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**DATUM** 20 juni 2016  
**KENMERK** CGM/160620-03  
**ONDERWERP** Aanvullend advies post-market environmental monitoring van MS8xRF3xGT73  
n.a.v. verschijnen EFSA opinie

Geachte mevrouw Dijkma,

Naar aanleiding van een adviesvraag vanwege het verschijnen van de EFSA opinie over import en verwerking van de genetisch gemodificeerde koolzaadlijn MS8xRF3xGT73 (EFSA/GMO/NL/2009/75) van Bayer CropScience N.V. en Monsanto S.A. deelt de COGEM u het volgende mee.

**Samenvatting:**

Genetisch gemodificeerde koolzaad MS8xRF3xGT73 is tolerant voor glyfosaat en glufosinaat-ammonium bevattende herbiciden en bevat daarnaast een gecontroleerd bestuivingsmechanisme.

De COGEM heeft eerder geadviseerd over import en verwerking van deze gg-koolzaadlijn en geconstateerd dat het ingediende monitoringsplan onvoldoende was. De EFSA heeft de bezwaren van de COGEM niet meegenomen in haar recent verschenen opinie over deze koolzaadlijn en het monitoringsplan is niet gewijzigd. De eerdere bezwaren van de COGEM blijven daarom overeind.

De COGEM is van mening dat langs koolzaadtransportroutes (wegbermen, spoorwegen) en bij koolzaadoverslagstations gemonitord moet worden op de aanwezigheid van MS8xRF3xGT73 opslagplanten. In Nederland kunnen op deze plaatsen kleine koolzaadpopulaties ontstaan op verstoorde grond. Zeker wanneer glyfosaat en/of glufosinaat-ammonium worden gebruikt om onkruid te bestrijden, kan het niet worden uitgesloten dat MS8xRF3xGT73 opslagplanten zich daar vestigen. Opslagplanten kunnen andere (gg-) koolzaad opslagplanten bevruchten, waardoor transgene eigenschappen van verschillende gg-koolzaadlijnen in één gg-koolzaadplant gecombineerd kunnen worden. Het kan op voorhand niet worden uitgesloten dat een dergelijke combinatie van transgene eigenschappen tot een schadelijk effect zou kunnen leiden. De COGEM is daarom van mening dat het voorkomen van gg-koolzaadplanten gemonitord moet worden. Voordat een vergunning verleend kan worden, is uitbreiding van het monitoringsplan met monitoring langs transportroutes en op overslagstations noodzakelijk.



De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,

Prof. dr. ing. Sybe Schaap  
Voorzitter COGEM

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                  Mr. J.K.B.H. Kwisthout, Ministerie van IenM

# **Additional advice on import and processing of genetically modified oilseed rape MS8xRF3xGT73**

## **COGEM advice CGM/160620-03**

### **Introduction**

EFSA recently published its scientific and overall opinion on the application for placing on the market of genetically modified (GM) oilseed rape MS8xRF3xGT73 and subcombinations MS8xGT73 and RF3xGT73.<sup>1,2</sup> The application concerns import and processing and several food and feed uses. The EFSA opinions do not concern subcombination MS8xRF3, because it is currently authorised.<sup>3,4</sup>

The Ministry of Infrastructure and the Environment asked COGEM whether its previous comments on the application for import and processing of MS8xRF3xGT73 have been sufficiently addressed by EFSA.

### **GM oilseed rape MS8xRF3xGT73**

MS8xRF3xGT73 was produced by conventional crossbreeding of the three parental lines. It expresses both genes of a pollination control system, i.e. the *barnase* gene (present in MS8) which confers male sterility and the *barstar* gene (present in RF3) which restores male fertility. In addition, MS8xRF3xGT73 expresses the *cp4 epsps* and *goxv247* genes, and two copies of the *bar* gene resulting in tolerance to glufosinate ammonium and glyphosate containing herbicides.

### **Previous COGEM advice**

In 2013, COGEM published its opinion on import and processing of MS8xRF3xGT73 (EFSA/GMO/NL/2009/75).<sup>5</sup> COGEM concluded that the event in itself does not pose a risk to the environment in the Netherlands, but expressed concerns with regard to the post-market environmental monitoring (PMEM) plan. COGEM pointed out that the submitted general surveillance plan was insufficient and needed to be improved before authorising MS8xRF3xGT73 oilseed rape. COGEM had several comments on the PMEM plan. Most importantly, the general surveillance plan did not include monitoring along transport routes (roadsides and railway beddings) and transshipment areas and no special attention was paid to the areas where viable MS8xRF3xGT73 oilseed rape seeds could be spilled unintentionally. In case of GM oilseed rape, this is necessary to enable the identification of direct or indirect, immediate, delayed or unanticipated environmental effects.<sup>5</sup>

