

To the Minister of
Infrastructure and Water Management
drs. C. van Nieuwenhuizen-Wijbenga
Postbus 20901
2500 EX Den Haag

DATUM 23 februari 2021
KENMERK CGM/210223-01
ONDERWERP Additional advice authorisation renewal gg-maize MON88017xMON810

Dear Minister,


On January 6, 2020, COGEM advised on the application for renewal of the authorisation for import and processing of genetically modified (GM) maize MON88017xMON810 (EFSA/GMO/RX/017).¹ This stacked event expresses the *cry3Bb1*, *cry1Ab* and *cp4 epsps* genes, conferring resistance to certain coleopteran and lepidopteran insects, and tolerance to glyphosate based herbicides.

As part of the application for renewal of the authorisation, the applicant updated the molecular characterisation and bioinformatic analyses, provided annual monitoring reports and conducted a literature search to identify new information relevant to the safety evaluation of MON88017xMON810. In the application, these bioinformatic analyses are performed with sequence data present in the previous application. COGEM carried out the environmental risk assessment under the assumption that the sequence data of MON88017xMON810 is identical to the sequence data assessed during the original application, and concluded that import and processing of this GM maize poses a negligible risk to the environment in the Netherlands.

Recently, the European Food Safety Authority (EFSA) published its scientific opinion on the renewal of the authorisation of MON88017xMON810², which also took into account the scientific comments submitted by the EU member States. The Dutch portal for European

¹ COGEM (2020). Advies hernieuwing vergunning voor import en verwerking van gg-maislijn MON88017xMON810. COGEM advice CGM/200106-02 [Confidential advice]

² Naegeli H. *et al.* (2021). Assessment of genetically modified maize MON 88017 x MON 810 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-017). EFSA Journal 19:6375

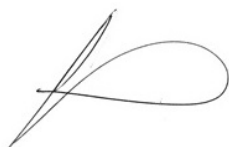


market applications (the Food-Feed-portal) asked COGEM whether its comments were sufficiently answered by the EFSA. COGEM notices that EFSA, like COGEM, evaluated the data³ under the assumption that the DNA sequence of MON88017xMON810 considered for renewal is still identical to the sequence submitted with the previous application. According to EFSA's administrative guidance on the submission of applications for renewal of authorisation of genetically modified food and feed, it is not required to resequence an event. The risk assessment of GM food and/or feed for renewal is conducted under the assumption that the events' sequence is identical to the previously submitted sequence.⁴

As there is no requirement to resequence an event in case of a renewal application, no new sequence data was submitted for MON88017xMON810. The assumption that the sequence is identical to the sequence in the original application remains valid and COGEM's conclusion on the environmental risk assessment remains unaltered. COGEM abides by the assessment that MON88017xMON810 poses a negligible risk to the environment in the Netherlands.

In view of the fact that the applicant is not obliged to resequence the GM event(s), COGEM points out there is no need to consult COGEM in future cases in which the environmental risk assessment is carried out under the assumption that the sequence of the event is identical to the sequence in the original application, and no information which alters this assumption is available. In such cases the conclusion of the initial environmental risk assessment remains applicable.

Sincerely yours,



Prof. dr. ing. Sybe Schaap
Chair of COGEM

c.c. Dr. J. Westra, Hoofd Bureau ggo
Ministerie van IenW, Directie Omgevingsveiligheid en Milieurisico's
DG Milieu en Internationaal
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, 2018)

⁴ European Food Safety Authority (2019). Administrative guidance on the submission of applications for renewal of authorization of genetically modified food and feed under Articles 11 and 23 of Regulation (EC) No 1829/2003. doi:10.2903/sp.efsa.2019.EN-1668