the results of the field trials support the conclusion that from an agronomic and phenotypic point of view, MON89034x1507xMON88017x59122x DAS-40278-9 is equivalent to conventional maize, except for the inherited lepidopteran and coleopteran protection with tolerance to glufosinate-ammonium, glyphosate, 2,4-D and to certain AOPP herbicides.

In conclusion, COGEM is of the opinion that there are no indications to assume that the introduced traits in MON89034x1507xMON88017x59122xDAS-40278-9 allow the maize line to survive or establish in the Dutch environment.

Conclusion: There are no indications that the introduced traits allow MON87427x MON89034x1507xMON88017x59122xDAS-40278-9 to survive in the Netherlands.
MON89034x1507xMON88017x59122xDAS-40278-9 does not have an increased potential for the establishment of feral populations in the Netherlands.

4. Food/feed assessment

This application is submitted under Regulation (EC) 1829/2003, therefore a food/feed assessment is carried out by EFSA and national organisations involved in the assessment of food safety. In the Netherlands, RIKILT carries out a food and/or feed assessment for Regulation (EC) 1829/2003 applications. The outcome of the assessment by other organisations (EFSA, RIKILT) was not known when this advice was completed.

5. Post-market environmental monitoring (PMEM)

The applicant supplied a new post-market environmental monitoring (PMEM) plan. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan,[37,38] but considers the current GS plan adequate for import and processing of maize MON89034x1507xMON88017x59122xDAS-40278-9.

6. Overall conclusion

COGEM is of the opinion that import and processing of MON89034x1507xMON88017x59122xDAS-40278-9 maize and GM maize consisting of sub-combinations of its parental GM maize lines poses poses a negligible risk to the environment in the Netherlands.
COGEM abstains from giving advice on the potential risks of incidental consumption since other organisations carry out a food/feed assessment.

References

1. European Commission (2008). Commision Decision of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 (MON-89Ø34-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2009/813/EC). Official Journal of the European Union. 5.11.2009 L 289/21
2. European Commission (2006). Commission Decision of 3 March 2006 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2006/197/EC). Official Journal of the European Union 9.3.2006 L 70/82-86
3. European Commission (2005). Commission Decision of 3 November 2005concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium (2005/772/EC). Official Journal of the European Union 5.11.2005
4. European Commission (2009). Commission Decision of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON88017 (MON-88Ø17-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2009/814/EC). Official Journal of the European Union 5.11.2009 L 289/25

5. European Commission (2007). Commission Decision of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2007/702/EC). 31.10.2007 L 285/42
6. European Food Safety Authority (EFSA) (2016). Scientific Opinion on an application by DOW AgroSciences LLC (EFSA-GMO-NL-2010-89) for placing on the market the genetically modified herbicide-tolerant maize DAS-40278-9 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. The EFSA Journal 14(12):4633
7. European Commission (2011). Commission Decision of 17 June 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × MON88017 (MON-89Ø34-3xMON-88Ø1 7-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. 23.6.2011 L 163/55
8. COGEM (2007). Import and processing of maize MON89034. COGEM advice CGM/071022-02
9. COGEM (2009). Molecular characterization of maize MON89034. COGEM advice CGM/090126-01
10. COGEM (2003). Insect resistant and glufosinate ammonium tolerant transformation event 1507 maize. COGEM advice CGM/030115-01 [in Dutch]
11. COGEM (2015). Renewal of the authorization for import and processing of genetically modified maize line 1507. COGEM advice CGM/150928-01
12. COGEM (2003). Insect resistent and glufosinate ammonium tolerant transformation event 1507 maize. COGEM advice CGM/030919-04
13. COGEM (2007). Import of genetically modified maize line MON88017. COGEM advice CGM/070308-01
14. COGEM (2005). Import and processing of maize variety 59122. COGEM advice CGM/051122-01
15. COGEM (2016). Renewal of the authorisation for import and processing of genetically modified 59122 maize. COGEM advice CGM/161129-01
16 COGEM (2011). Import and processing of genetically modified maize DAS-40728-9. COGEM advice CGM/110510-01
17. COGEM (2009). Import and processing of genetically modified MON89034x1507xNK603 maize. COGEM advice CGM/090930-01
18. COGEM (2017). Advise import and processing of genetically modified maize MON89034x1507xNK603xDAS-40278-9. COGEM advice CGM/170131-01
19. Hin CJA (2001). Landbouwkundige risico's van uitkruising van GGO-gewassen. Centrum voor Landbouw en Milieu (CLM) [in Dutch]
20. Treu R & Emberlin J (2000). Pollen Dispersal in the Crops Maize (*Zea mays*), Oil Seed Rape (*Brassica napus* ssp. *oleifera*), Potatoes (*Solanum tuberosum*), Sugar Beet (*Beta vulgaris* ssp. *vulgaris*) and Wheat (*Triticum aestivum*). Evidence from Publications. Soil Association
21. Andersson MS & Carmen de Vicente M (2010). Gene flow between crops and their wild relatives. The John Hopkins University Press, Baltimore, Maryland, The United States of America
22. Miedema P (1982). The effect of low temperature on *Zea mays*. Advances in Agronomy 35: 93-128

