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To the Minister for the Environment
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DATE	22 mei 2023
REFERENCE	CGM/230522-01
SUBJECT	Additional advice on import and processing of GM oilseed rape MS8, RF3 and MS8xRF3

Dear Minister,

In January of 2022, COGEM advised on the application for the second renewal of the authorisation for import and processing of genetically modified (GM) oilseed rape MS8, RF3 and MS8xRF3 (EFSA/GMO/RX/024), filed by BASF Agricultural Solution Seeds US LLC.[1] GM oilseed rape MS8 is a male sterile line which expresses the *barnase* gene, resulting in a lack of viable pollen and preventing self-pollination. GM oilseed rape RF3 is a fertility restorer line and expresses the *barstar* gene. The Barstar protein inhibits the Barnase protein, restoring male fertility. As a result, GM oilseed rape MS8xRF3, the crossbreeding product of MS8 and RF3, is fertile and capable of seed production. GM oilseed events MS8 and RF3 (and consequently also MS8xRF3), contain the *bar* gene as well, conferring tolerance to glufosinate ammonium-containing herbicides.

As part of the application for the second 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.

In its previous advice on the second renewal of the authorisation for import and processing of GM oilseed rape MS8, RF3 and MS8xRF3, COGEM stated that the provided Post Market Environmental Monitoring (PMEM) plan needed to be adapted before the market authorisation could be renewed. Spillage of GM oilseed rape seeds during transport and transshipment can lead to the establishment of feral populations along distribution routes and handling areas. The presence of feral GM oilseed

1. COGEM (2022). Advice on the second renewal of the authorisation for import and processing of genetically modified oilseed rape MS8, RF3 and MS8xRF3. COGEM advice CGM/220124-01

rape could result in potential gene flow within the genus (in particular to the species *Brassica rapa*), and can lead to stacked GM oilseed rape events with new combinations of GM traits, of which potential adverse effects on the environment cannot be evaluated in advance. COGEM therefore stated that monitoring along transport routes (including roadsides and railway beddings) and transshipment areas should be included in the PMEM plan.

The comments made by COGEM were submitted to the European Food Safety Authority (EFSA) by the Dutch Competent Authority. EFSA recently published its assessment of GM oilseed rape events MS8, RF3 and MS8xRF3 in the context of the renewal of the authorisation for import and processing, which also took into account the comments submitted by the EU Member States during the Member State consultation period. The Dutch portal for European market applications (the Food-Feed-portal) asked COGEM whether COGEM's remarks on the application were sufficiently answered by EFSA.

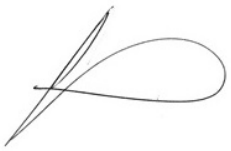
In its opinion on the renewal application for MS8, RF3 and MS8xRF3, EFSA states that the scope of the PMEM plan is consistent with the scope of the requested authorisation for oilseed rape MS8, RF3 and MS8xRF3. EFSA states that monitoring is related to risk management and that the final adoption of the PMEM plan falls outside EFSA's mandate. In response to COGEM's concerns, EFSA states that unintended release by accidental spillage, e.g. during loading and unloading of the product, is addressed in the PMEM plan. EFSA also mentions that an advantage for GM oilseed rape MS8, RF3 or MS8xRF3 is expected in areas where glufosinate ammonium-containing herbicides are used, i.e. in managed areas. EFSA argues that this advantage will not overcome other biotic and abiotic factors that limit persistence and invasiveness in undisturbed habitats.

In reaction to EFSA's response, COGEM notes that the current PMEM plan does not explicitly mention monitoring along transport routes and transshipment areas. In the annual monitoring reports, no mention is made that transport routes are included in the general surveillance. Feral oilseed rape populations (non-GM) have been detected along transport routes in several countries in the European Union.[2] As mentioned in the previous advice of COGEM,[1] also GM oilseed rape plants have been detected along railway lines and at transshipment areas in Switzerland.[3,4,5,6] In Germany, GM oilseed rape was detected in the harbour where transshipment takes place.[7] In addition, GM oilseed rape was recently detected in France along a roadside that links a port terminal to a crushing facility.[8] If feral GM *B. napus* populations arise, gene flow between different GM oilseed rape events could give rise

2. Sohn SI *et al.* (2021). A Review of the unintentional release of feral genetically modified rapeseed into the environment. Biology 10: 1264
3. Hecht M *et al.* (2014) Detection of feral GT73 transgenic oilseed rape (*Brassica napus*) along railway lines on entry routes to oilseed factories in Switzerland. Environ. Sci. Pollut. Res. 21: 1455-1465
4. Schulze J *et al.* (2014) Unexpected diversity of feral genetically modified oilseed rape (*Brassica napus* L.) despite a cultivation and import ban in Switzerland. PloS One 9: e114477
5. Schulze J *et al.* (2015) Low level impurities in imported wheat are a likely source of feral transgenic oilseed rape (*Brassica napus* L.) in Switzerland. Environ. Sci. Pollut. Res. Inter.22: 16936–16942
6. Schoenenberger N & D'Andrea L (2012) Surveying the occurrence of subspontaneous glyphosate-tolerant genetically engineered *Brassica napus* L. (Brassicaceae) along Swiss railways. Environ. Sci. Eur. 24:23
7. Franzaring J et al. (2016). Exploratory study on the presence of GM oilseed rape near German oil mills. Environ. Sci. Pollut. Res. 23: 23300–23307
8. Reuters (2023). France tightens GM rapeseed import checks after wild plants found. https://www.reuters.com/article/france-rapeseed-gmo-idUKL8N3454RY (accessed: May 8th 2023)

to stacked GM oilseed rape events with a new combination of GM traits, or feral GM *B. rapa* harbouring GM traits. Herbicide tolerance may not provide a selective advantage for GM *B. napus* in undisturbed habitats, but it cannot be excluded beforehand that a newly generated stacked event could have a selective advantage in undisturbed areas. As the potential adverse effects of stacked events on the environment are still unknown, COGEM remains of the opinion that monitoring along transport routes and transshipment areas should be explicitly included in the PMEM plan for MS8, RF3 and MS8xRF3 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. 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