

Aan de minister van
Infrastructuur en Waterstaat
drs. C. van Nieuwenhuizen-Wijbenga
Postbus 20901
2500 EX Den Haag

DATUM 05 december 2019
KENMERK CGM/191205-01
ONDERWERP Aanvullend advies over de hernieuwing van de importvergunning van de ggmalslijn MON89034, naar aanleiding van een recente EFSA opinie

Dear Minister,

On February 13th 2019, COGEM advised on the application for renewal of the authorisation for import and processing for use in food, feed and other products containing or consisting of genetically modified (GM) maize MON89034 (EFSA/GMO/RX/015).¹ This event expresses the *cry1A.105* and *cry2Ab2* genes, conferring resistance to certain lepidopteran insects.

As part of the application for renewal of the authorisation, the applicant updated bioinformatic analyses, provided annual monitoring reports and conducted a literature search to identify new information relevant to the safety evaluation of MON89034. COGEM noted that no new sequence information was provided by the applicant, and that the monitoring report from the year 2012 was missing in the application. Provided that the sequence of MON89034 at time of renewal was identical to the original event sequence, and the monitoring report from 2012 did not contain reports of adverse effects or incidents, COGEM concluded that import and processing of MON89034 poses a negligible risk to the environment in the Netherlands.

Recently, European Food Safety Authority (EFSA) published its scientific opinion on the renewal of the authorisation of MON89034², which also took into account the scientific comments submitted by the EU Member States. The Dutch portal for European market

¹ COGEM (2019). Renewal of the authorisation for import and processing of genetically modified maize MON89034. COGEM advice CGM/190213-01 [Confidential advice]

² Naegeli H *et al.* (2019). Assessment of genetically modified maize MON 89034 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-015). EFSA Journal, 17: 5845

applications (the Food-Feed-portal) asked COGEM whether COGEM's comments were sufficiently answered by EFSA.

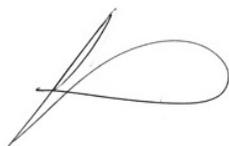
COGEM studied the responses of the GMO panel on the comments and opinions submitted by Member States during the 3 month consultation period, and the scientific risk assessment by EFSA on the renewal of the authorization of MON89034. For the assessment by EFSA, the GMO Panel states that it has taken notice of the comments made by COGEM regarding the missing monitoring report and the lack of new sequence information, but did not specifically address these comments.

EFSA, like COGEM, evaluated the data³ under the assumption that the DNA sequence in MON89034 considered for renewal is identical to the sequence of the originally assessed event. In the application, bioinformatic analyses are performed with sequence data that has also been used in previous applications. This does not necessarily imply that no sequence changes have occurred, as no indication is given that the applicant compared the current sequence with the originally assessed event. Any changes in sequence information may affect the outcome of the bioinformatical analyses. This raises the question whether the assumption of no sequence change is at all verified, and by whom.

EFSA did not directly address the missing monitoring report from 2012. In the original application for renewal, the monitoring reports from 2011 and 2012 were identical and both covered the monitoring performed from July 2010 to July 2011. After scrutinising the adopted dossier, it became clear that EFSA later (February 21st) received the missing monitoring report from 2012. EFSA concluded that in evaluating the post-market monitoring reports, no adverse effects were reported by the applicant.

In conclusion, EFSA did not address all comments posed by COGEM. The assumption of sequence similarity still requires verification.

Sincerely yours,



Prof. dr. ing. Sybe Schaap
Voorzitter COGEM

c.c. Dr. J. Westra, Hoofd Bureau ggo
Mr. J.K.B.H. Kwisthout, Ministerie van IenW
Dr. C.P.E. van Rijn, Food-Feed loket

³ In accordance with the GMO Panel guidelines for renewal of applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015)