23. CAB International (2007). Crop Protection Compendium. *Zea mays* (maize). CD-ROM edition, Wallingford
24. Kos SP *et al*. (2012). Can transgenic crops go wild? A literature study on using plant traits for weediness pre-screening. COGEM research report CGM 2012-01
25. Organisation for Economic Cooperation and Development (OECD) (2003). Consensus Document on the Biology of *Zea mays* ssp. *mays* (Maize)
26. Pascher K (2016). Spread of volunteer and feral maize plants in Central Europe: recent data from Austria. Environ. Sci. Eur. 28: 30
27. van de Wiel CCM *et al*. (2011). Crop volunteers and climate change. Effects of future climate change on the occurrence of maize, sugar beet and potato volunteers in the Netherlands. COGEM research report 2011-11
28. Drury SM *et al.* (2008). Composition of forage and grain from second-generation insect-protected corn MON 89034 is equivalent to that of conventional corn (*Zea mays* L.). J. Agric. Food Chem. 12: 4623-4630
29. US-EPA (U.S. Environmental Protection Agency). Biopesticide registration action document, Cry1Ab and Cry1F Bacillus thuringiensis (Bt) corn plant-incorporated protectants (2010). https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/decision_PC-006481_1-Sep-10.pdf (visited: June 19th 2017).
30. Devos Y *et al.* (2012). *Bt*-maize event MON 88017 expressing Cry3Bb1 does not cause harm to non-target organisms. Transgenic Res. 6: 1191-1214
31. Herman RA *et al.* (2002). Binary insecticidal crystal protein from Bacillus thuringiensis, strain PS149B1: effects of individual protein components and mixtures in laboratory bioassays. J. Econ. Entomol. 95: 635-639
32. Funke T *et al*. (2006). Molecular basis for the herbicide resistance of Roundup Ready crops. PNAS 103: 13010-13015
33. Herman RA *et al.*(2010). Compositional safety of event DAS-40278-9 (AAD-1) herbicide-tolerant maize. GM Crops. 1: 294-311
34. Organisation for Economic Cooperation and Development (OECD) (1999). Consensus document on general information concerning the genes and their enzymes that confer tolerance to phosphinothricin herbicide
35. Wohlleben W *et al*. (1988). Nucleotide sequence of the phosphinothricin *N*-acetyltransferase gene form *Streptomyces viridochromogenes* Tü494 and its expression in *Nicotoana tabacum*. Gene 70: 25-37
36. COGEM (2014). Reconsideration of het molecular characterisation criteria for marketing authorisation of GM crops. COGEM topic report CGM/140929-02
37. COGEM (2010). General Surveillance. COGEM topic report CGM/100226-01
38. COGEM (2015). Advice on improving the general surveillance of GM crops. COGEM advice CGM/150601-02