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To the Minister of
Infrastructure and Water Management
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DATUM	January 3rd, 2018
KENMERK	CGM/180103-01
ONDERWERP	Additional advice on the renewal of the authorisation for feed, import and processing of genetically modified oilseed rape MS8, RF3 and MS8xRF3

Dear Minister,

COGEM has previously advised on the application for renewal of the authorisation for feed containing or consisting of genetically modified (GM) oilseed rape lines MS8, RF3 and MS8xRF3 and products other than food and feed containing or consisting of them (EFSA/GMO/RX/004).[1] The oilseed rape lines are tolerant to glufosinate-ammonium containing herbicides and express a pollination control system.

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 MS8, RF3 and/or MS8xRF3.

European Food Safety Authority (EFSA) recently published its scientific opinion on the renewal of the authorisation of MS8, RF3 and MS8xRF3.[2] The Netherlands Ministry of Infrastructure and Water Management asked COGEM whether COGEM's comments were sufficiently answered by EFSA.

[1] COGEM (2017). Renewal of the authorisation for import and processing of genetically modified oilseed rape MS8, RF3 and MS8xRF3. COGEM advice CGM/170112-01
[2] EFSA (2017). Assessment of genetically modified oilseed rape MS8, RF3 and MS8xRF3 for renewal of authorisation under regulation (EC) No 1829/2003 (application EFSA-GMO-RX-004). EFSA Journal 15(11): 5067

In its previous advice on the renewal of the authorisation of GM oilseed rape MS8, RF3 and MS8xRF3, COGEM raised two objections. COGEM noticed that the literature search focused on food and feed safety. The applicant did not evaluate whether the retrieved publications contained information on aspects relevant to environmental safety. Publications relevant to the environmental risk assessment were, however, mentioned in the annual monitoring reports. COGEM pointed out that the systematic literature search could be improved by expanding the evaluation of the retrieved publications to include publications with potential relevance to the assessment of environmental risks.
More importantly, in its advice on the application for renewal of the authorisation, COGEM concluded that the provided Post Market Environmental Monitoring (PMEM) plan was insufficient. Because of the inadequate PMEM plan, COGEM did not advice positively on the renewal of the authorisation. COGEM is of the opinion that the PMEM plan must be improved before a renewal of the market authorisation is granted.

Like COGEM, EFSA noted that the publications retrieved in the systemic literature search were evaluated for potential relevance to food/feed safety, but not for their potential relevance to environmental safety. EFSA therefore requested the applicant to redo the systematic literature search and to assess the retrieved publications for their relevance to the environmental risk assessment (ERA) of MS8, RF3 and MS8xRF3. The applicant provided a renewed literature search and included relevance to the ERA in their evaluation. The applicant identified 12 relevant publications. The information in these publications does not change COGEM's conclusion that MS8, RF3 and MS8xRF3 pose a negligible risk to the environment.

The applicant did not provide an improved PMEM plan. In its opinion on the renewal application for MS8, RF3 and MS8xRF3, EFSA states that the scope of the PMEM plan is consistent with the scope of the requested authorisation for oilseed rape MS8, RF3 and MS8xRF3. In addition, EFSA points out that monitoring is related to risk management and that the final adoption of the PMEM plan falls outside EFSA's mandate.
However, in its response to COGEM's concerns EFSA mentions 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.
COGEM welcomes any steps taken to improve the PMEM of GM oilseed rape. However, from EFSA's response on COGEM's comments, COGEM cannot deduce who will initiate the necessary discussion on the improvement of the PMEM plan. It is also unclear whether the monitoring activities that COGEM considers necessary are part of the desired outcome of these discussions. 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 transshipment areas. When GM oilseed rape is

observed, *Brassica rapa* populations in the vicinity of the observed population should be monitored as well.[3]

COGEM expects that a decision on the renewal of the authorisation of MS8, RF3 and MS8xRF3 will be taken before the discussions on the improvement of the PMEM plan are completed. COGEM remains of the opinion that the PMEM plan for MS8, RF3 and MS8xRF3 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 MS8, RF3 and MS8xRF3.

Sincerely yours,

Prof. dr. ing. Sybe Schaap
Chair of COGEM

c.c. Drs. H.P. de Wijs, Head GMO Office
Mr. J.K.B.H. Kwisthout, Ministry of Infrastructure and Water Management

[3] 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