

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

DATUM 12 juli 2021
KENMERK CGM/210712-01
ONDERWERP Additional advice on import and processing of GM oilseed rape 73496

Dear Minister,

In 2013, COGEM advised on the application for import and processing of genetically modified (GM) oilseed rape 73496 (EFSA/GMO/NL/2012/109).¹ Oilseed rape 73496 expresses the *gat4621* gene which confers tolerance to glyphosate containing herbicides. It was produced by biolistic transformation using gold particles coated with the gel-purified PHP28181A restriction fragment (2112 bp) containing the *gat4621* expression cassette.

In its previous opinion on GM oilseed rape 73496, COGEM had two major and several minor comments. One of COGEM's major concerns was the incomplete characterisation of the insertion region. A putative triose phosphate translocator (*tpt*) gene was identified in the 5' border region, but not in the 3' border region. The applicant did not provide a rationale for these results. As the absence of similarity to the putative *tpt* gene in the 3' border region could be caused by a deletion in the 3' border region, COGEM was of the opinion that the applicant had to provide more information to assure that the insert region is completely characterised.

Another major concern was the Post Market Environmental Monitoring (PMEM) plan. COGEM pointed out that it could be improved on several points. Most importantly, COGEM advised to include monitoring of roadsides and railway beddings near oilseed rape transshipment and transport sites for spillage of GM oilseed rape and stacking of event 73496 oilseed rape.

¹ COGEM (2013). Advisory report on import of glyphosate resistant oilseed rape 73496. COGEM advisory report CGM/130208-02



The Dutch Competent Authority submitted the two major concerns of COGEM to the European Food Safety Authority (EFSA). Recently, EFSA published its scientific opinion on import and processing of GM oilseed rape 73496, which also took into account the scientific comments submitted by the EU member states during the member state consultation period. The Dutch Ministry of Infrastructure and Water Management (IenW) asked COGEM whether EFSA sufficiently answered the previously submitted comments.

The applicant provided additional information on the insertion site. The immediate 5' and 3' sequences of the 73496 insert were mapped on the genome sequence of the parental oilseed rape line 1822B, which was used to generate 73496. This revealed that in the parental line the immediate 3' sequence of the insert in 73496 is located more than 9 Mb away from the site where the insertion occurred, and is present in the opposite orientation. This change in the location of the sequence is explained by a chromosome-internal inversion that occurred during the transformation process leading to 73496. Using 42 Single Nucleotide Polymorphism (SNP) markers in the flanking regions of the insert the applicant concluded that there is no evidence of deletions.

COGEM is of the opinion that the insertion site is now adequately characterised. The provided information clarifies the absence of similarity to the putative *tpt* gene in the 3' border region. The inversion that occurred during the transformation process, disrupted a *tpt* gene. Oilseed rape contains multiple copies of the *tpt* gene family, which explains why the phenotype of 73496 does not seem to be affected by this disruption.

Genome rearrangements, such as the inversion of part of chromosome 12 that occurred during transformation of oilseed rape line 1822B, occur in nature and during conventional breeding. COGEM, therefore, considers such rearrangements to belong to the baseline of conventional plant breeding. No new issues relevant to the environmental risk assessment were identified in the additional analyses that were carried out to characterise the insertion site.

COGEM notices that the applicant did not provide an improved PMEM plan. In its response to COGEM's concerns, EFSA mentions that the accidental release into the environment of viable oilseed rape 73496 seeds during transportation and/or processing is not a potential unanticipated or unforeseen adverse effect, and thus not in the scope of general surveillance.

As mentioned in several of its previous advices, COGEM considers a PMEM plan which includes monitoring along transport routes (including roadsides and railway beddings) and transshipment areas necessary.² Feral oilseed rape populations can arise from GM oilseed rape seeds spilled during transshipment and transport, and prolonged use of the corresponding herbicide may lead to the establishment of feral herbicide tolerant GM oilseed rape. Subsequent gene flow between different GM oilseed rape events could give rise to stacked GM oilseed rape events with a new combination of GM traits. It cannot be excluded beforehand that such a newly generated stacked event may become more persistent than conventional oilseed rape, increase in population size and have an adverse effect on the

² 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



environment. The presence of GM oilseed rape volunteers is a prerequisite for such a scenario to occur. To monitor the fulfilment of the first step of this putative scenario, COGEM is of the opinion that the PMEM of GM oilseed rape 73496 should include monitoring of GM oilseed rape volunteers along transport routes (including roadsides and railway beddings) and transshipment areas. In COGEM's view, monitoring the presence of GM oilseed rape in these places is necessary for PMEM to function as intended, i.e. as an early warning signal for adverse effects.

COGEM's comment on the insertion site of 73496 has been sufficiently addressed, but COGEM's concerns with regard to the PMEM plan of oilseed rape 73496 remain. COGEM remains of the opinion that the PMEM plan needs to be adapted before an authorisation is granted. COGEM therefore urges the European Commission to include the above mentioned monitoring requirements in its Commission Decision on GM oilseed rape 73496.

Sincerely yours,

Prof. dr. ing. Sybe Schaap
Chair of COGEM

c.c. Drs. Y. de Keulenaar, Hoofd Bureau ggo
 Ministerie van IenW, Directie Omgevingsveiligheid en milieurisico's,
 DG Milieu en Internationaal
 Ing. M.A.C. Möllers, Food-Feed loket