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ONDERWERP Additional advice on import and processing of GM oilseed rape MON88302

Geachte mevrouw Hermans,

Samenvatting:

- De COGEM is n.a.v. het verschijnen van de EFSA-opinie over de hernieuwing van de vergunning voor import en verwerking van de genetisch gemodificeerde (gg-) koolzaadlijn MON88302 gevraagd of haar eerdere commentaar op deze vergunningaanvraag voldoende is beantwoord;
- De COGEM heeft eerder geadviseerd dat het plan voor monitoring van MON88302 verbeterd moest worden alvorens de vergunning voor import en verwerking kan worden hernieuwd:
- De EFSA heeft de bezwaren van de COGEM niet meegenomen in haar recent verschenen opinie over de gg-koolzaad en het monitoringsplan is niet gewijzigd;
- De eerdere bezwaren van de COGEM over het monitoringsplan dat langs koolzaadtransportroutes en bij overslagstations gemonitord moet worden op de aanwezigheid van gg-koolzaadplanten blijven daarom overeind.

Op verzoek van het Food-Feed loket voor ggo-markttoelatingen is het advies in het Engels geschreven.

In August of 2024, COGEM advised on the application for the second renewal of the authorisation for import and processing of genetically modified (GM) oilseed rape MON88302 (EFSA/GMO/RX/031), filed by BASF Agricultural Solution Seeds US LLC.^a MON88302 was produced by Agrobacterium tumefaciens-mediated transformation. In MON88302, the *cp4 epsps* gene is expressed, conferring tolerance to glyphosate containing herbicides.

a COGEM (2024). Advice on the renewal of the authorisation of import and processing of genetically modified oilseed rape MON88302. COGEM advice CGM/240819-01

In its previous advice on the renewal of GM oilseed rape MON88302, COGEM concluded that import and processing of oilseed rape MON88302 poses a negligible risk to the environment in the Netherlands. However, COGEM expressed concerns with regard to the Post Market Environmental Monitoring (PMEM) plan and stated that the 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 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. Additionally, as GM oilseed rape seeds can potentially be introduced in the environment via bird feed mixtures, this introduction route should also be considered in the PMEM plan.

The Dutch Competent Authority submitted the major concerns of COGEM to the European Food Safety Authority (EFSA). EFSA recently published its scientific opinion on import and processing of GM oilseed rape MON88302, which also took into account the comments submitted by the EU member states during the consultation period.^b 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 MON88302, EFSA states that the scope of the PMEM plan is consistent with the scope of the requested authorisation for oilseed rape MON88302. EFSA states that monitoring is related to risk management and that the final adoption of the PMEM plan falls outside EFSA's mandate. In its response to COGEM's concerns, EFSA mentions that the accidental release into the environment due to accidental spillage is addressed by the applicant in the PMEM plan. EFSA also states that the applicant indicates that procedures will be implemented to limit losses and spillage of viable seeds, and that adventitious oilseed rape plants will be controlled by the current practices, such as mechanical or chemical removal, with the exception of herbicides based on glyphosate.

Besides COGEM, competent authorities of other member states also expressed concerns with regard to the PMEM plan of MON88302. In reaction to EFSA's response, COGEM notes that the current PMEM plan only mentions monitoring at loading/unloading sites and does not explicitly mention monitoring along transport routes and transshipment areas. In the annual monitoring reports, there is no indication that either transport routes or the introduction of GM oil seed rape via bird feed mixtures are considered part of the general surveillance. Feral oilseed rape

b EFSA Panel on Genetically Modified Organisms (GMO) *et al.* (2025). Assessment of genetically modified oilseed rape MON 88302 for renewal authorisation under Regulation (EC) No 1829/2003 (dossier GMFF-2023-21220). EFSA Journal 23: e9378.

populations (non-GM) have been detected along transport routes in several countries in the European Union.^c As mentioned in the previous advice of COGEM,^a also GM oilseed rape plants have been detected along railway lines in Switzerland and at transshipment areas in Switzerland and Germany.^{d,e,f,g,h} In addition, GM oilseed rape was recently detected in France along a roadside that links a port terminal to a crushing facility.ⁱ GM oilseed rape seeds can also be present in bird feed mixtures.^{j,k}

If feral GM *B. napus* populations arise, gene flow between different GM oilseed rape events could give rise to stacked GM oilseed rape events with a new combination of GM traits, or feral GM *B. rapa* harbouring GM traits. While herbicide tolerance may not provide a selective advantage for GM *B. napus* in undisturbed habitats, 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 MON88302 before the authorisation is renewed. COGEM therefore urges the European Commission to include the above-mentioned monitoring requirements in its Commission Decision on MON88302.

Hoogachtend,

Prof. dr. ing. Sybe Schaap Voorzitter COGEM

c Sohn SI *et al.* (2021). A Review of the unintentional release of feral genetically modified rapeseed into the environment. Biology 10: 1264

d 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

e 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

f 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

g 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

h 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

i 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)

j Smets G et al. (2022). Bird feed and flower seed mixtures: potential for disseminating genetically modified seeds. COGEM report CGM 2022-02.

k COGEM (2022). Aanbiedingsbrief bij onderzoeksproject 'Bird feed and flower seed mixtures: potential for disseminating genetically modified seeds'. [In Dutch] COGEM advice CGM/220623-01

c.c.

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