### **The EFSA opinion and COGEM's response**

Besides COGEM, several competent authorities of other member states expressed concerns with regard to the PMEM plan of MS8xRF3xGT73. In response to these comments, EFSA states that monitoring is related to risk management and therefore the adoption of the PMEM plan falls outside its mandate. COGEM acknowledges the limitations of EFSA's remit, however it is puzzled

by EFSA's seemingly ambivalent attitude on post-market environmental monitoring. EFSA has published several documents on post-market environmental monitoring of GM plants,<sup>6,7</sup> routinely assesses the annual PMEM reports of MON810,<sup>8</sup> and states in its opinion on MS8xRF3xGT73 that the scope of the PMEM plan is consistent with the scope of the application and agrees with the proposed reporting intervals. Indeed, a final decision on the content of the PMEM plan should not be made by EFSA, but by the European Commission. However, EFSA is the scientific advisory body of the European Commission and, therefore, a thorough scientific assessment of the design and quality of the PMEM plan falls within EFSA's scope.

In case of GM oilseed rape, COGEM is of the opinion that a more elaborate PMEM plan is needed. As explained below, COGEM is of the opinion that the PMEM plan of MS8xRF3xGT73 should be improved.

### **Post-market environmental monitoring of MS8xRF3xGT73**

In the Netherlands oilseed rape populations with GM plants can arise at roadsides, railways and handling areas where spillage of GM oilseed rape seeds occurs during transshipment and transport. Spilled herbicide tolerant GM oilseed rape seeds will have a selective advantage over other plants if herbicides are used for weed control. Prolonged use of these herbicides may lead to the establishment of feral herbicide tolerant GM oilseed rape.

Pollen from GM oilseed rape may fertilise other oilseed rape plants. If a GM oilseed rape plant with other GM traits is fertilised, the resulting progeny may possess a novel combination of GM traits. Unintentional stacking of herbicide tolerance traits in oilseed rape has been observed under natural conditions in regions where GM oilseed rape is imported as well as in GM oilseed rape cultivation areas.<sup>9,10,11,12</sup> Oilseed rape pollen may also fertilise *Brassica rapa* and to a lesser extent *Brassica juncea* and *Brassica oleracea*, and generate hybrid plants. Transgene flow from oilseed rape to *B. rapa* has been reported in natural conditions.<sup>13</sup> Additionally, back-cross progeny and the stable incorporation of a herbicide tolerance transgene into a *B. rapa* plant has been observed in the wild.

Spillage of GM oilseed rape seeds may eventually generate feral GM oilseed rape expressing multiple transgenes from different oilseed rape events, and feral herbicide tolerant *B. rapa* harbouring GM traits. It cannot be excluded that the combination of several GM traits and/or a possible interaction between gene products from different *B. napus* events, results in a potentially adverse effect.

Based on the above mentioned considerations, COGEM is of the opinion that the general surveillance plan of MS8xRF3xGT73 should include monitoring along transport routes (including roadsides and railway beddings) and transshipment areas. If GM oilseed rape is observed, *B. rapa* populations in the vicinity of the observed population will have to be monitored as well. The authorisation holder should involve railway companies and/or companies in charge of the maintenance of railways in activities to monitor for the occurrence of GM *B. napus* and *B. rapa* with GM traits along railways, as glyphosate is an important herbicide to control weeds along railways in the Netherlands and glufosinate ammonium is used along railways as well.<sup>14</sup>

### **Post-market environmental monitoring: early detection of potential long-term effects**

As mentioned by EFSA in its guidance document on the environmental risk assessment of GM crops, the potential occurrence of long-term effects should be assessed.<sup>15</sup> In order to predict and assess the potential occurrence of long-term effects, information on the 'receiving environment', including information on the presence of other GM plants in the environment, is needed. Knowledge on the presence of GM oilseed rape can be obtained most efficiently by monitoring the occurrence of GM oilseed rape along transport routes and at transshipment areas. The involvement of qualified existing monitoring networks in general surveillance activities is important in order to detect possible unanticipated effects.<sup>16</sup>

General surveillance is also the method of choice to identify (in)direct, unanticipated, delayed, potentially adverse environmental effects and allows the detection of potential unanticipated long-term adverse effects. A PMEM plan that includes monitoring of GM oilseed rape along transport routes and at transshipment areas, allows a timely detection of potential unanticipated long-term adverse effects.

### **Conclusion**

COGEM considers monitoring of oilseed rape transport routes (including roadsides and railway beddings) and transshipment areas a prerequisite to grant an authorisation for import and processing of all GM oilseed rape events.<sup>17</sup> Therefore, COGEM is of the opinion that the post-market monitoring plan of MS8xRF3xGT73 and its subcombinations needs to be adapted before an authorisation is granted.

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