

BEZOEKADRES:
A. VAN LEEUWENHOEKLAAN 9
3721 MA BILTHOVEN

POSTADRES:
POSTBUS 578
3720 AN BILTHOVEN

TEL.: 030 274 2777
FAX: 030 274 4476
INFO@COGEM.NET
WWW.COGEM.NET

Aan de staatssecretaris van Infrastructuur en Milieu Mevrouw S.A.M. Dijksma Postbus 20901 2500 EX Den Haag

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KENMERK CGM/170522-01

Additional advice on import and processing of genetically modified oilseed rape

MON88302xMS8xRF3

Dear Minister,

In 2014, COGEM issued an opinion concerning the application for import and processing of genetically modified (GM) oilseed rape (*Brassica napus*) MON88302xMS8xRF3 (EFSA/GMO/NL/2013/119). This event is tolerant to glufosinate-ammonium and glyphosate containing herbicides due to the expression of the *cp4 epsps* and *bar* genes. MON88302xMS8xRF3 also expresses the *barnase* and *barstar* genes, which are part of a pollination control system, used to facilitate the production of hybrid seed. COGEM previously concluded that import and processing of GM oilseed rape MON88302xMS8xRF3 poses a negligible risk to the Dutch environment, but expressed concerns regarding the provided Post-Market Environmental Monitoring (PMEM) plan.

Recently, European Food Safety Authority (EFSA) published its scientific opinion on import and processing of oilseed rape MON88302xMS8xRF3.² The Netherlands Ministry of Infrastructure and the Environment asked COGEM whether EFSA sufficiently answered COGEM's previous comments.

In its advice of 2014, COGEM concluded that the submitted general surveillance plan did not meet the requirements for import and processing of oilseed rape, and needed to be improved. Herbicide tolerant oilseed rape events have a selective advantage over other plants

COGEM (2014). Import and processing of herbicide tolerant oilseed rape MON88302xMS8xRF3. COGEM advice CGM/140807-01

² EFSA (2017). Scientific Opinion on application EFSA-GMO-NL-2013-119 for authorisation of genetically modified glufosinate-ammonium and glyphosate-tolerant oilseed rape MON88302xMS8x RF3 and subcombinations independently of their origin, for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Monsanto Company and Bayer CropScience. EFSA Journal 15(4):4767

if herbicides are used for weed control. Spillage of oilseed rape seeds during transport and transshipment can lead to the establishment of feral populations along distribution routes and handling areas.3 Cross-pollination can occur between GM and non-GM oilseed rape, and wild relatives, such as Brassica rapa. 4,5 Cross-fertilisation may lead to stacking of transgenes and new GM trait combinations. The possible interaction between these transgenes and their gene products have not been investigated, and it cannot be excluded that stacking of new GM trait combinations may lead to long-term adverse environmental effects.

Several other competent authorities of member states (Austria, Denmark, Finland, Germany, Hungary, Italy and Spain), also expressed concerns with regard to the PMEM plan of oilseed rape event MON88302xMS8xRF3. However, these comments have not resulted in changes in the PMEM. In response to these comments, EFSA stated that seed spillage is not considered an unanticipated adverse effect and is therefore not part of general surveillance, and that monitoring and its practical implementation are related to risk management, which falls outside the mandate of EFSA.

COGEM is of the opinion that general surveillance of feral GM oilseed rape populations along transport routes (roadsides and railway beddings) and transshipment areas is necessary to identify direct or indirect, immediate, delayed, or unanticipated environmental effects.⁴ COGEM therefore remains of the opinion that the PMEM plan of GM oilseed rape MON88302xMS8xRF3 and its subcombinations needs to be adapted before authorization can be granted. COGEM urges the European Commission to adopt these necessary changes in its Commission Decision.

Sincerely yours,

Prof. dr. ing. Sybe Schaap

Voorzitter COGEM

c.c. Drs. H.P. de Wijs, Hoofd Bureau ggo Mr. J.K.B.H. Kwisthout, Ministerie van IenM Ing. M.A.C. Möllers, Food-Feed loket

³ Luijten SH & de Jong TJ (2010). A baseline study of the distribution and morphology of *Brassica rapa* L. and Brassica rapa L. in the Netherlands. COGEM report CGM 2010-03

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

Andersson MS & Carmen de Vincente M (2010). Gene flow between crops and their wild relatives. The John Hopkins University Press, Baltimore, Maryland, United states of America