

To the Minister of
Infrastructure and Water Management
drs. C. van Nieuwenhuizen-Wijbenga
Postbus 20901
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DATUM 14 september 2020
KENMERK CGM/200914-01
ONDERWERP Additional advice on the renewal of the authorisation for feed, import and processing of GM oilseed rape GT73

Dear Minister,

In 2017, COGEM advised on the application for renewal of the authorisation for import of feed containing or consisting of genetically modified (GM) oilseed rape GT73, and products other than food and feed containing or consisting of GT73, with the exception of cultivation (EFSA/GMO/RX/002).¹ GT73 expresses the *cp4 epsps* and *goxv247* genes, conferring tolerance to glyphosate containing 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 GT73.

In its advice COGEM concluded that import and processing of GT73 in itself poses a negligible risk to human health and the environment (the assessment of GT73 was carried out under the assumption that the sequence data of the GT73 event is identical to the sequence data assessed during the original application). COGEM did, however, express concerns with regard to the provided systematic literature review which was limited to food and feed safety, and the proposal of the applicant to discontinue post-market environmental monitoring (PMEM).

¹ COGEM (2017). Renewal of the authorisation for import of feed of genetically modified oilseed rape GT73. COGEM advice CGM/170322-01



The European Food Safety Authority (EFSA) recently published its scientific opinion on the renewal of the authorisation of GT73 and its response on the comments the member states submitted on the application.^{2,3} The Netherlands Ministry of Infrastructure and Water Management asked COGEM whether COGEM's comments were sufficiently answered by EFSA.

Like COGEM, EFSA noted that the publications retrieved in the systemic literature search were evaluated for potential relevance to food and feed safety, but not for their potential relevance to environmental safety. EFSA requested the applicant to amend the literature search and evaluate publications that might be of relevance to the environmental risk assessment. The applicant revised the literature search to retrieve information on potential adverse effects on human and animal health and the environment. Upon a second request of EFSA, the applicant performed an additional literature search to retrieve relevant publications published during the period the application was assessed. In addition, a systematic literature search was carried out in May 2019 as part of the obligatory post-market environmental monitoring of GT73.

These literature searches did not retrieve any publications that change the outcome of COGEM's environmental risk assessment.

More importantly, the application for renewal of the authorisation of GT73 did not contain a PMEM plan. The applicant proposed to discontinue PMEM of GT73. Upon a request of the European Commission, the applicant did submit a PMEM plan. In its opinion, EFSA states that it considers the scope of this PMEM plan to be consistent with the scope of the requested authorisation for oilseed rape GT73, but also points out that monitoring is related to risk management and that the final adoption of the PMEM plan falls outside its mandate.

As mentioned in its previous advices on GM oilseed rape, COGEM is of the opinion that PMEM should include monitoring along transport routes (including roadsides and railway beddings) and at transshipment areas. When GM oilseed rape is observed, *Brassica rapa* populations in the vicinity of the observed population should be monitored as well.⁴ COGEM evaluated the submitted PMEM plan and noticed that it does not include monitoring along transport routes and around processing plants.

In its response to the comments of the member states on the PMEM of GT73 EFSA did not address COGEM's comment. In general, EFSA states that it considers further discussion with applicants and risk managers on the practical implementation of the PMEM for GM plants for import and processing (e.g. actual data gathered on exposure and/or adverse effects as implemented in existing monitoring systems) necessary.

² EFSA (2020). Assessment of genetically modified oilseed rape GT73 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-002). EFSA Journal doi: 10.2903/j.efsa.2020.6199

³ EFSA (2020). Application EFSA-GMO-RX-002 (oilseed rape GT73) Comments and opinions submitted by member states during the three-month consultation period.

⁴ COGEM (2013). Genetically modified oilseed rape (*Brassica napus*). Aspects in relation to the environmental risk assessment and post-market environmental monitoring of import applications. COGEM advisory report CGM/130402-01



COGEM welcomes any steps taken to improve the PMEM of GM oilseed rape, but cannot deduce who will initiate the necessary discussion on the improvement of the PMEM plan. COGEM notes that in 2017 EFSA responded in a similar way to member state comments on another GM oilseed rape application with a similar scope.⁵ It is unclear whether any progress has been made since 2017. It is also unclear whether the monitoring activities that COGEM considers necessary are part of the desired outcome of these discussions.

COGEM remains of the opinion that the PMEM plan for GT73 needs to be adapted before the authorisation is renewed. COGEM therefore urges the European Commission to include the above mentioned monitoring requirements in its Commission Decision on GT73.

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
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Dr. C.P.E. van Rijn, Food-Feed loket

⁵ EFSA (2017). Application EFSA-GMO-RX-004 (oilseed rape MS8, RF3, MS8 x RF3) Comments and opinions submitted by member states during the three-month consultation period.